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NUCLEAR REGULATORY COMMISSION

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MEDICAL RULEMAKING WORKSHOP

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THURSDAY

AUGUST 11, 2011

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HOUSTON, TEXAS

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The Workshop convened at the Marriott Houston, 6580 Fannin Street, Houston, Texas, at 8:30 a.m., Susan Salter, Facilitator, presiding.

PANEL PARTICIPANTS:

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BRADLEY PRESTIDGE, M.D., Memorial Hermann Southwest Hospital

HERBERT W. MOWER, Sc.D., American Association of Physicists in Medicine

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DAVID WALTER, Organization of Agreement States

JAMES WELSH, M.S., M.D., Advisory Committee on the Medical Uses of Isotopes

RONALD ZELAC, Ph.D., US Nuclear Regulatory Commission

NRC STAFF PRESENT:

SUSAN SALTER, Facilitator

MICHAEL FULLER

MICHAEL WEBER

GRETCHEN RIVERA-CAPELLA

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P R O C E E D I N G S

8:30 A.M.

MS. SALTER: Good morning. I want to thank everyone for coming today to the NRC's workshop on issues associated with Medical Event definition and other medical issues in 10 CFR Part 35 that are currently being considered for rulemaking.

My name is Susan Salter. And I'm going to be your facilitator for the next two days. My role is really to manage the process, make sure we stay on time, make sure that everyone who wants to participate has an opportunity to do so.

Before we get started with some opening remarks, just a couple of housekeeping items. If you could please put your electronic devices on the silent mode, we would appreciate that. If you need to take a call, we certainly understand that. We just ask that you leave the ballroom and go out into the reception area to do that.

Rest rooms are right out these doors to the left, if you need those. And you can see on the agenda where we have breaks and that type of information.

So without any further delay to get things started, I would like to introduce Michael Weber. Mr.

Weber is the Deputy Executive Director for Materials Waste Research State Tribal and Compliance Programs at the Nuclear Regulatory Commission. He's going to start our meeting off with some opening remarks.

MR. WEBER: Well, good morning. Allow me to add my welcome to all those who are participating with us. It's a pleasure to see you here today as we embark on a very important topic and that is the medical use regulation. We appreciate all of you taking time out of your busy schedules. We know that you've got many things to do and your devotion of time and attention to our topics during this two-day workshop is very important for us. And that includes both those of you who are here with us in Houston, Texas, as well as others who are joining us by the web or by telephone lines around the country.

As Susan has introduced me, I'm one of NRC's Deputy Executive Directors for Operations. Some of you may not be familiar with our structure. There are roughly 4,000 employees of the Nuclear Regulatory Commission and the Commission is headed by a five-member Commission that are appointed by the President and confirmed by the Senate. Most of the NRC employees report through the Executive Director for Operations, my boss, so I assist Bill Borchardt in

providing strategic leadership for the Agency.

This workshop is important to the NRC because we get to hear your perspectives on very important topics to us as safety regulators. We also recognize that these issues are important to you as medical practitioners and as patients who are the beneficiaries of the care.

We would like to extend a special welcome to our distinguished panel, both the panel today and the panel tomorrow who are representing a variety of different groups including our Advisory Committee on Medical Uses of Isotopes or ACMUI, as you'll hear it referred to throughout this workshop, also, our Agreement States, several professional societies, patient rights advocates, NRC staff and members of the public who are participating with us.

Public involvement in our activities at the NRC is the cornerstone of a strong, fair, regulatory program. We recognize the public's interest in both the safety and security of radioactive materials uses and the proper use by the NRC of regulation to accomplish those intended outcomes.

When the NRC was established more than 35 years ago, the Commission acknowledged that nuclear

regulation is the people's business. And so we strive to provide opportunities for stakeholder participation in the regulatory process. Consistent with our approach to open government, the NRC is committed to providing meaningful opportunities for involvement throughout the NRC's decision-making process. And your participation here today and tomorrow allows you the opportunity to contribute ideas and comments, perspectives that we, your public servants, will use in enhancing the effectiveness and the efficiency of nuclear regulation.

As you are probably aware, the NRC's mission is to ensure the safe and secure use of radioactive materials. And as a regulatory agency, we accomplish our mission by authorizing uses of radioactive materials through licensing. We judge the adequacy of license applications against rules, requirements established by rules, and by orders. We also oversee the safe and secure use of these materials through a comprehensive program including inspection, enforcement, assessment, investigations and incident response.

So why are we here today and tomorrow? Now the NRC is very interested in the views, the perspectives, and the comments from our stakeholders

on possible revisions to our regulations on the medical uses of radioactive material in 10 CFR Part 35. Specifically, the Commission directed the staff to work with the ACMUI, as well as the medical community and other stakeholders, to develop revised regulations. And among the objectives of these regulations is to develop a Medical Event definition that both protects the interests of patients and allows the physicians to have the flexibility to take the actions they deem medically necessary while preserving NRC's ability to detect misapplications of the use of radioactive materials and failures and process, procedures and in training.

The last ACMUI meeting held in April was set aside primarily for the discussion of this specific issue, in addition to other topics which we'll touch on throughout this workshop. The NRC also held an earlier workshop on these same set of topics in June in New York City.

Over the next two days, we want to hear from you, our stakeholders, as we explore together the definition of Medical Events, specifically associated with permanent implant brachytherapy, the relaxation of the preceptor attestation requirements, and extending grandfathering to certain certified

individuals and a number of other medical issues that are currently being considered for rulemaking in addition to those that I just mentioned.

We will listen and we will seek to understand your comments and perspective. We will give thorough and thoughtful consideration to what we hear from you as we determine the best path forward to amend or update 10 CFR Part 35.

The NRC's main objective for these workshops is to listen and learn more about our stakeholders' interests and perspectives on these important topics. We are looking forward to a very productive and active set of discussions. And with that, I'll turn you back over to Susan. And thank you for your participation.

(Applause.)

MS. SALTER: Thank you, Mr. Weber. So next I'm going to invite Michael Fuller to come on up to the podium and Mr. Fuller is the lead for the Medical Radiation Safety Team in the NRC's Office of Federal and State Materials and Environmental Management Programs. And he is going to kind of go over the agenda for the next couple of days.

MR. FULLER: Thank you, Susan. Can everybody hear me okay? As Susan said, I'm the team

leader for the Medical Radiation Safety Team back in Rockville, our headquarters office. And we are the folks that support our regions as they do their inspections and licensing and so forth and also work to help develop some of the policies and work with our rulemaking partners to develop any new rules.

I want to also thank everyone for coming. I especially want to thank our panelists as well. I really believe that we have been very successful in assembling a panel that consists of some real experts in this area, both today's panel and tomorrow's panel.

I want to reiterate what Mike Weber said about why we're here. We, as NRC staff, are here to listen and learn what we can learn from not only our distinguished panelists but also other members of the public, both here in person and also by way of the webinar. We're very, very early in this rulemaking process and I believe that this is probably the best or one of the best opportunities that our stakeholders have for influencing where we might head or where we might go with regards to rulemaking. The reason I say that is that it is very, very early in the process. For most of the issues that we'll be talking about the next two days, we have not developed proposed rules yet. We are in the process of gaining information and

learning what we can before we start that.

Now we have started writing some rule text, some draft rule text, that I'll talk about in just a minute. But for the most part, this is an opportunity to tell us what you think we should do or shouldn't do before we start the process of drafting new rules.

A little bit about the agenda today, we have devoted the entire day to talking about the Medical Event definition as it relates to permanent implant brachytherapy and the needs or the possible needs for changes to that rule. This morning, we'll have a series of presentations by our experts up here on the panel and then there will be a discussion amongst them, the panelists. After that, then we will have an opportunity for everyone, either in person or again through the webinar to provide us with your comments, your suggestions, your recommendations or perhaps even to ask questions of our panelists to get further clarification on something you may have heard this morning.

Tomorrow, we will have another panel assembled that will talk about, first of all, the potential relaxation of attestation requirements and for certain individuals, certain certified individuals

and also some grandfathering aspects of certified individuals. So that will be tomorrow.

And then we have a number of other things that are under consideration currently for changes to 10 CFR Part 35 or changes to those rules and we'll have a few, a couple of staff presentations. Again, the entire focus and purpose and objective here is to have a number of the things that we know we're going to need to work on over the next months and years to revise our rules and to hear from you on how we might ought to do that.

There are three documents that I would like to call your attention to that I'd like for you to at your -- on the break or when have some time to -- that are available. One is the FRN. Now in everyone's packet there's a copy of the FRN that we've published back in, I guess it was March or April. I'm not exactly sure. And we listed all of the issues that are currently being considered for rulemaking. At the end of the day tomorrow, we will have a session where we will be interested to hear from our stakeholders about any of those -- those are the things that are not specifically on the agenda I should so. So at the end of the day tomorrow, there will be an opportunity to provide us with comments on

those.

Another document that is not in your package, but is available on the table outside where we have a number of handouts is something that was published in regulations.gov. It is what we refer to as our draft -- Josie, you can keep me straight if I don't get it right -- draft preliminary rule text. Now these are some of the things that the folks who are currently working on the 10 CFR Part 35 revision have seen as things that are not very controversial, not very complex, things that might be somewhat straight forward to sort of fix things that were just in need of adjustment or amendment. And so we have actually published some preliminary rule text and -- but again, this is just text -- this is rule text that has been developed by staff. It has had no management review or anything like that. It's out there so people can comment and be aware of it. So again, there will be an opportunity at that last session tomorrow afternoon, to hear from our stakeholders on what you think about those things.

The other thing I would like to point out which is also in your packet is we have developed a summary of what we've heard when we were in New York. We had a very productive, in my opinion, a very

productive session, two-day session or workshop in New York City. We had a very similar set up as we have here for these two days. I debated, I actually thought about was it best to provide that information and somehow bias or risk biasing folks here in Houston or somehow shortchanging the folks here in Houston. But the more I thought about it, I think there are three different ways that you might want to provide us some insight based upon your review of that summary of what we heard in New York.

One, you might agree and want to reiterate what we heard. Want to make sure we heard it. Another thing you might want to do is say yes, but, and then expand on it. And another thing you might want to do is say no, I think they got it wrong in New York and you think about something different. So that's why it's important that we provide, I thought it was a good idea to provide you with a summary from New York.

At the end of this workshop, I'll develop -- our team will develop another summary and we'll consolidate what we heard when we were in New York with what we've heard in Houston. And then that will be used by our rulemaking folks as we go forward in this process.

Again, thank you all for being here. If you need anything, I'll be around all the next two days. Catch me on break if there's anything you need me to be aware of or any problems, but again, thank you and we'll get started.

MS. SALTER: Thank you, Mr. Fuller. Did you want to cue Ron's presentation while you were up there.

MR. FULLER: Oh yes, that's my other job.

(Laughter.)

MS. SALTER: He's earning his salary today. All right, so before we move into the panel presentations, I just want to go over a couple of things that we can all do to help this process run a little smoother and help the NRC with getting an accurate transcription of the meeting. We are transcribing the meeting and Brandon is over there in the corner doing that for us.

So some things that we can do to make sure that that's an accurate transcription is to keep sidebar conversations down to a minimum. Again, if you need to take a phone call, go out of the room. And again, when we get to the public comment period, make sure that you wait to be called and you come up to a microphone and same with our panelists at the

front.

So all of those things will help us get an accurate transcription and help the meeting run smoothly and help everybody be able to hear what's being said.

The first two activities today, this morning actually, are going to be involving only the panelists up front. They're going to start with brief presentations of their perspectives, positions, on these issues, the issue of the Medical Event definition. And after that we're going to take a short break and then the panel is going to engage in an open dialogue on any topic that they -- on any issue related to the Medical Event definition. So we don't have a scripted or specific set of questions that they had to follow. They're able to take this discussion in any direction that they want.

The thing that I want to reinforce is that during this morning, it's only the panel presentation. We're not going to be going out to the audience to comment or ask for clarification. However, we have the whole afternoon devoted to public comment as well as individuals on the webinar. So we ask that you hold those comments or questions for the panelists until after lunch.

I also want to introduce Gretchen Rivera-Capella who is back in the corner. She's manning our webinar and for folks on the webinar, you will have an opportunity to participate this afternoon when we get to the public comment period. You will actually type your question in and Gretchen will read it throughout the afternoon. I'll go to Gretchen for any questions from the webinar.

For those of you who are here, what I need for you to do is if you want to make a comment this afternoon, you have these blue cards on your table. There's also a lot more out on the registration desk. I just need you to fill out the card and drop it off at the registration desk before lunch if you can.

Now there's a section on here for comments. You do not have to put in there what your comment is. That is for individuals who perhaps don't want to get up in front of the group and make the comment and they want me to read their comment which I'm happy to do. So don't feel like you have to put your comment in that section. What we really need is your name and your affiliation and I ask please print so that we can hand that off to our transcriber and he can have an accurate spelling of your name and who you're affiliated with.

There's also a place on the blue card, if you want to get added to the NRC's mailing list on issues related to medical regulations and you're able to do that with this blue card. If you want to sign up for the mailing list, but you don't want to speak, there's a yellow card out at the front registration desk. And if all of this has confused you, just go out to the registration desk and the women out front can help you fill out the right card.

The final thing I want to say on this is if you don't right now want to make a comment this afternoon, but 3 o'clock rolls around and you want to make a comment, no problem. You have these cards here, just fill them out, hold them up. I'll come by and collect them. But they do help me as the facilitator to be able to queue people up to speak, to get a list together, and also to have accurate spelling of your name and your affiliation. So blue cards if you want to speak. If you know you want to speak, fill one out and drop it off at the registration desk before lunch, but don't worry if you change your mind. There's time to do that later as well.

So I think I've covered all the housekeeping issues. So just the final reminder, as

Mike said, the NRC is in the early stages of the rulemaking process. And this is really an opportunity to reach out to stakeholders to enhance that process, to get as much input as we can. Inevitably, you're going to hear some things that you agree with. And you're going to hear some things that you don't agree with. And I just remind everyone that we want to show respect for everyone, including the panelists and the audience members who may have opinions that are different from yours. So just keep that in mind.

So with that being said, I'd like to get started with our panel presentation and I am going to do a brief introduction of them. However, in your packets you have detailed bios, if you'd like more information. In addition, there are copies of their presentation on the information table that's out by the registration desk if you want to pick those up later.

So our first speaker is Dr. Ron Zelac. He 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 by the U.S. Nuclear Regulatory Commission and is presently focused on 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. Welcome.

DR. ZELAC: Thank you, Susan. Good morning. Can you all hear me? Good.

My task this morning is to kick things off by giving you a little idea of how it is that we got to where we are at the moment and also give you a road map, if you will, to how you can get further information above and beyond what I can cover in this short seven minutes or so that are allotted to me.

As Susan said, I am a member of NRC's Medical Radiation Safety Team. To give you a road map to information because I will be mentioning several publications from NRC this morning, all of them are available on the NRC's public website, nrc.gov, and in order to get to them you would go to the website and then click in order first NRC Library, next document collections, then Commission. Everything that I'll mention is either a Commission paper or a Staff Requirements Memorandum and you would appropriately, depending on what you're looking for, click the appropriate section.

And as one last thing, the documents are

listed by number and title. The first part of the number which identifies a document is the year in which it was created.

Now to the background. SECY refers to a paper prepared by staff which is headed to the Commission for their consideration. This particular one, as I was saying you can see SECY-05 was produced in 2005 and the next number is simply the sequential order number.

In this paper, staff recommended that for all permanent implant brachytherapy Medical Events involving treatment site should be defined in terms of total source strength variances, not absorbed dose variances. The current rule deals with variances from the intended absorbed dose to the delivered absorbed dose. This recommendation to the Commission was that these regulations dealing with Medical Events for permanent implant brachytherapy change from dose-based to source-strength based.

The staff's recommendation was based on a recommendation that had been received from our ACMUI, our Advisory Committee on the Medical Use of Isotopes.

I'm going to read very briefly from this paper. I think it is somewhat instructive. "During its March 2004 meeting" -- so you can see this issue

has been around with us for quite a while -- "the ACMUI considered the issue of defining Medical Events involving permanent implant brachytherapy. It concluded that the plus or minus 20 percent variance from the prescription criterion in the existing rule was appropriate, if both the prescription and the variance could be expressed in units of activity or source strength, rather than in units of dose as there is no suitable clinically used dose metric available for judging the occurrence of Medical Events."

And one more thing from this same paper, again, hopefully instructive: "The staff also recommends that for permanent implant brachytherapy, the Commission approve the staff's plan to revise the Medical Event definition and the associated requirements for written directives to the activity base instead of dose based."

We then had a Staff Requirements Memorandum and in it the Commission approved staff's recommendation to move ahead with these regulatory changes.

Now we move on a couple of years to a proposed rule that was published to implement exactly what had been recommended. In this paper, staff provided the Commission with a proposed, modified rule

for the use of total source strength variance rather than absorbed dose variance for defining Medical Events for permanent implant brachytherapy treatment sites.

And in the Staff Requirements Memorandum which the Commission gives to us, how to move ahead, the Commission approved the proposed rule for publication in the Federal Register for comment. The rule was published. Comments came in. And we had one additional thing occur during this same period of time. During the 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 the data from these events. Based on its evaluation of this information, including an independent analysis by an NRC medical consultant, the staff, and I'm quoting from the paper now, this paper that again went to the Commission as a re-proposed rule, "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 effect of the proposed rule would have been that some significant events would not be identified, categorized, and reported as Medical Events. Therefore, the proposed rule language and rationale have been modified to reflect this new information."

So staff went to Commission and asked for direction and it received that direction in the Staff Requirements Memorandum. The Commission disapproved publication of the reproposed 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 that's why we're here today.

To quote from the paper, The Staff Requirements Memorandum, "The staff should work closely with the Advisory Committee", etcetera. You have heard Mr. Weber summarize what we had heard from the Commission.

So here we are and we have a challenge. A challenge is there for you to see. How do we appropriately balance between the general medical community's desire to define a Medical Event in terms of clinical significance with NRC's need to have

mistakes in the process or variances in the process of consequence, potential consequence, reported to us, even if there is no actual negative consequence to the patient. That's why we're here to discuss exactly this issue.

I've used a couple of acronyms and you'll see them in the printed version of what I've had to say. ME for Medical Events. SECY for the Office of the Secretary Commission papers. SRM, Staff Requirements Memorandum.

And finally, at any time during the meeting, afterwards, in the future, if you would like to get in touch with me to discuss any of these issues, here is the way to do it. Thank you.

MS. SALTER: Thank you, Dr. Zelac. I just wanted to let you all know what you're hearing coming through the speaker, there's a couple of folks on the webinar that are somehow getting through and we're working on fixing that, so I apologize for that. But if you hear anything, that's what it is.

So moving to our next speaker, Mike, do you want to help him? Karl David Walter is the current chair of the Organization of Agreement States. He holds a Bachelor of Science in Biology from Auburn University and has been involved in radiation safety

and health physics for the past 28 years. He is currently the Assistant Director of the Alabama Office of Radiation Control and the Director of the Radioactive Material Licensing Branch for the Office and as such, he is responsible for all licensing and registration services for over 450 specific licensees.

Mr. Walter?

MR. WALTER: Thank you, Susan. As Susan said, I'm the current chair of the Organization of Agreement States, the OAS. We consist of 37 states who have agreements with the NRC to regulate the use of byproduct material in our states. Those 37 states regulate some 87 percent of the licensees in the country for byproduct material. And so we have a very large stake in this and want to work hand in hand with the NRC as much as possible.

When we were asked to get involved in these meetings, we quickly set up a questionnaire that we put on our website and asked as many as possible of the Agreement States to take part in. I was kind of pleased that in a two-week period which is all we had before we had to take it down and put together the compilation of data, in two weeks, we had 14 states that responded.

So I'm going to give you a little bit of

what we found during these questionnaires and this questionnaire and the data that we got from it.

Of those 14 states, 11 had had at least one permanent implant brachytherapy event. Now all of the states have definitions the same or more restrictive than the NRC's and all inspected the written directives and the licensees' procedures. Twelve of those routinely reviewed patient charts for errors or inconsistencies. But even so, four indicated that they were awaiting guidance from the NRC regarding Medical Event criteria. How do you go about when you're doing your inspections, which is where the rubber meets the road for us, how do you go about determining whether there's been a Medical Event?

Another question asked about the criteria a state used to help determine if a Medical Event had occurred. As you can see, the states use a variety of criteria. Some of the additional comments, which is where really all of the good stuff came from, indicated they included insuring licensees commit to a written policy and procedure that used published scientific protocols that meet the current regulatory requirements. Or allowing licensees to put reasonable criteria together for Medical Events, formalizing them

in their written directive procedures and then submitting those for review and approval by the Agreement State.

In general, many states are giving licensees a great deal of leeway in deciding what constitutes a Medical Event. Now while this gives a lot of latitude to the licensees, it's at the expense of consistency.

Another question was whether the states considered it to be a Medical Event if the dose to an organ or tissue outside the target volume exceeds 120 percent of the dose to an organ or tissue as specified and approved in the treatment plan. While many stated that yes, that's true, they've also added other criteria which linked the final decision to written procedures that the licensee has adopted. So it's not automatic that these states would flatly consider this a Medical Event.

Another question asked the states to describe their general position regarding prostate Medical Event criteria. Many rely on the licensee to report Medical Events. But there is some doubt as to whether the Authorized Users and/or medical physicists understand the relationship between the rules and what constitutes prostate bracytherapy Medical Event.

This leads one to consider the training on the interpretation for Medical Events might be helpful and since many of the licensees are given some latitude in defining these criteria, such training might have to be by the licensee following their own written Medical Event criteria.

So in summary, and I'm going to cut it really quick so we're going to catch up here very quickly, while most states have the same Medical Event regulations as the NRC, the different interpretations result in sometimes large inconsistencies. Given the leeway that is afforded to the licensees by many states, training of what constitutes a Medical Event at a given licensee may be necessary.

None of the states though believe that using activity to promote reporting requirements was useful. Using activity alone was inconsistent with radiation safety. If dose was not considered, radiation safety was not considered. We cannot assume that the dose prescribed can be equated to a given activity.

Thank you very much.

MS. SALTER: Thank you, Mr. Walter. Our next panelist is James Welsh and Dr. Welsh since 2007 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 he's 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: Well, thank you. What I will be discussing today represents a synopsis of the ACMUI Subcommittee recommendation, as well as input from other ACMUI members on this and related topics.

I'm going to start in the way of some background here to put things in perspective. In 2010, there were a series of Medical Events that were reported. Part of the ACMUI's annual task is to perform a review of Medical Events and in this review we identified 26 Medical Events involving 75 patients; 69 were permanent prostate brachytherapy patients and of these cases there were 8 overdoses. One was excess dose to normal tissue. One was incorrect seed activity. And one of these overdoses was retracted,

based on repeat post-implant dosimetry. And this fact underscores the fact that this is not an exact science and it is critical to do the post-implant dosimetry at the appropriate time because if not, this will be repeated over and over again.

The rest of these cases were under doses. Importantly, just as I mentioned, if you do the post-implant dosimetry at an inappropriate time, you can get misleading results and two of these under doses were retracted because the prostate dwelled, and upon reevaluation at a more appropriate time, the final dose was within 20 percent and the Medical Event designation was removed.

Also, in this series of events in 2010, we identified a very unusual event that was actually labeled initially as a Medical Event, but subsequently retracted. The D90 was less than one percent which immediately is, of course, a serious red flag. But this was not considered a Medical Event because 39 out of the 41 seeds were within the target. They were all implanted in a single line, an isoline, of sorts. And this is what I and many others have said could never happen in our discussion about Medical Events and the use of seed placement because we thought when people said what about the case where everybody puts all the

seeds in one spot, I and many others have said that just would never happen. Well, it did. So it's something real and it did happen and we have to come up with a definition that would accommodate this as well as all the other more commonly-encountered Medical Events.

The practitioners stated that they could have placed the seeds in a better location. I suppose so. This was attributed to poor image quality, but irrespective of the actual cause it was something that certainly caught a lot of attention.

The majority of these Medical Events were based on dose, for example, D90. And the question that arises is would these so-called Medical Events still be so labeled if we used an activity or source-strength based definition. Preliminary analysis of the events in the VA as Dr. Zelac has mentioned, suggest that many of these labeled Medical Events would not meet the criteria and that is a source of controversy right now that has prompted this and other workshops.

Importantly, in this series of Medical Events that were reported during 2010, we learned that many of these occurred much earlier, 2005, 2006, etcetera, but were reported during this time frame

because many of the states were going back and re-analyzing their cases. And therefore, there most likely will be many, many more cases next year.

So some of the key points that our Subcommittee have identified are that number one, the original activity-based, source-strength based metric for the definition of Medical Event remains appropriate and remains preferable. And the Subcommittee has suggested that NRC seek specific help from stakeholders and thus these workshops were initiated.

Most members of the ACMUI feel that the Medical Event should represent an event that is of clinical significance. And this definition should be sensitive enough to identify potential harm to a patient, understanding that harm can be overdose to normal tissues causing damage or under dose and not effectively controlling the patient's cancer. But the ACMUI understands that the NRC also would like Medical Events to identify trends and patterns that could eventually lead to harm through overdosing or under dosing and this is a very careful balancing act.

It is acknowledged that the term Medical Event has a negative connotation. As a physician, I know that the term Medical Event does not mean

something good. It means something very negative to my patients and to other practitioners. And we understand that the term Medical Event has come about as a synonym to replace misadministration which sounds maybe even worse, but most people know that there is no term misadministration anymore and Medical Event is just a synonym that has replaced the older terminology and therefore continues to have that same negative connotation.

Another important point that the ACMUI has considered is regarding post-implant dosimetry. There is unanimity regarding the opinion of how important post-implant dosimetry is. We all agree that this is critical and a program that does not perform post-implant dosimetry is not an adequate program. But as far as how to convert this into regulation, it's very tricky.

A proposed 60-day time line has -- a 60-day time line has been proposed. And the ACMUI is divided on this. While from a medical perspective, perhaps 60 days would be a very reasonable time to do post-implant dosimetry. From a regulatory perspective, some of the Subcommittee does not feel that it would be appropriate to call a delayed post-implant dosimetry procedure a Medical Event, perhaps

another terminology such as violation would be more appropriate. And of course, patient-related factors such as a patient declining to show up for the post-implant dosimetry should be excused from Medical Event or violation terminology all together and be so called as a patient-related factor.

The Subcommittee was divided on this topic as well. Some of us felt that because prostate permanent implant brachytherapy is so different from say lung brachytherapy, that the two categories could be separated. Some of us have suggested the separation of the two categories, those which result in significant rearrangement of the implant location during the completion of the surgical implant procedure such as mesh brachytherapy in a lung implant procedure and those procedures that do not have such anatomic rearrangement, such as prostate implants.

In practice, this would be prostate and non-prostate.

Another point that the ACMUI Subcommittee felt relatively strongly about and was unanimous about was this section about the 50 rem to an organ or tissue and 50 percent or more of the dose expected. First, 51 rem is a very, very small amount compared to the therapeutic dose that's being prescribed, much

less than 1 percent. Secondly, a 50 percent overdose could be very medically inconsequential if the expected dose to that tissue was quite low, for example, dose to the penile bulb in prostate brachytherapy to the femoral heads in prostate brachytherapy. We normally don't even calculate doses to the femoral head, but if we did and it was going to be 51 centigrade and we wound up administering a little over 100 centigrade, we would wind up with a Medical Event simply because we tracked the dose to the femoral heads. And this would meet the definition of Medical Event and most of us feel that this is outdated and inappropriate.

Additionally, this section uses units that are inconsistent and confusing and it is suggested that the final rule use appropriate units in a consistent matter of preferably just drop this section all together.

The ACMUI understands that the NRC perhaps included that previous section because of an insistence on having something that is dose based. Therefore, the ACMUI has proposed an alternative that is dose based, but I have to provide the caveat that we are not uniformly endorsing this and there was considerable division within the Subcommittee on this

particular topic. But nonetheless, if NRC insists on maintaining a dose-based definition, we felt that it would be more appropriate for ACMUI and stakeholders to provide such a dose-based definition rather than have staff come up with their own.

So what we've proposed here was a D90 less than 70 percent and -- and critically, this is an important Boolean and -- and less than 5 percent of sources occupying any octant of the PTV except by intent to under dose to a specific area or dose escalate, for example, and this would be specified in the written directive. And for normal tissues, D5 ccs would have to exceed 150 percent of the prescription dose or for the urethra or D5 would exceed 150 percent of the final approved dose distribution.

The definition in principle would catch events such as the one that I described earlier where all the seeds were bunched along an isoline or in one place. It would not signify as a Medical Event any implant in which sources were missing an octant, provided the D90 was above 70 percent.

So how safe is prostate brachytherapy? It's extremely safe and it's an effective procedure. Of 20,000 some-odd procedures, 69 Medical Events were identified for a 0.33 percent Medical Event rate.

This seems low, but it is too high by our standards, because we understand that many of these Medical Events were perhaps mislabeled and although it seems like a very -- it is a very low number, in practice, far fewer than this number of people were harmed by prostate brachytherapy and this number as low as it seems is perhaps a bit misleading.

It is safe. It is effective. But this is an important point that has been elucidated through our analysis. In 2004, there were 192,000 so-odd prostate cancer treatments, about 42,000 permanent implant procedures. Twenty-two percent of prostate cancer patients who were treated got prostate brachytherapy in other words. But if you fast forward beyond the VA Medical Event series to 2009, we see that there was a significant increase in the number of prostate cancer diagnoses and treatments; 219,000 treatments, but a significant reduction in the number of implants. And importantly, not as just an absolute drop in the number of implants, it's a very significant drop in the percent of prostate brachytherapy procedures down to only eight percent.

Sure, there are competing factors here, improved surgical technologies and intensity-modulated external beam radiation therapy that compete with

prostate brachytherapy, but many of us suspect that the negative publicity associated with these Medical Events has had something to do with this significant drop.

Thank you for your attention.

MS. SALTER: Thank you, Dr. Welsh. I just want to let everyone know because you may be getting texts or emails from colleagues, we're having some trouble with the bridge line for the webinar, so we are aware of that. We are working diligently to get that back on line.

So our next speaker is Dr. Michael Hagan. Dr. Hagan is currently the Veterans Health Administration National Director for the Radiation Oncology Program. He is 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.

Dr. Hagan?

DR. HAGAN: The last time I was in this hotel was the day before I interviewed as a medical

student over there.

(Laughter.)

And it's changed a little bit since then.

In 2005, as you have heard, the ACMUI sent a letter to NRC advising the switch to an activity-based metric. This came after deliberation from an illustrious assembled group of experts in prostate brachytherapy.

In 2009, after the VA recognized that reports out of Philadelphia had substantial problems in the analysis for Medical Event assembled a blue ribbon panel. That blue ribbon panel consisted of national experts who published over 500 reviewed papers on prostate brachytherapy and were responsible for thousands of implants. They agreed in their recommendation to the Under Secretary that the activity metric should be employed and in fact proscribed the use of an absorbed dose metric and gave us the evaluation tools to reevaluate Philadelphia.

And so what I want to do today is to show you why these two panels made this decision, what was it about the use of absorbed dose metric that in their opinion didn't work.

The next slide shows you the two reporting criteria. Let's see. It shows you the two reporting

criteria that are in the current rule. Our panel of experts was required to look at the current regulation and provide recommendations that are consistent with the current regulation. So two areas, the target site and then other organs or tissues and my comments for the rest of this presentation are going to involve the target site or the treatment site, a Medical Event definition, although I think we are prepared to have some interesting discussion among the panelists on the second criteria, other organs and tissues, as you've heard Drs. Welsh and Zelac already raised to you.

So what is it about the D90 that makes it or an absorbed dose metric that makes it a parameter that just doesn't work under this consideration for regulatory evaluation? Well, the D90 is a clinical parameter and it recognizes and reflects the dose to the periphery of greater than 90 percent of the prostate target. It's not the design of D90 in clinical reporting to be an absolute measure that could fall within 20 percent of the dose that actually is physically being received within the prostate. And the D90 itself, as you'll see in the next few slides, is subjective.

Here is a prostate, a CT scan of a prostate with seeds that have been implanted. And the

D90 is 95 percent for this prostate. We see one slice taken one day out of the life of this prostate. The isodoses are shown there in the colors indicated. And you can see three things that I think are well worth noting. First of all, the coverage here is -- it says excellent. Actually, adequate, I think. The 100 percent isodose covers the red contour which is the prostate, but notice that more than 50 percent of the prostate is receiving over 150 percent of the prescription dose, clearly well beyond the 20 percent limit that the regulation requires for regulatory evaluation.

But also notice that the contour in blue which represents the limit for a Medical Event, that is the D90 now is less than 80 percent, is within 3 millimeters of the green contour and at any day in the life of this implant, edema could push the prostate contour out 8 to 10 millimeters, 3 times the size of the distance between excellent coverage and a Medical Event. So you can see D90 is not only is it subjective, but it doesn't have the precision that you need. It's very insensitive in terms of its reliance on volume and here, a small change in volume makes a big change in D90. At the same time, it hides the fact that most of the prostate is receiving a

substantially higher dose.

The next two slides, I think, will show you this a little more cogently. These come from two implants. The first is a palladium implant that was performed and then imaged on Day 1 and then imaged again at Day 30. So the original volume and ultrasound, 29 ccs, the patient comes the day after surgery has a CT evaluation. The contouring physician does his best to guess from the CT where the prostate edge is. It doesn't take much for you to look at that CT image and recognize that the prostate contour is not something that jumps out at you, but is a visual guess by the contouring physician.

Here, the prostate volume is 35 ccs, representing some edema that's taking place at the time of surgery. And as a result, the D90 is 80 percent. It's a Medical Event. By D90 criteria, it falls in the Medical Event range.

Same patient comes back in at 30 days. Now most of the edema has resolved. The prostate volume is now 30 ccs. The D90 is 99 percent and so this is not a Medical Event. It's an excellent coverage at Day 30.

So what happened between Day 1 and Day 30? The Authorized User didn't do anything. Just the

edema resolved. What if this patient couldn't come back in at 30 days? What if this patient came from overseas and now is back in his home country and he can't come for a CT. We can't do the evaluation. Is this patient then appropriately reported as a Medical Event because we can't image him at Day 30? And we're interested, notice this is a palladium implant, we're interested in the dose the prostate received. Well, palladium half life is 17 days. So by the time we're looking at Day 30, over 80 percent of the dose has been deposited.

Well, what size prostate was it deposited in? It was deposited somewhere between Day 1 and Day 30. We have no idea what the track of that edema resolution was. We can guess, but we can't measure it. So we don't have the precision that we need for a tool to give us a Medical Event.

So here's a 125 implant that shows you the other side of this issue. This patient is originally imaged at 59 ccs and then comes at Day 1 with a 77 CT, grossly edematous prostate. But his D90 is okay. It's 94 percent. He comes back in at Day 30. Now much of the edema has resolved, but not all. And now his D90 is 120 percent. He fits the criteria for Medical Event on the upper end, if we apply 20 percent

criteria.

But as you look at that, also notice below that the current evaluation criteria for a Phase 3 protocol run by the American College of Radiology through the Radiation Therapy Oncology Group uses D90 in a range from 80 to 130 percent. So 120 percent is not only a per protocol. It's a very good implant, yet we would report this as a Medical Event if we used D90 criteria on the upper end.

So you can see edema causes a real issue and that was, in fact, the issue at Philadelphia. In Philadelphia, these were all Day 1 CTs. When they were reevaluated, we had to compensate for the edema that had been caused and that was the basis of the reevaluation and the basis of the errors in Philadelphia.

So global measures of absorbed dose are useful for comparisons from program to program and within a clinical entity, but there's large operator dependence. There's large dependence on that guess of where the prostate contour is. The report reflected clinical outcomes, so they're really not all that useful in terms of comparing clinical outcome from prostate to prostate. But they're the best we have. They lack precision for regulatory reporting and AAPM,

the two task groups that have reported on clinical evaluation, Task Group 64 specifically said that their recommendations were not to be used for regulatory evaluation.

Ravi Nath's Task Group 137 did not specifically state that in the Task Group Report, but that was their intent and you give Ravi a call and he will absolutely tell you that was -- their consideration was that no one would use Task Group 137 as a justification for regulatory evaluations. AAPM had already spoken on that subject.

So what can you use if D90 -- not everybody who does implants today reports based on D90 or a V100 as we have heard presented. So what do they use?

Well, many report on an activity-based or a source-strength based system now. And the reason for that is that we must by regulation define dose and report based on 20 percent of a dose discrepancy and the same regulations define dose for manual brachytherapy as you see. So dose can be defined under the current regulation as total source strength plus the exposure time which is infinite in a permanent implant.

So what about this activity-based metric

then? How does it work? How is it better? Well, it measures the physician's performance. We determine where the seeds go. During the implant, a written directive is completed that describes the treatment site. At the end, that treatment site is imaged. We count those seeds that are in the treatment site and those seeds that missed the treatment site. If 20 percent of the seeds missed the treatment site, then that's a Medical Event by an activity metric.

It documents what the physician actually accomplishes in the OR. And so here is its application in two slides. First, this is a prostate from the Philadelphia series that's labeled a Medical Event. We went back and reanalyzed Philadelphia, we determined out of 114 implants, there were actually 17 that should have been reported. We looked at those from a dose standpoint. We looked at those from an activity metric standpoint, 17 implants. And they were the same implants with the exception of one and that's the one.

This is an implant where the practitioner stated that because the patient was low risk, he was not going to cover the anterior base. The pathology that is in the literature that supports such a decision is shown there on your left where typical

tumors are, the top of those prostates, that is the anterior prostate is under represented for typical tumor presentation based on this kind of logic. The physician wanted to under implant the anterior base. Now I may not agree with that, but that was his decision. He accomplished a plan and the seeds were implanted in the intended way. The operative note, the physician says seed distribution as I intended.

Unfortunately, his written directive said that he was treating the prostate. It didn't say he was treating part of the prostate. It didn't say he was not going to treat the anterior prostate. His written directive said prostate.

So when we evaluate the implant by a D90 metric, the only thing we can do is evaluate the volume that was stated in the written directive and 69 percent is the D90 associated with that, largely because of the lack of coverage of the anterior base. But using an activity metric, his treatment site is identified. He has stated that he placed the seeds where he wanted in terms of the seed distribution. And you can count seeds with regard to his treatment site. So the activity metric would be -- he would be fine.

Although the activity metric, I'll quickly

say, needs to be consonant with the written directive. So the written directive needs to say what he says in his operative note, that he did not intend to implant the anterior base.

Here are two physicians in our VA consortium who have very different styles of implants. The two implants shown in the top are from a physician who places all the seeds within the prostate. He uses actually a different activity in the core. And here you can see from the pre-plan, the seeds are within the prostate and the post-plan of that same prostate shows the seeds were put in as they were indicated. And the activity metric is easy to calculate here. We can see the treatment site, we can calculate seeds inside and outside.

Down below is an implant where the practitioner likes to put seeds in of a higher activity and implants them outside the prostate. Most of the seeds are outside the prostate. And with this, you treat a larger volume, but one of the advantages is that the dose is largely insensitive to swelling. The prostate swells within this larger volume. The edema resolves within this larger volume. Whatever day I do the CT, I get a very similar result. So if I applied D90, I can apply D90 very nicely to the

practitioner on the bottom and the CT date is not really that important. But the implant from the top, the D90 depends very significantly on the residual edema at the time of that implant.

And can I then pick a time, 30 days with the implant at 30 days, the edema is resolved. Well, unfortunately, there are percentages of patients where the edema doesn't resolve for 30 days. In fact, doesn't resolve for 60 days. So we need a regulation that fits everyone.

So the absorbed dose metric is subjective. It's inaccurate. It lacks the precision that you need for regulatory evaluation, but placement of byproduct material into the right patient, into the right site is what we can hold that Authorized User to. That's what he's assigned to do on his written directive. That's how we can evaluate him with post-operative imaging. The assessment of placement within the treatment site, the intended treatment site and that documentation should be sufficient for regulatory compliance.

MS. SALTER: Thank you, Dr. Hagan. I heard that we are back on line with the webinar. I apologize to those folks for the trouble we had with the bridge line. Just to make sure that nobody comes

through, we ask that folks on the webinar mute their phone. If you don't have a mute button, you can hit *6 to mute.

Our next speaker is Dr. Bradley Prestidge. Dr. Prestidge has over 23 years' experience in brachytherapy and is considered an international expert in the field with particular expertise in permanent prostate brachytherapy. He is currently the Vice President of the American Brachytherapy Society, and was elected President for 2012.

After earning his medical degree from the Uniform Services University of the Health Sciences in Washington, D.C., he did his post-graduate training in Internal Medicine and Radiation Oncology at Stanford University where he learned brachytherapy techniques.

As a member of the United States Air Force, Dr. Prestidge initiated the first prostate brachytherapy program in the United States military healthcare system and subsequently trained military physicians throughout the country. Welcome, Dr. Prestidge.

DR. PRESTIDGE: Thank you, Susan. And thank you very much for this opportunity. It's my pleasure to make this presentation on behalf of the American Society for Radiation Oncology. For those

who may not be familiar, ASTRO is the largest radiation oncology society in the world, more than 10,000 members who specialize in treating patients with various kinds of radiation therapy. 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 that patients receive the safest and most effective treatments.

ASTRO's statement at the workshop held in June in New York provided more detail in our position that a target-based definition of Medical Events is preferable to one based solely on dose.

I will first give a brief overview of our position and then try to focus on some topics that arose during that discussion in New York and subsequently.

ASTRO believes that the current definition of Medical Event for permanent implant brachytherapy or one that relies on estimates of absorbed dose is particularly problematic and requires practitioners to report events that are medically acceptable. In prostate brachytherapy, there are very few serious

complications so there is very little data to guide us. And the quality of the data is quite weak.

In Part 35, in Section 35 of the CFR, it is deemed to be a Medical Event if a total dose delivered differs from the prescribed dose by 20 percent or more. ASTRO believes that such a rule is not appropriate for permanent implant brachytherapy. If the NRC definition is rigidly applied, many medically acceptable and appropriate implants will be deemed Medical Events creating unnecessary patient apprehension about patient -- about physician quality.

Further, we're concerned that dose-based measure encumbers regulatory bodies such as the NRC and the licensees with clinically irrelevant costly investigations. Hence, a dose-based definition of Medical Event is not suitable for permanent implant brachytherapy.

Instead of a rule based on estimates of absorbed dose, ASTRO recommends using a target-based definition, greater than 20 percent of its source strength, implanted outside of the planning target volume to define Medical Events for regulatory purposes. We believe a target-based criterion for Medical Events will correctly identify cases in which a large number of sources have been improperly

implanted outside the treatment site, but is less likely to generate spurious Medical Events.

In addition, our recommendation accounts for the reality that the source strength, total source strength implanted within and around the prostate is under the control of the Authorized User. But the subsequent prostate volume and the resultant dose of the prostate is not. And I think Dr. Hagan has illustrated that quite well in some of his CT images.

The actual dose and dosimetric parameters will vary considerably depending upon when and how the post-implant images were obtained. How the prostate was contoured, the amount of radioactivity implanted and the amounts of swelling and edema as was just presented.

One of the issues raised during the New York workshop that we would also like to address involves defining the treatment site. Because prostate tumors are found in the periphery of the gland, ASTRO believes that the physician must be permitted to define the treatment site in a written directive. And that treatment site must be allowed to include the area just outside the prostate gland itself.

Under the current definition, it's not

considered Medical Event if a physician is overly cautious and implants the seeds far away from the periphery and thus far away from the tumors being treated. While not a Medical Event, it might be to the detriment of the patient since the tumor may not be properly treated. This is an example of why we must rely on the physicians to define the treatment site and why it is so important that the seeds reach the intended physician-determined target.

In addition to the physician determining the target in the written directive, the physician must be allowed the flexibility to update the written directive up until the time the patient leaves the care of the physician who is the Authorized User. Permanent implant brachytherapy for prostate cancer is a dynamic procedure impacted by changes in prostate size and shape as well as the imaging modalities that are used. Some flexibility must be allowed during the procedure to make changes just as flexibility is allowed during traditional surgical procedures.

ASTRO acknowledges that there are highly unlikely, yet potential scenarios where a target-based criterion would not adequately identify Medical Event such as when all or most of the sources are implanted in one area of the target volume, leaving either a

substantial portion of the treatment site uncovered or a substantial portion of the treatment site over-covered.

Under these circumstances, some of the target will be over dosed and other areas under dosed or damage could be caused to otherwise healthy structures. To address these rare events, ASTRO recommends that after the implant is completed, the Authorized User be required to affirm in writing on the written directive that the distribution of the sources within the treatment site was, as intended, per the pre-implant written directive and physics dosimetry plan. Then, should a Medical Event occur it would be found when the post-implant dosimetry images were compared to the written directive in the physics dosimetry plan.

We understand the concerns that a physician might revise a written directive in an attempt to cover up a Medical Event. However, we believe that such a physician would be unlikely to self-report a Medical Event to the NRC in the first place and would be identified and investigated through a traditional regulation of medical practice by the State Medical Licensing Board with appropriate notification to the NRC.

In the Federal Register notice announcing these workshops, the NRC asked what an appropriate time frame should be required for post-implant dosimetry. ASTRO believes that the requirements for post-implant dosimetry should be left to the judgment of the medical specialty societies, institutions, and individual providers.

In addition, each institution has the distinct patient population and must be allowed to practice according to their specific needs and capabilities. Such post-implant dosimetry should become a regulatory requirement. There will always be outliers with medically-acceptable reasons: comorbidities, geography, inability to travel. An example was given by Dr. Hagan for perhaps a patient coming from out of the country. It would be unfair to label those situations as Medical Events.

We also would like to respond to an issue that arose at the workshop in New York when an NRC representative stated in interest in examining events that would be considered near misses so the potential for serious patient harm can be avoided.

While we greatly appreciate the intent to ensure patient safety by preventing errors via the examination of near misses, we're concerned that by

requiring the reporting of near misses the NRC may be straying from its authority and into an area of medicine outside of its expertise.

ASTRO believes that addressing system breakdown to prevent harm is critical. But it's the responsibility of the hospitals, clinics, professional societies, and healthcare and quality experts. We don't believe that the NRC has the resources or expertise to use such information to improve medical practice, nor does the Agency have the legal confidentiality protections to ensure that reported information is not used inappropriately such as in spurious medical liability cases.

ASTRO, as part of its target patient safety program is exploring working with a federally-designated Patient Safety Organization, or PSO, that would collect reports of errors and near misses and recommend system changes to prevent future errors. The information submitted to these organizations is protected and confidential under the Patient Safety and Quality Improvement Act of 2005.

Under such a system, the NRC and other regulatory bodies would have access to the identified aggregate data. ASTRO believes that this type of patient-safety activity is best handled in the context

of a PSO.

So in conclusion, ASTRO believes that a target-based definition is essential to ensure that those implants that could potentially cause serious patient harm are categorized as Medical Events, while not capturing medically-acceptable implants.

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

Thank you very much.

MS. SALTER: Thank you, Dr. Prestidge. I would ask that our speakers, we had a request from the webinar, try to move the microphone as close to you as possible. We can hear you fine in this room, but apparently sometimes it's a little more difficult for folks on the bridge line. So I don't know how you can move that, but just make sure it's as close to your mouth as possible.

Our next speaker is Dr. Herbert Mower and he 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 and has been active in the American Association of Physicists in Medicine in the American College of Medical Physics.

Welcome, Dr. Mower.

DR. MOWER: For those on the webinar, you missed my first comment. I stood back from the microphone in order to cough. I figured you probably didn't really want to hear that.

What I'm going to do is I'm going to briefly go to the various questions that were asked before the meeting and give you what the AAPM responses are to these.

Do the regulations have a specific section for prostate implant brachytherapy rather than combined with all other permanent implant brachytherapy? The AAPM's response and standing on this is no. This is something that should apply to any permanent implant brachytherapy and not separate sections in the regulations.

Should the criterion for defining a

Medical Event for permanent implant brachytherapy be activity based only? AAPM's response is yes, written directives should be at the time of the implant prior to the patient being discharged from the facility. It relates to real-time planning in the OR. Pre-plan is merely a guidance which is used for ordering the seeds for the implant and should not be used for anything else.

Should the criterion for defining a Medical Event for permanent implant brachytherapy be dose based only? Again, no, not dose based, but activity based.

Should the criterion for defining a Medical Event for permanent implant brachytherapy be a combination of activity and dose-based criterion? Again, no, not dose based, but activity based.

Should the NRC require training on how to identify Medical Events? No, training in general is part of the licensee's ALARA training program and it's covered there.

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

appropriate time frame? Our response is that the NRC should not specify a time frame to the regulations. This can vary from same day to one month, depending upon patient availability for any individual licensee.

There's also a sidebar comment from the AAPM that we would like to see as we go forward that the regulations start moving towards the terms of source strength rather than activity, keeping up with the current international system of units.

That should put us back on our time frame, huh?

MS. SALTER: You always get us right back on time, Dr. Mower.

DR. MOWER: They give me an extra dessert at lunch for keeping us back on our time schedule. I don't like custard.

(Laughter.)

MS. SALTER: I'm not sure what we're having today, but we'll sure we have something.

Our final speaker is Joanna Smith and Ms. Smith is currently the CEO of Healthcare Liaison, Incorporated, a healthcare consulting firm based in Berkeley, California which provides medical professionals an opportunity to gain certification as healthcare advocates.

She has 27 years of professional experience in the fields of medicine and mental health, with 20 years as a licensed psychotherapist in the San Francisco Bay Area.

Ms. Smith received her Master's in Social Work from Tulane University and her Master's in Public Health in Maternal and Child Health from the University of California, Berkeley. She is a Licensed Clinical Social Worker in the State of California and is a member of the Academy of Certified Social Workers.

Welcome.

MS. SMITH: Thanks, Susan. Okay. Let's try this. As I'm as close as I can be.

Good morning. I am going to ask you all to switch your frame of reference a little bit because you've been listening to a lot of technical information. I'm coming at this from a different perspective, so I represent what I call the consumer. I do not talk about people in terms of them being patients, because we've now entered a new world of consumer-based healthcare. So that's the terminology I'm going to be using.

That's the evolution of the world. We talked about people previously in terms of them being

patients, say I see them now as consumers. I think that's a really important mind switch for everyone to be aware of.

When we went into the world of managed care in the '80s, we brought in the concept of high deductibles in health plans. We brought in the concept of the consumer paying first dollar for their healthcare. We made changes under HITECH where currently now if people actually opt to pay for treatment themselves and they do not ask the insurer to pay, the insurer is not entitled to the data and the healthcare information on that particular treatment or procedure. So we've entered a new world in terms of how consumers look at their healthcare.

The medical community and regulators have dominated the discussion on Medical Event definition, but with increased financial input from the consumer comes an increased demand on the consumer side for transparency and what is occurring in the course of their healthcare delivery. Consumers are now considered payment sources. They want increased information on safety, efficacy, choices, and on outcomes.

With the activity and dose metrics, the goal should be to err on the side of very, very high

sensitivity where more events may be detected and consequently reported to the consumer. Consumers should know the difference between what was intended and what was achieved as well as the dosage. If post-procedure imaging can be completed on a regular basis and there always are a lot of complexities to whether people can return or choose to return for that post dosimetry, then the data would strengthen choices.

I want to remind people about the concept of an informed consent for any kind of procedure. There really are four steps to informed consent. The consumer first of all has to understand actually what the diagnosis is and be able to articulate that in their own terms. The second step is they need to understand what the treatment options are that are being considered and not considered. But the third step in informed consent which I think is most relevant here is people have to understand what the risks and the benefits are to any considered treatment.

Under risk, we have to look at the whole concept of Medical Event and I would argue that listening to the discussion this morning on activity base and dose base, I think we need to err on the side of high sensitivity and look at merging the two

parameters so the consumer has more of an ability to understand when there's been a Medical Event. I would add in perhaps we need a designation of preliminary Medical Event when occurrences happen that look initially like it is an reportable event, but over the course of time it resolves. So there will be two criteria: preliminary Medical Event and then actual designated Medical Event.

The other part of informed consent which is informed consent which is always critical is for the consumer to understand what happens if we do nothing.

The questions from consumers clearly on this issue are are my providers giving me appropriate information to make informed consent to permanent implant brachytherapy? The consumer needs to know about this discussion of the risk and of potential Medical Events happening because we've seen they do happen.

What assurance does the consumer have that medical and regulatory community is protecting the consumer rather than really reducing the risk of law suit? This is a dynamic on the world of consumer-driven healthcare that we're going to run into time and time again. It is the trust that the consumer has

in the medical community. I would argue that if we fall on the side of high sensitivity a more likely identification of Medical Event, we increase the consumer trust in what we're delivering.

From the public health side because I come from the world of public health also, Medical Event definitions should use the most sensitive metrics to ensure consumer and public safety. And treatment and determination of Medical Events affects the community at large, not just the individual consumer. So for example, if people travel to a site to receive treatment and there is some kind of Medical Event that could potentially expose people around them to increased risk, that needs to be identified: airplane passengers, hotel guests, and staff, and especially immediate family and friends.

Consumer public notification should be a requirement in any event defined as an ME. And people with potential direct exposure after a Medical Event should be provided with information, protected measures and follow up. I will just add that I'm coming at this from the perspective of someone who has a practice doing healthcare advocacy. I also am the founder and current president of the National Association of Healthcare Advocacy Consultants which

is a soon-to-be nonprofit which has as its members all of the people in this country that are doing this kind of work and working with consumers. Thank you.

MS. SALTER: Thank you, Ms. Smith. Well, that completes our panel presentations and I'd like to thank everyone for preparing those and sharing with us this morning.

We're about 15 minutes ahead of time and I don't know how much flexibility we have with the agenda if we can cut the break to 10:30 or if we need to stick to the 10:45 agenda. That will be a 45-minute break. I'm turning to Mike. 10:30. Okay, we're going to go ahead and take our break now, but we instead of doing 10:15 to 10:45. We're going to do 10 to 10:30. So come on back here at 10:30. That will give us a little more time for the discussion and worst cases we break a little earlier for lunch and have a little more time for that. So see you back at 10:30.

(Off the record.)

MS. SALTER: All right. Welcome back. We'd like to go ahead and get started, so if everyone can find their seat, we'll go ahead and get started in a minute or so. Am I missing a panelist? There he comes.

Wow. I like that. I wish that worked at home.

So we're now going to start the second part of the program which is the open dialogue with the panelists. And once again just to remind everyone in the audience or maybe you came late, this is the opportunity for the panelists to have a discussion. We will not be going to the audience for comments at this time, but we have all afternoon to do that. Once again, I want to remind you if you do wish to make a comment and you know you want to do that now, please go ahead and fill out that blue card and drop it off at the registration desk.

This discussion or dialogue is not scripted in any way. The panelists are free and encouraged to take this in whatever direction they would like as we discuss this issue of defining a Medical Event. But to kick it off and to get us started, I'm going to throw out a question and I'm going to start with Dr. Hagan. And I'm going to just ask you to elaborate on the issue of dose to other organs and tissues aside from the treatment site and get the panelists started on that topic.

Once again, I just want to remind you, please pull that microphone as close to you as

possible so folks on the webinar can hear. Thanks.

DR. HAGAN: Thanks. Is the mic on? It's sounds like it to me. Yes.

Thanks, Susan. The issue of that second portion of the requirement for regulatory evaluation of a prostate implant, the dose to other organs or tissues, is stated in fairly straight-forward language, but when you get into the details, the application is difficult and that application has now been completed for the VA, all across the country, starting with the implants from Philadelphia. So let me tell you about that and then I'd like to tell you why that's not my recommendation for where we should go with that regulation rewrite.

The requirement is for reporting of dose, donor organs and tissues that exceeds after we define a minimum dose, then exceeds the expected value by 50 percent or more. So what's the expected value? How do you determine the expected value?

Well, if you think of expected value as that value which statistically is expected from the implant done the way you intend to do the implant and the only way that you can provide that data is if you have a database of well-done implants. And for prostate brachytherapy, this is the case. There is

one recognized database for well-done implants that is managed by radiation therapy oncology group from Dr. Prestidge's protocol. And there are about 400 implants, I think, that had been reviewed as being per protocol. And so the blue ribbon panel realized that they could use that as an asset to determine what the expected dose to other organs and tissues, by defining the adjacent organs, the bladder, the rectum, and periprostatic tissue, not otherwise described.

In doing that, the analysis of those data involved a couple of contracts from the VA and at the end of the day, demonstrated that the dose that you expect to a volume as small as 1 cc is the highest dose for an uninvolved bladder or rectum or periprostatic tissue was approximately the prescription dose. It actually was a little lower than the prescription dose. And so that provided a mechanism for determining criteria. Then 50 percent greater than that would then be 150 percent of the prescription dose and then that was applied through the VA system.

Well, if you were to adopt dosimetric requirement based on the expected dose then for an implant, for a volume implant, then that's going to vary from site to site, that is, the specific dose to

the specific adjacent material. It's going to vary whether you're doing a lung implant or a breast implant or a GYN implant or a prostate implant. And until you have a well-vetted group of implants, you're not going to be able to demonstrate what the expected dose should be.

So isn't there a more straight-forward way of doing that? And I think the construct that ACMUI presented in 2005 was an excellent construct. So in the recommendation in 2005 to go to a source strength or activity-based metric, they also included consideration of other organs and tissues and that was in the following way. You could consider all dose either to the site that you're treating, or to another site, i.e., the correct site or a wrong site.

And for dose to a wrong site, that is, other organs and tissues, other than the target site, other than the treatment site, then there are only two categories of other organs and tissues, those that are adjacent to your implant and for which received dose for a well-done implant because they are adjacent to the organ you're implanting and then those that are non-adjacent. And they had two recommendations and I think those two recommendations are easily applied.

One, is to sit for the adjacent material

to use the same criteria as you're using for the treatment site. So if you have 20 percent of source material that's outside the treatment site, well, then it's treating non-target tissue. It's in the patient and it's not treating the target site, it's outside the treatment site. So adjacent, non-target tissue is being treated to a dose greater than that which was expected, that which was anticipated. And you need to have an amount of activity that would correspond to an unacceptable dose. Since you're already using 20 percent for the target site for the adjacent site, why not just use that same? If you have 20 percent of seeds that are outside your treatment site, then you're dosing adjacent tissue.

That leaves you with a problem of doing wrong site. And wrong site, I think you can easily or more easily see through an analogy. And that's the physician that, for instance, is going to implant the right breast and puts the first seed in the left breast and then says oh my gosh, I was supposed to implant the right breast. But all of the rest of the seeds where he intended those seeds to go, but clearly he has implanted a wrong site. Clearly, it's not an adjacent organ, and clearly, it's distant from the treatment site. There is no way you could argue that

that seed in the left breast is going to deliver dose to the right.

So that's clearly a Medical Event. If we did that today regardless of NRC regulations, we would tell the patient afterwards, this is something that you clearly would disclose to the patient and to the referring physician and you would document in your operative note as a matter of course. So easy to see in that setting.

So for a prostate, what would correspond to being so far away that you'd need to report it? Well, far enough away that clearly this seed intentionally placed is not contributing to the dose in the treatment site. So what sort of dose? Well, a practical limit that the panelists concluded and included in that recommendation in 2005 was three centimeters for prostate brachytherapy or for the type of sources we use for volume implants. And three centimeters is a reasonable value.

Now we could argue whether it's two or five or some other number, but to say that you intentionally place a seed, that is you direct the needle to a site that is three centimeters or greater from the site you intended to place it and you leave the seed there, then that's a Medical Event. One

seed. That's a Medical Event. And that's easy to score. It's easy to know whether you've done it or not. And what you need to do to qualify that is to say -- the regulation currently says, if the seed gets there through some patient intervention or through migration, well, it doesn't count. So a seed is in a vein and travels, well, that seed, the migration of that seed was not within an Authorized User's control.

Similarly, if the seed migrates under vacuum of removable needle or bone wax that's on the end of the needle, drags the seed back, so that the operator intended, the Authorized User intended and through imaging placed the seed in the correct spot, but then through the removal of the applicator, the seed then migrates, well, that's a seed that's migrated just as if the seed had migrated through soft tissue or had migrated through a vessel. So a seed that migrates is not something the Authorized User can control. So eliminating those seeds that migrate, any seed that is through intent placed greater than some fixed distance and I would say the three centimeters is as good as any, would constitute inappropriate dose to nontarget tissue and a reportable Medical Event.

So in thinking about that, went back to 13 years of implants involving almost 1200 patients done

at the VA in Richmond and with implants done by attendings and attendings with resident supervision and there's not one instance of a seed that was intentionally placed three centimeters away from a treatment site. So I think that it's a robust guideline as well and I would throw that out to the other panelists as something that we should consider. I realize we're going back in time to 2005, but I think the deliberations that produced that in 2005 were really pretty good ones.

MS. SALTER: Any other panel members want to follow on that comment?

All right, Dr. Zelac?

DR. ZELAC: Where are you? Oh, there you are. I would like to ask Dr. Hagan the following: when this approach was withdrawn from our proposed regulation, part of the reason was that some individuals claimed that it would be difficult, if not virtually impossible to know whether a seed, in fact, had been misplaced initially or had migrated or had through suction been drawn back. In other words, it would be there as a requirement, but it would be so subjective in terms of actually implementing it and using it that it could not pass muster as a regulation.

Could you --

DR. HAGAN: Yes. And I understand that concern and at the end of the day there's going to be some part of that concern that is not possible to resolve. So at the end of the procedure you image the patient. And you can see the treatment site and you can see the seeds. You can see those seeds that are outside the treatment site. And you can count them and you can measure how far they are from the treatment site on your imaging and if you determine that a seed is more than three centimeters away, then you have to make a determination. Who makes the determination? The team, the Authorized User. And perhaps that's something that could be included in the regulation is who has to sign on the location of the seed afterwards, but let's say the Authorized User has to sign whether that seed was placed where it was through migration or whether that seed was placed in the act of conducting the implant.

And so just like the -- in the activity metric, you're going to rely on the Authorized User's operative note which is done at the end of every procedure and describes whether or not this procedure has been done in accordance with the design of the surgeon or whether there were complications along the

way or whether there was any untoward issue that had to be resolved and is included in that operative note. And so the operative note also needs to identify the material that's placed within the prostate as whether it's placed there by design or whether that source distribution does not agree with the surgeon's design. And so the surgeon through attestation is going to attest whether the seed that is three centimeters or more away from his treatment site was placed there intentionally or migrated. So I don't think you can do anything better than requiring that to be in the best judgment of the Authorized User.

MS. SALTER: Dr. Welsh?

DR. WELSH: Not sure if this microphone is working.

MS. SALTER: They should all be turned on.

DR. WELSH: I believe that --

MS. SALTER: Can you pull it just a little closer.

DR. WELSH: How about now?

MS. SMITH: Yes, yell into it.

DR. WELSH: I believe that part of the controversy surrounding the three centimeter suggestion may stem from imprecision in the definition of the treatment site back in 2005 and earlier.

Back then, I believe that treatment site was synonymous with prostate gland. And ACMUI and many others have spent a good deal of effort in trying to educate all parties involved that modern radiation therapy terminology has evolved so that we have a gross tumor volume, a clinical target volume and a planning target volume. And at the time that the three centimeter suggestion was put forth, there was imprecision about what target -- what treatment site really meant.

Now if we fast forward to the present time, I believe everybody in this audience understands the critical differences between a GTV, CTV, and a PTV. And if we grant the Authorized Users the latitude to define treatment site as any one of the three, perhaps documenting it in the written directive, the three centimeter suggestion may not be as imperative as it might have been back in 2005.

For example, if one seed is three centimeters beyond the prostate in 2005, that would have been a problem. But if now using modern terminology the PTV extends beyond the prostate gland perimeter, then that same apparently errant seed would not be beyond what might be clinically acceptable if we have defined PTV.

And this is part of the reason why I and others may not be as much in favor of the three centimeter policy as previously because as Dr. Zelac pointed out, it is difficult to distinguish between a seed that might have been misplaced because of a vacuum effect, versus a seed that was just poorly placed on the part of the Authorized User. But if we say that the definition of Medical Event is 20 percent or a certain percentage of seeds that are beyond the planned seed distribution that would provide the coverage of the PTV, then we would be a little bit better off than if we have just one or two seeds that are on an arbitrary three centimeter boundary. That's just my take on some of these things with modern terminology included.

MS. SALTER: Okay. Ms. Smith, did you have hand up before?

MS. SMITH: I did. I was trying to figure out how to formulate what's in my brain. I think my question is whether it's by design or by migration, what happens and what is communicated to the consumer when there is a difference between what was planned, if we set it up at three centimeters or we look at the PTV, whatever parameter we use, what happens for the consumer whether there is a difference by design or

migration? What would the clinician communicate to the consumer about what transpired during that specific procedure?

MS. SALTER: Dr. Hagan?

DR. HAGAN: That's a good way to frame the question. And what it does is it parses out the apples and oranges from Dr. Welsh's comment.

So if we are looking at seeds outside of a treatment site, that treatment site is defined as anyone's favorite planning volume, that treatment site is that volume into which you intended to place seeds. That's your treatment site. And if you're counting seeds that are outside of that treatment site, then that's a way to evaluate the dose to the treatment site. But the patient and hard for me to think of them as consumers, but if the patient has a seed that is substantially outside of the treatment site so that it does not convey dose to the treatment site, it does not assist with the treatment of the treatment site and that seed was intentionally placed there, like my example of left breast and right breast, then the patient -- that act needs to be disclosed to the patient and there needs to be a similar equivalent in every volumetric implant.

So there needs to be some distance beyond

which it's clear that the seed does not contribute to the dose to the treatment site. It is clearly outside of that volume where the practitioner just simply missed and is so egregious that it's clear that that involves an implanted material that was a mistake, an implant material that was in error.

And though it's easy to see with left breast and right breast implant, there needs to be an equivalent for the prostate as well. For instance, we image the base of the prostate instead of the prostate itself. Or we image the base of the penis instead of the prostate itself. And so because the imaging is a little fuzzy and the person is not particularly good who is doing the imaging, places the first seed in a wrong volume in the base of the penis instead of the prostate, then recognizing the imaging is wrong, readjusted image and then does the rest of the implant well.

Well, that first implant, that first seed was implanted into a wrong site and that's a Medical Event. And there is very little room, I believe, for controversy in saying that I put a seed in the wrong place. I put a seed in the bladder when I meant to put a seed in the prostate, that should be a Medical Event. And the consumer should know. We should be

required to disclose that to the patient.

Now if we're looking at seeds that were intended to be put in the treatment site and they have missed the treatment site marginally by a few millimeters, well, then there needs to be a total criteria and that's what we have been discussing in terms of the source strength metric for the treatment site. And 20 percent is clearly an arbitrary figure, but 20 percent seems to work in the minds of most who have looked at this. So there needs to be some designation for how much of the activity outside of the treatment site is unacceptable, but there also needs to be a definition of how far away before we say that a seed intentionally placed that far away is a reportable error.

So there are two different aspects of the implant, each of which should require disclosure to the consumer, disclosure to the patient in my opinion.

MS. SALTER: Dr. Prestidge?

DR. PRESTIDGE: Just in follow up also to answer your question, I think that you don't necessarily have to have a Medical Event to feel compelled as a physician to reveal an outcome that wasn't as intended. And I'm not sure how you regulate such a thing. It has to do with ethics and good

medical practice and so forth. Because if you look closely enough at enough seed implants, particularly among those who are not doing them all the time and there's a lot of doctors out there that don't do them all the time, you'll see seeds that are not contributing meaningfully to the dose of the target. There's different reasons why.

Dr. Hagan mentioned migration is one and patients are oftentimes scared to hear this, but you can put a seed inadvertently in a vessel around the prostate and it ends up in the heart or it ends up in the lung. And those cases have been well studied and it's an incidence that's very uncommon. It's maybe one or two percent in most series. And to date, with rare exception, none of them have ended up having a clinical consequence to the patient, no adverse outcome to the patient. But still those patients should be informed, I believe. And I think most practitioners do, that they had a migrated seed and that is something they should be aware of and would be monitored for, that sort of thing. But I don't think by anyone's definition such an event should be considered a Medical Event, if that makes sense.

MS. SALTER: Dr. Welsh?

DR. WELSH: If I might add a few comments

here, I would agree that a seed placed in the left breast rather than the right is going to be a Medical Event. But I have some mixed feelings about whether or not a single errant seed more than three centimeters beyond the treatment site when we're dealing with prostate or any type of permanent implant brachytherapy should be also called a Medical Event.

In either case, I would agree that this needs to be disclosed to the patient and with all due respect to Ms. Smith, I'm going to continue to call these people patients. I just will never be comfortable with the idea that a patient in the emergency room, with a gunshot wound to the head is a consumer. Understanding that we're talking about a different situation entirely, but consumer is not the terminology that I might -- anyway, the individual, the patient does need to know that there may be a seed that is X number of millimeters or whatever distance from the originally-planned treatment site.

There needs to be a discussion about the potential medical consequences of this and as I think about this, perhaps the reason why I agree that a left breast single seed would be a Medical Event, if the intent was to put seeds in the right breast, lumpectomy cavity, is because this is clearly a wrong

site Medical Event. Whereas, a single errant seed that is beyond three centimeters from the prostate treatment site, I don't think would be as easily categorized as wrong site.

So I do think that when you have something that is clearly the wrong site, such as left breast instead of right, Medical Event -- the term Medical Event may be appropriate, even if it is a single seed, whereas if a single seed is beyond three centimeters from the perimeter of the prostate gland, I'm not as convinced that that should qualify as a Medical Event. It should be disclosed to the patient. There should be discussion about the medical consequences, whether it's going to compromise the cure probability or increase the complication rate, but a single seed as opposed to more than 20 percent of the activity in my opinion should not qualify as a Medical Event.

MS. SALTER: Dr. Hagan?

DR. HAGAN: I'll just point out that I think the logical extension is that we agree and the issue is the three centimeters. So there is a distance beyond which that is clear that that seed that was placed is placed so egregiously that we need to report it as a Medical Event. And the question is what is that distance? Maybe it's not three

centimeters. Maybe it's 15 centimeters away, but there is a distance.

MS. SALTER: Dr. Prestidge?

DR. PRESTIDGE: I guess my problem is with having one set distance as well. I like the idea of a target base or prescribed target definition because I don't think three centimeters would apply to all kinds of brachytherapy. For example, there are forms of brachytherapy in the brain where three centimeters would be horrific. So imprecision would vary and have much more impact, clinical impact, depending on the kind of brachytherapy. But if you're doing a brain implant on a brain tumor, you are defining a target and whatever the PTV is and then based on that, it's going to -- that will apply to any kind of brachytherapy being performed.

MS. SALTER: Ms. Smith, did you have your --

MS. SMITH: Not yet.

(Laughter.)

MS. SALTER: Okay. Mr. Walter?

MR. WALTER: Yes, Dr. Welsh, during your talk you had made a statement that kind of piqued my interest in asking the NRC a question. That's a round about way to getting back here to you, Ron.

(Laughter.)

You talked about the highly unusual retracted Medical Event where you had all the seeds inside the target volume, right along the isoline, but the dose distribution wasn't what you were expecting. All the dose goes to the target volume. Is that a Medical Event because distribution is off? Was that ever defined as a Medical Event by the NRC? Would something like that ever been defined as a Medical Event?

MS. SALTER: Dr. Zelac, and I would ask you to pull it real close because you're kind of soft spoken and they're having trouble hearing you on the webinar.

DR. ZELAC: Thanks for the warning. What we have to look at is what our current regulation is based on which is dose. So it's on the basis of dose and whatever parameter you're going to be using to determine that dose that calls that a Medical Event has or has not occurred are made.

What parameter to use, of course, is a function of what the physician chooses to use in the written directive and any comparisons then on the outcome should be in the same term. So if a physician chooses to describe the intended outcome in terms of

D90, then that's what the physician will be held to under the current regulation. So in the case that was mentioned of essentially all the seeds or many of the seeds being in one portion of the treatment site, resulting in low dose, unacceptably low dose to the rest of the treatment site, then that would under the current regulations be appropriately labeled as a Medical Event. That's not to say where we're going, but that's where we are at the moment.

MS. SALTER: Mr. Walter?

MR. WALTER: Okay, thank you for the clarification on that. We do have at least one state at this point in time that has adopted D90, at least, one, there may be two. I can't remember if the second one is actually using D90 or if it's using one of the V100 or 150s.

However, they are also looking at the practice of medicine and I am unaware if anyone out there or any of the members here who work in Agreement States are aware of a situation where the dose was within the target volume, but the dose distribution was not what was anticipated or hoped for, and was therefore considered a Medical Event? I'm unaware of anyone doing that and so I thought that was an interesting statement that you had made. Yes, that's

one of the -- where the practice of medicine as far as we were concerned would be you messed up, but it's the practice of medicine. You didn't mess up as far as the dose to the target volume overall because we just look at the target volume, not everything within the target volume.

So if anybody has anything that's happened where they have considered it a Medical Event because of that, I'd be interested in hearing about it.

MS. SALTER: Dr. Zelac?

DR. ZELAC: Just one comment and that relates to where we started with this. As I mentioned, this goes back to 2004. It was recognized by staff at NRC and I think correctly so, that there simply is not a clinical descriptor of the dose distribution that's suitable for regulatory purposes.

D90 is usable for under dosing of the treatment site, but it has no value and shouldn't be used as the parameter for high dose to the treatment site. So it was exactly the reason that we don't have a good parameter and there isn't really, unless someone has come up with one since, a good one available that the initial thought for moving from dose base to source strength base criteria for a Medical Event came into being.

MS. SALTER: Ms. Smith?

MS. SMITH: So following up on what you're saying, what would be the reasoning not to combine the two metrics if D90 is effective on the under dosing side, but not effective on the over dosing site, but activity based would be? Why would we not look at using both metrics to complete a full picture?

MS. SALTER: Does anyone want to respond to that?

Dr. Hagan?

DR. HAGAN: Well, D90 doesn't work on the under side. It may be better there than on the high side, but for reasons that we've shown here today in terms of changes in prostate volume, it doesn't work on the under sided.

MS. SALTER: Dr. Prestidge, hold that microphone real close.

DR. PRESTIDGE: Just to follow up on that comment as well, it's not completely agreed among all investigators that the D90, and I think Dr. Hagan made a mention of this, that the D90 is as straight forward as we once thought in terms of predicting cancer control. In other words, the higher D90 means you're going to more likely be cured of your cancer. There are a number of published reports that don't see any

correlation to D90 in terms of cancer control. So if that's the case, a low D90 you can have a patient with low D90 who is cancer controlled for 10 or 15 years, but their D90, according to the criteria we've been using it was as sub-optimal implant, yet, they're cured of their cancer. I don't understand it. I can't tell you that anyone can explain why that is exactly, other than it has something probably to do with the natural history of the cancer. And in some cases you may have a low D90, but the dose happened to be right where the cancer was and was in the low dose areas happen to coincide where there wasn't cancer.

So it's an imperfect, as Dr. Hagan, I think has pointed out, it's an imperfect measure. It may be the best we have for making comparisons between implants, but it isn't perfect in terms of predicting outcome.

MS. SALTER: Dr. Welsh?

DR. WELSH: I might supply some comments to Mr. Walter and Ms. Smith regarding some of their questions.

I think the point was brought up about the unusual case in which all the seeds were bunched in a single linear location. Should this or should this not be a Medical Event? Well, clearly, from a

clinical perspective, yes. This is very far from the intention of any Authorized User. The problem that we face is that with a dose-based definition, a D90 of 1 percent clearly would be tagged as a Medical Event, but in that particular case, all the seeds, well, 39 out of 41, I believe, were replaced within the target volume and therefore more than 20 percent were not beyond the target volume or treatment site volume. And the last time we reviewed this case, it was being retracted as a Medical Event because of that chosen criteria. So there is a problem with this case and it underscores the difficulty with the entire situation.

Perhaps a bizarre case like this could be identified appropriately as a Medical Event without going back to the D90 concept by using the ASTRO-proposed definition which has as an addendum the Authorized User must state that the seed placement was in accordance to his or her intentions, according to the plan. I think that would catch such unusual cases, even if the activity or source strength is all within the treatment site volume.

Alternatively, the ACMUI suggestion about octant placement would catch something of this sort because unless documented in the written directive, those seeds should be distributed in certain pattern

and finally, all of this could be verified by comparison of the seed distribution on post-implant dosimetry, compared to the planned seed distribution on the intra-operative or pre-procedure plan and therefore compared with the written directive in that form, rather than a simple piece of paper, the written directive, one could actually look at the computer-based treatment plan for comparative purposes.

MS. SALTER: Does anyone want to comment on the ASTRO definition or elaborate on that?

Mr. Walter?

MR. WALTER: Well, I understand the basis for doing something like that. During the break I was talking about one of the things that came up in our questionnaire that indicated that perhaps giving leeway to the licensee to come up with their own definition of what a Medical Event would be, running that written procedure and proposal by the regulating agency seems right now to be working to a certain extent in the states. However, like I said, it's not consistent across all state lines, not even consistent across county or parish lines and would lead to a very large discrepancy between what you would see from one place to another. And I believe that that itself would also lend itself to an inconsistency that you

really wouldn't know how to define it and therefore inspect it. And if it's not inspectable, for a regulator, it's worthless.

MS. SALTER: Does anyone want to comment on the issue of inconsistency?

Dr. Hagan?

DR. HAGAN: I think we need a definition that applies to everyone's practice. We can't have an implant that would be a Medical Event on one side of the street and would not be a Medical Event practice on the other side of the street because they have differing definitions. And I think it would be useful for us to answer whether there is a single seed equivalent Medical Event for prostate brachytherapy.

Is there a circumstance under which the placement of one seed in a prostate brachytherapy, one errant placement that is so egregious that that constitutes a Medical Event? So I think that's a good question to pose to the other panelists and see if there is any consensus.

MS. SALTER: Anyone want to respond to that question?

Mr. Walter?

MR. WALTER: We have to remember that one of the things that came out in all of this is that we

want to have a single standard for all permanent seed implants, whether it be prostate, brain, lung, whatever. So whatever we decide has to be across the board. And it's already been explained that we started going that route, we're going to have to take the most restrictive of all of them and apply it to the prostate as well. So bear that in mind. If you're not going to have a multitude of rules and definitions that you're going to have to deal with a worst case scenario in all areas.

MS. SALTER: Dr. Welsh?

DR. WELSH: I would agree 100 percent with what Mr. Walter has suggested about basically having a definition that works from county to county, parish to parish, state to state. It's imperative that we have some kind of consistency and if we're going to have a definition that is consistently applied, it had better be an appropriate definition and thus we're having these workshops right now.

The lack of an appropriate definition and therefore the lack of consistency from one place to another, state to state, whichever, leads to confusion. It leads to some controversy. It leads to procedures that are being tagged as Medical Events that might not necessarily be deleterious to the

patient. It leads to a lot of investigations that may not be necessary or appropriate as to whether or not Medical Event has occurred. It leads to patient consternation, referring physician consternation, anxiety about whether or not this investigation, whether it terminates in the label of the Medical Event or not, can have negative consequences on patient, practice, the referring physician, and prostate brachytherapy as a whole. And I believe that as one of my slides showed that this inconsistency in having an appropriate Medical Event definition and the consequent controversy surrounding this fact, has in my opinion, been instrumental in the declining use of prostate brachytherapy.

I don't know that it's because the consumers, patients, are choosing not to have prostate brachytherapy, it may be because of the negative publicity surrounding this in New York Times and other media venues. Or it could simply be that the physicians are shying away from it because why get into this morass of controversy about the Medical Event definition possibly having NRC inspection going on in my facility. How about I just stop doing prostate brachytherapy and offer external beam radiation therapy alone.

This is a potential and I think real problem surrounding prostate brachytherapy right now. And the net result is that patients who could benefit from this modality to cure their prostate cancer safely, effectively, and efficiently, maybe cost effectively, are no longer being provided this option, simply because it's dwindling in its availability.

Going back to Dr. Hagan's point about a single seed in an errant location qualifying as a Medical Event, I have a hard time with this problem. I recognize that it is a problem, but I think it's quite difficult in prostate brachytherapy. And this is part of the reason why the ACMUI has bounced back and forth between its sentiments surrounding the separation of prostate brachytherapy or more generally speaking implants in which anatomical rearrangement does not typically occur versus nonprostate implants or implants in which anatomic rearrangement exceeds normally occurs during the closure of the patient wound, for example, in lung brachytherapy.

It may still be appropriate to separate the two categories after all because of what Dr. Hagan has pointed out that it is very difficult to say when a single seed constitutes a Medical Event. Is it three centimeters? I would say no. Is it less than

that? No. Is it 15 centimeters? I don't know.

But when you're dealing with the breast as a more concrete example as Dr. Hagan pointed out, there is clearly a right side and a wrong side. If you're intending to put seeds in the right breast, but you put one seed in the left breast that, I believe, should be a Medical Event because it clearly is the wrong site..

But with prostate, it becomes a little bit more difficult to say what the wrong site is. There's only one prostate gland. And so it's somewhat difficult to say that if a single seed is in the rectum wall or in the bladder wall we have now got a Medical Event because that seed could be within the parameters needed to provide dose coverage to the planning target volume as intended. And without more than X number of X percentage, I should say of seeds that are so errantly located that it might be difficult in prostate brachytherapy to come up with an example and enforceable regulation which states that a single seed in this location or that location constitutes a Medical Event. And therefore, once again the content of separate prostate brachytherapy from other forms of brachytherapy may be worth reconsideration.

MS. SALTER: Let's go to Dr. Hagan, and then we'll go to Dr. Zelac.

DR. HAGAN: I fall back to my next line of defense which is to say then if we place a seed in a location where it cannot contribute to dose and the treating volume, that is that volume that was the target of our treatment. So those seeds, that seed is so far away that it cannot contribute.

Then at what point do we say that seeds that are placed in a way that they don't contribute would constitute a Medical Event and then I would sort of answer my own question and that's that perhaps at the end we have the Authorized User identify those seeds that are outside of the planning target volume or outside of the treatment site and as part of that attestation which now includes the seed distribution was as intended, then those seeds that are not contributing to dose within the treatment site are they there by migration or were they errantly placed for intent? And so that sounds like a reasonable evaluation that the Authorized User could do and something that we might be able to eventually turn into a criteria.

MS. SALTER: Dr. Zelac?

DR. ZELAC: Let me just repeat before I

start that NRC's primary purpose in having these meetings is to hear from others, so I'm certainly not going to expound and give lots of information as to where we are and what we should be doing from our perspective. However, I will mention that currently, our current regulations deal with the question of errantly-placed seeds by having other than treatment site tissues and organs and the doses that are delivered to those locations.

Now currently, just as a reminder, the criterion for reporting a Medical Event for other than treatment site doses is 50 centigrade, 50 rads and 50 percent higher than would have been and should have been if the treatment had gone as intended, delivered to that same site. Part of the criticism of this approach is well, one seed placed errantly will result in certainly a very high dose to the tissues immediately surrounding it. So on that basis, perhaps we, NRC, should talk about a volume of tissue or a portion of an organ in terms of volume that receives this dose level before we have a Medical Event.

So at the moment, we do have a regulation in place that deals with these misplaced seeds, but it's based on dose, not simply the placement of seed at a particular distance or location from the

treatment site. There's no question in there. It's just a comment.

MS. SALTER: Okay. Dr. Welsh?

DR. WELSH: So to continue our friendly debate with Dr. Hagan, first, I should point out that we're for the most part in agreement, for almost all part we're in agreement. However, this one point that's being brought up now about a single errant seed vexes me a bit.

So just as in the way of example, if we have a policy regulation in which a single seed that is misplaced by design is a Medical Event, but if that seed is errantly placed inadvertently because of vacuum effect or suction or bone wax, we are going to have some practical problems.

Hopefully, this would not happen, but if a seed is placed too inferiorly and it's in the penile bulb and the practitioner realizes after the fact that that's not where it should be, if it was placed there mistakenly, but intentionally, then it's a Medical Event. But if it was drawn back by the Mick applicator, it's not. So I would envision that could be a potential problem because Authorized Users are human beings and they're going to try to perhaps -- I don't like to say cover up, but sure, if this happened

inadvertently because of a patient moving or because the Mick applicator caused a vacuum, it's not a Medical Event, but if it's placed there inappropriately, but intentionally, but then realized to be a mistake, it's not a -- it would be Medical Event. So the physician would perhaps say it was because of the bone wax on that particular needle.

So you could have a little bit of a difficulty here. And so I would continue to argue that a single errant seed should not constitute a Medical Event. But if you have more than 20 percent of your seeds beyond the planned area of implantation, that's not something that can be attributed to early bone wax or to the Mick applicator causing -- that's a systematic mistake. And there's no way to justify that. That has to be a Medical Event. And that's why I continue to advocate the percentage of total seeds policy rather than a single errant seed.

Going back to the breast example, there's no doubt that when you have two sites with bilaterally paired organs as a good example, if you have the wrong site, it's a Medical Event, but when we're dealing with prostate, it's more subtle and the 20 percent or some percentage definition may be more appropriate than a single seed definition in my opinion.

MS. SALTER: Okay. Does anyone want to -- Ms. Smith?

MS. SMITH: So to draw this back a bit to the dose and activity debate because part of what I'm getting from Dr. Welsh's comment is that one of the problems with one errant seed is we start looking at what does that create in terms of dosing in the site where it's located, if I'm following you correctly.

So from my line of thinking then suddenly we're falling back on to the dose issue which to me argues again in favor of using both activity and dose. Because if I listen to the conversation here, we're talking activity and then we start talking about errant seeds, either one or 20 percent or however we define it, then suddenly we're back to looking at issues of dosage to other organs outside of the planned target volume.

MS. SALTER: So activity base versus dose base. Lots of discussion.

Mr. Walter, would you like to comment on that at all because I know you had -- you have already -- we've had a lot of discussion on that this morning, but I know that you in your presentation had favored the dose based. Do you see any solution or compromise to this or issue?

MR. WALTER: The 14 states that completed our questionnaire all indicated that ultimately they look at dose base. Everything I've heard here today starts off activity and ends dose base. Because in the end, well, in the beginning, the prescription is dose based. Goes through dosimetry and comes out with a certain amount of activity and numbers and distribution to match the dose to the target volume that was prescribed. And then in the end, if you go activity based to determine whether or not there's a problem as far as we've got this -- the total activity is within 80 percent that's inside the target volume, you're basing that still on dose because the dose outside of that is what I'm hearing is the main reason for saying there's a problem.

I mean you can't take activity by itself. It's all activity and placement and where it is in comparison to the target volume as to whether or not you've got a problem. So if you're going to use activity, and I don't believe that there's anybody here at any time from 2005 on who has said forget about dose completely because it doesn't matter. And so if you go activity base, you're still coming back to dose in the end. That's where the states were coming from. In the end, and in the beginning, the

first and last things you look at are the dose and how that's going to affect the patient.

The Authorized User is trying to determine what is the correct dose to the target volume to get the wanted results. The patient wants to make sure that that dose which that expert has determined is the right thing goes where that expert wanted it to go. And whether you use activity or anything else, the last thing that comes out is what's the dose of the target volume and what's the dose outside the target volume? And how can that affect the patient?

What we're doing here, I think, is we're trying to decide what are we going to do in the middle? Are we going to continue to just run the line down that dose line? Or are we going to say -- we're going to come along here and start off with dose. We're going to start using activity and then we're going to come back to dose line. Whichever way you want to look at it, what I'm hearing and what I've heard from the very beginning is it's ultimately going to be dose.

Now I do have a question because I know in Alabama, very, very few Authorized Users handle the Mick applicator. It's the urologists who are working under the supervision of the Authorized User who are

using the applicator. And so the question of whether it was intentionally placed there or not, when the Authorized User wasn't there to see it personally, it's going to be difficult.

Now I mean I'm just saying that because in our suites, the urologist is handling the applicator with the ultrasound tech and the physicist there and the Authorized User is usually not literally in the suite with them. Am I way off base?

MS. SALTER: Dr. Prestidge?

DR. PRESTIDGE: Is it on? This one works? In my experience and I've been involved in a lot of implants for a lot of years, I've never seen a urologist put seeds into the prostate. Part of the reason I thought that was the case is they are required to be licensed to do so. So I'm surprised to hear that that's a practice in some centers. How they reconcile that -- I've seen it done almost every which way it can be done, Mick and otherwise. I've seen urologists put the needles in and some of those cases, but in those cases the radiation oncologist comes behind them, connects the Mick and inserts the seeds. And that's what I've always told my urologists when they've asked. I say you're not allowed to do that. That's my job. That's why I have the license for the

isotope. That's my two cents.

MS. SALTER: Dr. Welsh?

DR. WELSH: I'll just reiterate what Dr. Prestidge said that I maybe heard of situations where it was contemplated that a urologist might want to handle the Mick applicator or the preloaded needles and put the seeds in, but fortunately I haven't heard of too many examples where that really is the case because it's my understanding that that is in strict violation of the regulations and how prostate brachytherapy should be performed. It should be that the Authorized User is the only one who can ultimately place those seeds and if a urologist who is not an Authorized User is actually doing that, that's a serious violation. Hopefully, it's not happening.

MS. SALTER: Mr. Walter?

MR. WALTER: The use of the radioactive material is under the supervision of an Authorized User, so if you're going to go and dose a patient with whatever, let's say 15 millicuries of I-131, the doctor will be in there. They'll talk to them. They'll brief their patient on what's going on and often will walk out while the tech gives the patient the dose.

Techs are doing patient dosages delivery

all the time. In the non-byproduct world, the physician is not there for external beam therapy. It's under the supervision of and -- it does not require other than in those locations in the rules where it states that -- such as Gamma Knife or HDR, it specifies someone must be physically present, whether it be the Authorized User -- the physician Authorized User or the physicist Authorized User.

So it would not, the way I interpret the rule, be a violation if the urologist working under the supervision of the Authorized User were to perform the procedure.

MS. SALTER: Okay. I heard lots of discussion on how a Medical Event is defined: activity source strength as the basis, dose, and then this discussion of possibly combining the two.

Would anyone like to comment on whether that's something that should be considered, and if so, what would that look like?

Dr. Welsh?

DR. WELSH: I might start off with a comment that -- going back to the single errant seed example. If this errant seed were too close to the skin, for example, it certainly could locally, to a very tiny volume perhaps or area, administer more than

50 rem and if you said well, what is the does plan to the skin? Well, it probably would be zero, so it would be more than 50 percent greater than what was planned to that tissue or organ and therefore it would meet the definition of Medical Event with the older proposed rules.

And I would contend that this is completely inappropriate and therefore we should abandon the old terminology or old paragraph 3.04583 that states that this dose of .5 Sievert, 50 rem, to an organ or tissue and 50 percent or more than the dose expected, I would suggest that that be abandoned altogether in the spirit of consistency of abandoning dose-based prescription of Medical Event altogether.

MS. SALTER: Anyone else want to follow up with that?

Dr. Mower?

DR. MOWER: I'm just the facilitator.

MS. SMITH: You're just passing the mic. Dr. Zelac?

DR. ZELAC: In response to that, I would simply ask the question, if we were to have the criterion that has been tossed around of greater than 20 percent of the total implanted activity being out of the treatment site, being the basis for a Medical

Event, what about the situation where it's not a Medical Event because you've exceed 20 percent? But the 19 percent are all localized in one place, the delivering dose to a site other than the treatment site. Wouldn't that be a Medical Event also or shouldn't it be?

MS. SALTER: Dr. Welsh?

DR. WELSH: I might respond to Dr. Zelac's point that with the recently proposed ASTRO suggestion that the Authorized User must also state that the distribution of the seeds is according to plan and this needs to be documented in the written directive. I think that no Authorized User or written directive would say that all 19 percent of the seeds are going to be bunched in a single location. So clearly that would be a Medical Event and would be captured by the ASTRO-proposed definition.

MS. SALTER: Dr. Mower?

DR. MOWER: To Dr. Welsh, doesn't the ASTRO distribution requirement refer to in the volume of interest as opposed to outside the volume of interest? And I think that Dr. Zelac's question is what happens if you have 19 percent of your seeds outside the intended volume, but in the same location?

MS. SALTER: Dr. Welsh?

DR. WELSH: I think that the ASTRO -- the spirit of the ASTRO definition is that the seed distribution should -- in reality should match what the Authorized User's intent was and the Authorized User must sign an attestation of that sort to say that he or she has indeed accomplished the aim in accordance to the plan. The plan will not call for 19 percent of the seeds all bunched up against the wall of the rectum outside of the prostrate. So under no circumstances would an acceptable plan ever call for something like that and therefore no Authorized User physician would ever sign an attestation saying that he or she intended to do that.

MS. SALTER: Dr. Hagan?

DR. HAGAN: Well, unfortunately, that brings us right back to the same issue. And if we are going to have that attestation apply to the distribution as a whole, that it was as intended or not as intended only with the caveat that migration doesn't count, then at what point does a single seed clearly placed outside of the intended distribution not by migration, then constitute a Medical Event because you can't sign the attestation that you intended to place the seed there.

MS. SALTER: Any other comments? We have

a few minutes left, about 10, 15 minutes.

One of the areas I know that the NRC was looking for some feedback on is the issue of timing and modality used to verify seed placement. I don't know if anyone wants to make a comment on that. I'll just throw that out there.

Dr. Prestidge?

DR. PRESTIDGE: Yes, I'll comment for Brad Prestidge and not necessarily for ASTRO, but the spirit of the ASTRO recommendation is that there be allowed flexibility for the very reason that there is no standard in terms of the type of imaging modality that's used or the timing that's done. There is a standard, I believe in the community that something should be done, some sort of post-implant dosimetry should be calculated, but there's so many variables that could be introduced to effect that, some of them mentioned this morning with regard, for example, to the patient himself being willing to or able to return, for example. And so I think what we would advocate or ASTRO would advocate and what I think is reasonable is that there be flexibility in that and that some form of dosimetry, post-op dosimetry be documented, an attempt -- that it be made and be documented and if for some reason the patient, for

example, is unable to or unwilling to return, that that will be documented and such a case would not constitute a Medical Event.

Most people use CT scanning as the imaging modality, but there are increasing numbers of centers that are using inter-operative ultra sound and based on that are using that as their post-operative dosimetry because they've compared it to their post-op CT imaging and there's a strong correlation. That has been something I've talked about doing or thought about doing for many years, partly to save cost for patients about -- to have to come and return, also time. And my consideration was to use post-interoperative dosimetry based on ultrasound. Most practitioners will agree is probably more accurate than CT scan anyway. And if it does not meet criteria for an optimal implant or an acceptable implant that then you'd have the patient return for post-op imaging or CT scanning later, but otherwise you would not. The assumption is based on the data that the post-op dosimetry parameters you achieve dosimetrically on the day of the implant, in general, almost always get with time because of edema resolution.

MS. SALTER: Dr. Mower?

DR. MOWER: We'll hit the second portion

of that first. The modality, it's an absolute disaster to write into any regulations a modality because what happens if next week, next month, next year, there's an improvement in another modality which makes it much more efficient to do the study or an equally good modality which is suddenly due to technology much cheaper to use for the patient, but cannot be used because the regulation states you use A instead of B, but A costs now three times what B costs for the same clinical result, or a new modality comes along or a better modality, you now have to wait for the months, years, decade plus that it takes regulators to manage to get into the law and the regulations that change for that. You've done a gross disservice to the patient, as well as to the national budget, if there still is one at that time.

What should be the timing? I'm not sure from a physics point of view exactly what it is, but I'm scared to death unless something is put into the regulations which covers the physician, the institution, in the case where for whatever reason the patient decides not to return because they were going to come back during that last week of a 30-day time period or what not, tornado, hurricane, occasionally in the Northeast we get Nor'easters and I'll explain

that to people later if you don't know what one of those is. Floods. Hopefully never again, but 9/11. Can't get there. We have several patients who come to us from Bermuda. What happens when for some reason the patient does not show up for that? Does that then become a liability against the institution and the AU as a Medical Event?

And guess what, if it's Day 30 and it's a 30-day window, you can't schedule them now for Day 20.

MS. SALTER: Dr. Welsh?

DR. WELSH: I think most of Dr. Mower's points are right on the money as far as the -- being prescriptive with regard to modality. I fully agree. As far as when to do post-implant dosimetry, I think this is a very sticky issue. I personally feel that post-implant dosimetry should be standard of care and I would not send a patient to a facility or a group of Authorized Users that doesn't routinely do post-implant dosimetry. At this point, it really is the standard of care.

Having said that, it's not synonymous with placing this into regulatory space because if you do say that post-implant dosimetry is required, it's regulated and if you don't do it, there's a Medical Event, then if you think about this, logically there

has to be an associated time frame. For example, if we don't put a time frame there, a year later, NRC comes by, oh we do our post-implant dosimetry at 375 days. You came just in time to remind us. Thank you.

So of course, there has to be some kind of time frame. And when is that time frame? Well, it's going to differ from isotope to isotope, the various organizations, American Brachytherapy Society, etcetera, have come up with recommendations. Sixty days may be appropriate, maybe 30 days for some situations. There may be appropriate times from a physics and a clinical perspective, but they are difficult to translate into a regulatory perspective. And for this reason, although I think that post-implant dosimetry should be performed and is the standard of care, I would not be in favor of insisting on post-implant dosimetry in the regulations for those reasons.

Having said that, it clearly is below the standard of care and I wish that there was a separate category so that if post-implant dosimetry is not done by 60 days, 90 days, 6 months, whatever, it's not a Medical Event which has a very serious negative connotation, but perhaps something like a violation of some sort.

MS. SALTER: Mr. Walter?

MR. WALTER: I whole-heartedly agreed with you. I believe that post-implant dosimetry is really the standard of care and it's really about the only way that we can check the dosimetry and such. We already have dealt with this in other instances in the rules. If it's patient intervention, in other words, the patient just says I'm not coming in and it's documented, it's not a Medical Event.

So if it's beyond your control, it can be written into the rules that way, but I do agree that I think there needs to be, if we're going to do this this way and we're going to have to have something from which to determine if a Medical Event has occurred ultimately, then there needs to be some time frame put on it. It can be whatever time frame has come up with, six months, six weeks, whatever, but we can always write into the rules that patient intervention, documented patient intervention rules out the possibility of the licensee having a problem with the regulator.

MS. SALTER: Dr. Zelac?

DR. ZELAC: Just a historical comment. In our current regulation, we do have a requirement for the written directive, the physician's order

essentially. And there is a requirement there for completion of the written directive. This is something that must be done before -- by completion of the written directive, but it's amorphous. We have no idea what that means. It's not determined. And some practitioners will say well, we're not done with the procedure until we do the post-implant dosimetry and we've chosen to do this a year later. So it's simply not good and not workable to have any regulation in effect that requires something to be done if you don't have some kind of a time frame associated with it.

MS. SALTER: We are down to about our last five minutes, so I would just like to give the panelists an opportunity if you've been holding back, now is the time to come forward. And I would also take the liberty of letting Dr. Zelac, if there was a particular issue that he would have liked to have heard that he didn't, this would be his opportunity to bring that up as we finish this part of the program.

Dr. Zelac?

DR. ZELAC: Always something to ask. Earlier on in this discussion and in the presentations, we've heard that having a criterion for Medical Event dealing with doses to other than treatment site which is currently at 50 percent above

what had been expected and 50 rem wasn't really workable because one, the dose associated with the 50 percent was too low.

So my question to any of the panelists would be if 50 rem is too low, what should the number be or should it be a floating number based on what the site is or how would you approach that if we are going to have that type of a criterion remain in the rule?

MS. SALTER: Dr. Welsh?

DR. WELSH: I'll try to answer that question as well as I'll provide a follow up response to that nagging question about that single errant seed. I believe that in my presentation I mentioned that ACMUI and the Permanent Implant Subcommittee, in particular, feels that the term Medical Event really should have some kind of a medical consequence associated with it.

I understand that NRC would like to be able to follow trends, but again, Medical Event might be a term that's just too harsh for just identifying trends. So in this vein, how would we deal with the single errant seed? Is it going to cause harm? Well, depending on where it is, of course, most likely it will not be causing any harm.

So although the 50 rem, 50 percent,

greater than expected dose that is in the current regulations may be nonsense, perhaps there would be some room for a Medical Event definition that could more appropriate identify harm from a single or single seed or percentage of seeds that are beyond where they're supposed to be.

And although I did mention that we would not be promulgating the ACMUI's alternative suggested definition, here is an example of where if NRC insists on having something that is dose based and we've heard from some of our distinguished panel members that dose may not be totally inappropriate and maybe some type of hybrid would be acceptable or appropriate. If NRC is going to insist on incorporating dose, we must abandon the old 50 rem and 50 percent statement that's in the current regulation as it is outdated, uses inappropriate terminology or inconsistent terminology and is clinically irrelevant and perhaps if NRC insists on having something that is dose based, that the ACMUI's suggestion of a small volume, D5 that exceeds 150 percent of the prescription dose, not the expected dose, but the prescription dose might be an appropriate definition that would still most likely not assign the term Medical Event to a single errant seed and would also not be so overly sensitive such as

the 50 rem and 50 percent statement, but nonetheless, be acceptable clinically and enforceful from a regulatory perspective.

MS. SALTER: Well, we are definitely going to continue these discussions this afternoon. However, we are going to at that time invite everyone in the audience to be able to make their comments and individuals on the webinar as well. If you're on the webinar, you'll type your question in and we will read it.

For those of you that are here and you would like to make a comment this afternoon and you know you'd want to do that, please fill out one of the blue cards you see in front of you and drop it at the registration desk.

I want to thank all of the panel members for being with us this morning and I believe most of them are going to be returning after lunch where we will be able to continue this dialogue regarding defining a Medical Event. So with that I'm going to let you go to lunch and we will reconvene in this room at 1:30.

(Whereupon, at 12:01 a.m., the meeting was recessed, to reconvene at 1:30 p.m.)

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

(1:32 p.m.)

MS. SALTER: Okay. We're going to go ahead and get started with our afternoon program, and this is the time when the audience, including those individuals on the webinar, will be able to enter into this discussion that we began this morning with the panelists.

Before we get started, I just want to remind everyone to -- if you have electronic devices to put those on the silent mode.

Once again, we are transcribing the meeting.

In addition, we have a number of people who are participating via webinar, which includes a phone line. And they are having some trouble hearing us, so, in addition to helping us get an accurate transcript to improve the participation of those on the webinar, ask once again that everyone keep sidebar conversations down.

When you speak, please use the microphone. And can I get the microphone maybe brought up here to the front, in the middle? Thank you.

Once again, if you want to make a comment, and you are here, please fill out a blue card. We

have a lot of those on the tables in front of you. I did pick up from the registration desk the blue cards that everyone turned in before lunch, so I have some of those.

And what I'll do is I will announce the first set of speakers. And when I call your name, I ask that you come up to the microphone and state your name and your affiliation. If during the afternoon you decide that you want to make a comment, just hold up your blue card and I will come by and collect it.

Once you fill out a blue card, if you want to make a followup comment or question, I don't need another blue card. Just raise your hand and I will call on you to come up to the mic.

Again, please talk into the microphone. State your name and affiliation.

For those individuals on the webinar, once we get through the first round of speakers here, I will go to Gretchen and ask her to read any questions or comments that came up over the webinar. When you submit your question or comment, please make sure that you -- Gretchen has your name, but she doesn't always have the affiliation or which organization you are affiliated with. So if you could put that in your comment as well that would help. That would help us

here to know who you are.

So I think I covered all the ground rules for that. And what we are going to do is similar to when we had the panel presentation, when someone makes a statement or a comment, I'll go to the panel members. If you'd like to make a followup comment or respond in any way, just raise your hand and I will call on you all and queue you up as well.

So I have three cards here for speakers. We have all afternoon, so I'm hoping that we get some interesting dialogue going. If not, I will just pitch some questions back to the panelists or allow the panelists to make a comment or pose a question to the audience.

So have no fear, we will have plenty to talk about this afternoon.

So the order for our speakers, we are going to first start with Dr. Sue Langhorst from Washington University in St. Louis. Then, we're going to go to Dr. Keunchul Lee from Meridian Health System, and then Ralph Lieto. So that's how we are going to start.

I just want to remind everyone on the webinar, although we don't hear you, you are in a listen mode, the members of the webinar can hear each

other. So please put your phone on mute. If you don't have a mute button, you can press star six. So just remind that.

So, Dr. Langhorst, if you'd like to get us started?

DR. LANGHORST: Okay. Sue Langhorst, Washington University in St. Louis and ACMUI. And I want to come back to Mr. Walter's comments on activity versus dose. And we are trying to establish a reasonable metric, and what we are talking about is activity or source strength, which provides that assurance that the dose distribution is acceptable or identifies dose distribution as not acceptable.

And an example of this that regulatory bodies use is something like effluent activity concentrations. We are trying to manage the dose -- public dose -- but we use activity concentration as our metric. And so I think that's what we're trying to gather here, and maybe an activity- or source-based metric doesn't cover every incident, but it covers a reasonable measure of that intended dose or measure -- metric of that intended dose.

MS. SALTER: Mr. Walter?

MR. WALTER: I understand where the ACMUI was coming from on this. The problem is that it's not

just the activity, it's placement.

Now, having said that, we also came to the conclusion, or at least I came to the conclusion in -- that if you have all of the activity, which starts off as I want this many centigray or gray to this target volume, and to get that you need to have 75 sources of certain -- of a certain activity placed in a certain way.

But if all of the activity and all of the dose -- "all of the dose," the primary dose -- is within the target volume, the dose distribution is the medical use. And so I'm not going to care about that part of it, because that's the practice of medicine. You got it all and you got all the primary dose, or all the activity, inside of the target volume, there's not going to be a medical event.

Now, that doesn't mean it's good medicine, but I'm not regulating good medicine. You say that it's going to go into a certain volume, and it all goes into that volume, however it's distributed, and it's not going to be a medical event to me. And I don't know of any states where they're doing that either. There may be some, but I don't know of any states that are doing that, because I don't know how each and every state is doing -- is taking care of

this.

DR. LANGHORST: Sue Langhorst. I agree with that, but what you had stated before was that it all has to come back to dose. And my point is is that it does all come back to dose, but you can base it on a criteria that uses activity and/or source strength to get reasonable assurance of that dose.

Now, your point with all of them bunched within the target volume, that may be something that is not appropriate for an NRC regulation. It definitely is a practice of medicine issue that should be dealt with in that regard, so I agree with you on that. But my point is is that the fact that you use activity doesn't mean that you are disregarding dose.

MS. SALTER: Dr. Walter.

MR. WALTER: Mr. Walter. I'm about the only one up here that's not, but -- sorry about that, folks.

The activity is great for -- but for one problem. You run into the problem where if you have 20 percent of the activity outside, because of the dose distribution inside of the area, if you put all of the -- if you've got a target volume and you put it all on the outlying areas of that target volume, and then you miss with 19.9 percent of them, and your

actual dose distribution into that target volume ends up being less than 80 percent, is that a medical event?

And under the rules, the way they are or the way they will be, if we keep 20 percent, they are going to -- it would be a medical -- it would be something that should definitely be told to the consumer, to the customer, because you're not going to have the efficacy, not necessarily going to have the efficacy that you are looking for, depending on where the dose distribution should have been.

So just using activity alone isn't going to do it either, and so what I said from the beginning was you start with dose, because that's what you know you want to do. You end with dose because you want to know whether you did what you wanted to do. What you do in the middle, as far as the activity-to-dose comparison, is what we are all here trying to figure out, how do we -- how do we tie those together?

Because it can't be just activity, because then you've got placement that could be off. It can't be just dose, because now you're talking about, well, it's going to mean that there's way too many medical events that aren't -- that don't have a medical significance to them.

And so if we're going to go this route, we're going -- and, again, we need to remember that it has been very strongly stated that we are only wanting to do one rule for all of these therapies. We don't want to go into a massive number of rules suddenly.

So we're going to have to work on not -- we need to think not just -- we need to think outside of the prostate as well, not -- you know, that's where most of them are, but that's not where all of these are going to be used, and so we need to consider the fact that we've got other places that we need to deal with as well.

Is this going to work all the way across the board, if you use just activity? I'm not sure.

MS. SALTER: Dr. Welsh, did you want to comment on that?

DR. WELSH: Yes. I agree with most of what Mr. Walter has said. But when he said, "Activity is great, but" -- and went on to discuss why activity may not be so great, I would just add that activity is great, but it's not perfect. But it's a heck of a lot better than using dose for regulation purposes.

And Dr. Hagan pointed out why this is the case. Ironically, dose is subjective when it comes to prostate brachytherapy, permanent implant

brachytherapy. That's not the way it is supposed to be, but that is the truth. Dose is a function of when you do the post-implant dosimetry, because of things like volumetric changes, shape changes, due to atrophy, hematoma, edema, shrinkage due to hormonal manipulation, etcetera.

So if the dose is changing as a function of time, where your calculated total dose, which in theory should be an immutable parameter, if that changes, depending on what day of the week or month or whenever you do your post-implant dosimetry, it's a subjective parameter. And it is not the object of criterion that we would want for regulatory purposes.

And if it is not objective enough, it may not be appropriate enough for regulation. It may be -- possibly, it may be valuable for clinical trials as a parameter for monitoring quality of implants and correlating something with outcomes. But, again, it's not the appropriate parameter for regulatory purposes, in my estimation.

Again, if all of the seeds, or source strength or activity, is within plus or minus 20 percent of the treatment site and -- importantly, and the authorized user signs an attestation that the seeds were placed in the distribution that he or she

intended them to be placed, then there should be no medical event, even if it is 19 percent or even if the dose calculated falls a bit shy of what might be considered by some to be optimal.

And, therefore, we continue to advocate in favor of an activity- or source strength-based definition rather than the subjective and, therefore, problematic dose-based definitions.

MS. SALTER: Anyone else want to comment on that before we move to our next speaker? Dr. Zelac.

DR. ZELAC: Just a quick comment I think to kind of fill in where we are currently and the direction that we intend to be going. NRC's long-standing medical policy statement makes it quite clear that we are not going to be regulating patient exposures, not going to get involved in patient treatments, except to the extent of trying to be confident that the patient in fact gets what the physician had intended.

If we go to, as has been suggested here, a medical event criterion which has, first, the fraction of the total implantation that winds up in the treatment site -- 80 percent or more -- and the statement that the distribution within the treatment

site was as the physician intended, I think we are quite in line with what our policy statement with respect to involvement in patient treatment covers. And I don't think we would be moving out of that confine that we try to operate and need to operate within.

So I'm just basically commenting in response to what I had heard earlier concerning, you know, the distribution within the treatment site is not necessarily of importance to us in terms of regulators. In this respect, it is.

MS. SALTER: Dr. Prestidge?

DR. PRESTIDGE: Just a quick point that occurred to me. It might be helpful for those who don't do prostate seed implants on a regular basis. As has been pointed out a couple of times, the dose calculated to the target varies according to the edema and how many days post-procedure that that imaging assessment is performed.

However, the sources within the target don't vary with time. So, in other words, as the prostate swells, the sources within the prostate move out with it, and when it retracts they come in together with it as well.

So, in other words, they don't move from

inside the prostate to outside the prostate routinely. I mean, that can happen, but for the most part -- and I think that maybe helps explain a little bit of the difference between looking at dose versus source activity here or number of sources.

Dr. Welsh?

DR. WELSH: I might also comment that some have perceived the difficulty with authorized user attestation, that the seed distribution is in accordance to his or her plan, because some have suggested that in order to get away with a bad implant and avoid having it labeled as a medical event, one might just change the written directive or say that, "Yes, this is what I plan to do."

But I would contend that regulators would be able to catch that kind of dishonesty, because there is going to be an objective computer-generated treatment plan. And that is the standard against which the seed distribution could possibly be compared.

Now, it may be difficult -- and it is difficult in practice -- to compare the post-implant seed distribution from the planned seed distribution, because we know that these seeds migrate, we know that sometimes they are -- we intend to place them in a

certain location, that the vacuum effect of the Mick applicator or the pre-loaded needle will cause an alteration of that position.

But if the authorized user has placed the seeds in accordance to that plan, and signs to that effect, the ultimate post-implant dosimetry CT study, or whichever study is chosen to -- for this purpose, should document that the seeds are in a position that approximates that planned seed distribution.

And that is one way to avoid the dishonesty that possibly could be -- could possibly occur if an unscrupulous authorized user were to sign an attestation falsely. So this is one way the regulators can stay ahead.

MS. SALTER: Okay. We are going to move to our next speaker, Dr. Keunchul Lee, if you could go up to the microphone.

DR. LEE: My name is Keunchul Lee, and I'm from the Meridian Health System from New Jersey. I missed the New York sessions, so I thought it's a good -- it's important for me, so I fly to -- up to here.

Actually, I had two issues to ask, but the first one was exactly the same as what she asked, so the -- I will go to the next one. From time to time, I hear that when this procedure is going on,

urologists and radiation oncologists goes together, and then put the needles by urologist and drop the seed by radiation oncologist. I think that's the right procedure, as I know.

But from time to time what I see is in many cases urologists not -- I mean, do not show up, and only radiation oncologists put in the needles and drop the seeds. But today I heard the opposite way.

So I have one question in that case. If the urologist puts the seed implant -- completely implant procedures, and then who has to do the post-implant dose calculations have to -- one or two days or right same days. And after assessment of that procedure, if we find some medical event, whose responsibility for that? That's my question.

MS. SALTER: Dr. Welsh?

DR. WELSH: So thank you for that question, and it gives us an opportunity to discuss some of the material that was brought up earlier by Mr. Walter.

I personally had not heard of scenarios in which the urologist is placing the needles and implanting the byproduct material, but today I have learned that that may indeed be occurring some places. And I stand corrected when it comes to the

regulations, but I remain standing in favor of the concept that that should never be happening.

The authorized user is the one who is legally responsible for managing that byproduct material and is the one who is going to be cited with the medical event if that seed distribution is not coincident with the plans.

And, therefore, I would be tremendously uncomfortable if I have a computer-generated plan that I planned, or I planned with my physicist, in order to cure my patient of his prostate cancer, and then leave it in the hands, literally, of another individual who is not going to be legally responsible with this medical event should something go wrong.

So although the regulation may not preclude a urologist doing this under the supervision of a radiation oncologist, I am strongly opposed to this particular practice, because, number one, it is bad medicine.

Number two, frankly, the radiation oncologist should have far more experience with placing these seeds and needles than the urologist would based on their training.

And, number three, it is a slippery slope in which the radiation oncologist authorized user

could be on the phone answering a page in the room next door, something of that sort, because it's not prescribed exactly what supervision truly is.

Therefore, today I am going to say that the radiation oncologist, who is the authorized user, should be the one that has to implant the byproduct material. And that should be the case, because he or she is the one who is legally responsible if this is a medical event.

MS. SALTER: Mr. Walter?

MR. WALTER: The way the rules were written at this point in time, the authorized user is responsible to supervise the use of the radioactive material in this case. So an authorized user can supervise, without physical presence, the implantation of these seeds by another individual.

If something goes wrong -- well, first off, go back to your second -- your second part of your question was, who does -- who decides whether or not the dose distribution and whether or not the -- what the dose to the target volume was? Generally, that is going to be the physicist who is going to start off with that, and then it would go back to the authorized user with it.

Who is responsible if something goes

wrong? The licensee. The authorized user will be responsible to the licensee for anything that happens on that license that they have done, or that they have been involved in. If they are supervising someone and that person screws up, we are going to hold the licensee responsible. We are not going to go to the doctor and say, "We're citing you. We're going to cite the licensee."

MS. SALTER: Dr. Mower?

DR. MOWER: A couple -- and I probably can't count correctly. I learned to count at Harvard. A couple of questions relative to that. The physicist does not decide that the distribution in the isodose is correct. He provides that information to the medical doctor. The medical doctor must make that decision.

The other thing that worries me about the radiation oncologist not being present, you see here we are and we are doing some brain surgery, and the anesthesiologist is there, and the neurosurgeon is next door, do you want the anesthesiologist operating on you? I don't.

The other thing is, relative to what the regulators are concerned about, there is a whole issue of radiation safety. Has that urologist had the

radiation safety training to know what he or she is doing with those radioactive materials at the time that they are being used without the authorized user being present in the suite.

MS. SALTER: Ms. Smith?

MS. SMITH: I would add to that from the consumer perspective that the consumer needs to have the most trained professional be the person responsible for completing the procedure, and that there is -- you know, in terms of how a consumer looks at it, I think we need to regulate as much as we need to to the lowest common denominator of performance out there, not to the highest.

So if we have many situations where it is the radiation oncologist who is actually doing the implantation, things are going fine, there is no problem with that or the licensee, but we have some other arenas where urologists are doing it and there are problems. We need to regulate to that lower level of performance.

MS. SALTER: Dr. Welsh?

DR. WELSH: I'd just comment on that statement by saying that urologists, unlike radiation oncologists who must have 700 hours of classroom training and years of direct clinical experience,

urologists don't have, for the most part, formal training in radiation safety issues, they don't have formal radiation physics, chemistry, mathematics, as part of their training curriculum.

And, therefore, if the urologist is the one that has the most experience in a facility, that facility shouldn't be doing prostate brachytherapy at all in my opinion.

So I think it's a very important point that Ms. Smith brings up that, yes, the least trained individual -- or you have to have the one with the most training to be the one that's the team leader in essence. If that one is not a radiation oncologist, there is something inherently wrong with that program, and I would not send a patient or consumer to that facility.

Having said that, in regards to the other comments that were brought up, it's true that the physicist is not the one who ultimately decides the seed distribution or the radiation dose distribution in the plan. It's the physician who gives it the final blessing.

And speaking from my own personal experience, which apparently may be different from most others in the country, I typically was the one,

as the authorized user and physician, who generated the treatment plan and ultimately decide the seed distribution.

I would have a physicist by my side or come in at the last second to verify that I wasn't doing something that was completely outrageous, or that this was not going to be possible, or that I was using the wrong units of activity, or whatever. But for the most part the physician was the one that made the plan of the seed distribution and the radiation dose distribution.

Additionally, I have never had a urologist in the operating room with me, and so to hear that there are some institutions where the radiation oncologist is in the room next door is something that is completely foreign to me, but it's, nonetheless, important for me and everybody to be aware of.

Having said that, I strongly disapprove of it, and, again, it's the one that has the most training that should be the one that is leading the show. And if it's not a radiation oncologist, there should be no show.

MS. SALTER: Okay. I think we are ready to go to our next comment from the audience, and that would be Ralph Lieto from the American Association of

Physicists in Medicine.

DR. LIETO: Thank you. Actually, I had three comments that I wanted to make, and two of them have already been taken, so I'm going to echo them anyhow. But I wanted to echo that I support what Dr. Welsh was saying about the issues regarding the dose-based versus activity-based criteria, and that the dose-based is a very subjective criteria.

And if you want people to be able to determine whether they have a situation that is clear-cut across all the states, the activity-based criteria is the better way to go, and has also been consistently, since 2005, what all the professional radiological societies have been putting forth, and as well as the ACMUI.

So I think it's -- to me, from my perspective at the table here, that the overwhelming consensus and support is for an activity-based rule criteria.

The only thing that seems to be a little bit undecided is, what is the magnitude of that deviation? Is it the one seed difference, or what I'll call the one percent value that Dr. Hagan was talking about? Or do we go to something in terms of the 20 percent value that has been proposed by some

others?

I think, really, the criteria that needs to be established right now is a -- or a consensus that needs to be established right now is, what is that magnitude of deviation from the activity-based criteria?

One thing about supervision of users -- I would have to also say that it has always -- having been an hour or so at a couple of large medical centers, it has always been my understanding that the authorized user is in the room when the seed implants are being done. The example that you gave to me is not really a delegation of authority, but more an abdication of authority by the authorized user, and I think that needs to be addressed in that type of a context.

And even though you have been reiterating what the rule NRC for supervision is, there is also other criteria for supervision that is required by the Joint Commission and CMS for these types of procedures that require that they be in the room.

So I think that's something that also needs to be -- and that is not in -- shall we say in NRC regulatory space, but is addressed.

So I'll get to my question, which is

another issue which had to do with your survey of the agreement states, Mr. Walter. It's not surprising that all the responses were based on a dose-based criteria.

In fact, I think if you would have gotten a response from all 50 states, and they all said that it was a dose-based criteria, I wouldn't have been surprised by that either, because that's what the current NRC rule is, and that's what the agreement states have adopted or have to adopt by their compatibility criteria.

I would have been absolutely astounded if even one of them had established an activity-based rule in their regulations. So my question is: are all the agreement states -- have they all adopted the activity -- or, excuse me, the dose-based -- the current dose-based criteria as a criteria for medical events?

Actually, I pose that to you, both you and Ron or if they want to punt it to maybe somebody else on the NRC staff who might have an answer to that, because it's -- I've heard that there are some states that have not even adopted the medical event rule as it currently exists.

MS. SALTER: Dr. Zelac?

DR. ZELAC: I don't have numbers either, as Mr. Walter has just said. But I think it's important to keep in mind what was pointed out earlier -- I believe it was in Dr. Hagan's presentation -- as to what our current rule says.

When it says "prescribed dose," for permanent implant brachytherapy, we are talking about either the actual absorbed dose or total activity and time. So there is no restriction currently on an individual licensee using total activity as their measure of dose in our current regulatory scheme.

MS. SALTER: Mr. Walter?

MR. WALTER: I am aware that there are at least -- there is at least one state that has not adopted Part 35 at all yet. But I do not know what their current rule states as far as what a medical event is. It may still be called a misadministration, for all I know.

I do know that of the 14 states that did respond, all of them had adopted the same or more restrictive medical event criteria, because it is -- from a compatibility standpoint, it is a C, which means that a state has to be the same or more restrictive than what the NRC's are.

And, let's see, I'm trying to remember --

there was one other question you had I think. Is that it?

DR. LIETO: Well, the last part of the question was: do you know how many states have not adopted? And there is not -- it sounds like there has not really been an assessment done at that level.

Ron, your response to my question, I mean, I totally -- I don't have any problems with that, but it didn't get to the -- what my specific point was is, do we know how many agreement states are out there that do not currently have -- or adopted even a current dose-based criteria for medical events?

MS. SALTER: Mr. Walter?

MR. WALTER: I do believe that the state that I'm thinking of has the old criteria prior to 2005 that are used in their actual license as -- and they're in the conditions of the license rather than in the rules. And some states do -- rather than adopt rules, because sometimes it can be really, really onerous to get rules adopted, will go ahead to try and meet the criteria of three years for compatibility, start putting those rules as conditions in their licenses.

So whether they have adopted the actual rule or not does not necessarily mean that they are

not using the same criteria. I just don't right now know what criteria that the one state I'm thinking of uses.

MS. SALTER: Okay. At this point -- oh, Dr. Welsh?

DR. WELSH: I'm going to switch gears a little bit and address one of the other points that Mr. Lieto brought up, which is regarding the authorized user abdicating responsibility by not being in the OR directly supervising the procedure or participating in the procedure directly.

I'm taken aback. I'm -- no, I'm frankly blown away by what I've heard today about what Ralph has eloquently called abdicating responsibility, because that is what it sounds like is happening.

So in the interest of the patient or consumer, I agree that the one with the most experience is the one that should be running the show. And I've stated before that that should be a radiation oncologist, and if it is not the program probably is not meeting standards and probably shouldn't be continuing.

But following up with what Dr. Mower said, in his analogy about a neurosurgical procedure going on, you certainly wouldn't want the neurosurgeon to be

in the room next door or answering a phone call while the anesthesiologist is performing the hemispherectomy.

Now, this is not brain surgery. It's far less involved perhaps than a neurosurgical procedure of that magnitude, but nonetheless it is a complicated and an involved procedure from the radiation safety perspective, the dosimetry, the physics perspective.

And, therefore, it should have a bit more direct involvement in supervision than what I have heard might be occurring in some practices. So unlike the 390 procedures, such as swallowing an iodine-131 pill for thyroid disease, which I can perhaps understand the authorized user delegating that responsibility to a technician.

The 490 procedures perhaps have a higher level of complexity and detail and should mandate direct supervision and physician presence, if that is not in the regulations, and apparently it is not. So although I don't want to get too far off course and start adding suggestions for further regulations today --

(Laughter.)

-- it sounds like I am.

(Laughter.)

And I would say that the authorized user should be physically present and supervising the implantation of byproduct material if he or she is the one that is going to be cited in the medical event 490 procedures. Perhaps not necessarily for the Part 1000 or 390 procedures, but for the 490, I think that most radiation oncologists would echo this sentiment.

The authorized user should be present and directly supervising that procedure. And I'm not advocating that a urologist be the one doing it, although I suppose that in principle it could be, but certainly for residents in training the authorized user needs to be present and directly supervising to make sure that the procedure goes well and meets the standards that are demanded by our patients or consumers, so that the best care possible can be administered.

MS. SALTER: Okay. Mr. Walter?

MR. WALTER: Dr. Welsh, just for clarification's sake, I hope you are just talking about permanent seed implants and not temporary. Or are you meaning both? I think the NRC needs to know that.

DR. WELSH: I may have to think about that, but I will tell you my personal perspective is

the authorized user should be there.

MS. SALTER: Okay. I am now going to go to Gretchen. We have a couple comments and a question from folks on the webinar. So --

MS. RIVERA-CAPELLA: Thank you, Susan. The first comment is from Mary Moore from the Philadelphia VA Medical Center, and her comment is in response to Dr. Zelac's discussion in the morning. She is saying that Dr. Zelac has identified a critical factor in addition to seed or seeds location, the volume to be contoured around the seeds need to be addressed for both clinical impact and in the determination of a medical event.

So our next comment is from Jeff Michalski from Washington University, and he is saying that, "I believe there needs to be a decision made between metrics used for quality of care and metrics necessary to report to the NRC for misapplications of radioactive material. While absorbed dose metrics have a role in quality assessment and quality improvement for patient care, they may not be ideal for regulatory purposes."

The use of the D90 metric in the NRC infringes on the physicist's -- or physician's, I should say, practice of medicine. I agree that the

activity metric into the target volume meets the regulatory requirement.

In our question -- do we have comments?

MS. SALTER: Do we have anyone that wants to comment on that? Dr. Welsh?

DR. WELSH: I think that was Dr. Michalski's comment, and I would say that ACMUI agrees with his perspective that different metrics may be appropriate for clinical trials versus regulations. And while D90 might be -- might be acceptable as a parameter for measuring outcomes in clinical trials, it is inappropriate for regulatory purposes, and for NRC or any regulatory agency to impose the use of D90 or another dose-based metric would be inappropriate. So we are in agreement with Dr. Michalski.

MS. SALTER: Can you elaborate on why that is? Why you believe that? I mean, you both stated what, but --

DR. WELSH: Well, briefly, for the reasons we have discussed this morning -- and Dr. Hagan presented in his slideshow about as an example, dose-based metrics such as the D90 being subjective. As weird as it sounds, ironically, dose is subjective. And if you were to attempt to calculate final total dose to the prostate on day one versus day 15 versus

day 30, you might come up with three different numbers because of edema, atrophy, hematoma resolution, etcetera.

And if you come up with three different numbers, that's not an objective parameter then. And so if it's changing from time to time, it is not going to be appropriate for regulatory purposes.

MS. SALTER: Okay. Just wanted -- because the people on the webinar can't kind of come back, so I just want to make sure we cover their issue.

And we had one final?

DR. PRESTIDGE: Susan, if I could just add onto that as well.

MS. SALTER: Oh, sure. Dr. Prestidge?

DR. PRESTIDGE: Yes, I appreciate Dr. Michalski's comment and agree with it completely as well, and I think it's a good point because I have been thinking that all morning and trying to -- a way to try and express that.

Dr. Hagan showed in his presentation one of the criteria for defining an implant that was outside the standards of an optimal implant -- one of them was a D90 of greater than 130 percent, and that's an example. That -- and I was part of the group that suggested that criterion for that protocol, and the

reason that we have those kind of criteria is we need some means to be able to compare implants and to follow patients over time and look at their outcomes and toxicity, and so forth, more subtle things, not necessarily whether or not cancer is controlled, although that is always important, but whether or not the patient has problems with their bladder and urethra and those sorts of things.

So we have to have some kind of bars to set for comparison. By the time we proposed those numbers, there were many others like that that defined an acceptable implant, you know, a deviation, a minor deviation, a major deviation, as we needed to have those kind of numbers, so that we can classify and keep track of the quality of the implants. But those were all set at the time based on the data that we had, and that was around the year 1999 or 2000, the best data that we had.

And I suppose -- I'm pretty sure that if we were to rewrite that protocol today those numbers would be different, and that's just because we have learned things over the past decade of what really defines a good implant and what's acceptable in terms of the high and the low doses, and so forth.

And having said all of that, as I have

said earlier, unfortunately, there is not a 100 percent correlation with the higher dose meaning that necessarily a patient will be cured, and vice versa.

So I think Dr. Michalski's point is very well taken, and an important point to make for the NRC is that there is a difference between trying to define more subtle aspects of quality between implants for comparison purposes and for teaching purposes and for learning, for the physician who is doing the procedures, and what qualifies or justifies being called a medical event -- in other words, something that has potential to cause harm to a patient.

MS. SALTER: Okay. And I think Dr. Michalski -- is that how you say it?

DR. MICHALSKI: Yes.

MS. SALTER: -- has a followup as well, so --

MS. RIVERA-CAPELLA: He is just saying that Dr. Welsh explained his rationale perfectly.

The question that we have is from Daren Perrero, and he is from Illinois Emergency Management Agency. How do members of the panel envision how an activity-based definition of a medical event would apply to treatment with a gamma knife, HDR, or teletherapy?

MS. SALTER: Dr. Zelac?

DR. ZELAC: I think that question brings up where we started from with this whole discussion. Everything that we have been discussing today is intended for permanent implant brachytherapy, period.

There has been consideration several years ago as to whether the dose-based criteria that we had for all of the various modalities of usage was at -- were appropriate or not in the regulations, and the decision was by staff advising the Commission, which the Commission then agreed with, the criteria that we have in place for all of the other modalities is quite adequate, as it is with the exception of applying it to permanent implant brachytherapy. And for that we needed something different.

We also recognize at the very same time, as I said earlier, that there really wasn't an appropriate dose metric that was utilized that would be suitable for this purpose, which is another reason why a change to something else, specifically source strength-based criterion, was considered to be the way to go.

MS. SALTER: Dr. Welsh, did you -- okay.

DR. WELSH: A quick comment. While we are advocating activity-based metrics as the criterion for

defining medical event in permanent implant brachytherapy, such as prostate brachytherapy, activity does not have an equivalent role at all when it comes to gamma knife radiosurgery or cobalt-60-based teletherapy, or even HDR, high dose-rate brachytherapy.

They are very, very different from permanent implant brachytherapy, and that's why we are having this workshop that is exclusively focusing on the latter. Having said that, I would say that unlike what Mr. Walter has said before about adamantly opposing having separate categories for prostate versus non-prostate, the ACMUI is not very fixed in terms of its opinion on this matter.

We have discussed it multiple times and come up with multiple different conclusions. In an ideal world, an ideal definition for medical event would be appropriate for all forms of permanent implant brachytherapy. But just as HDR is very different from LDR permanent implant brachytherapy, I think that there are subtleties that distinguish prostate brachytherapy from the other forms of permanent implant brachytherapy that are not just -- that are significant.

One is the anatomical difference in that

for lung brachytherapy, where we are sowing seeds into a mesh and then folding tissues together, there is anatomic rearrangement of those seeds. And, therefore, any dose-based metric is going to be very, very difficult to implement.

So a perhaps logical distinction might be made between seed implantation procedures where seed distribution is altered upon completion of the procedures, such as in lung, versus brachytherapy procedures in which there is not anatomical -- just changes in the seed distribution upon completion of the procedures, such as prostate.

In practice, this might amount to a distinction between prostate versus non-prostate. But in addition to that anatomical difference, the technology is so very different for prostate brachytherapy compared to what it is from -- in the other forms of permanent seed implantation brachytherapy in terms of the pre-treatment planning, the use of real-time ultrasound guidance, the intraoperative planning procedures that sometimes go on in comparison to a pre-treatment or pre-implant dosimetry, the followup post-implant dosimetry.

All of these things distinguish prostate permanent implant brachytherapy from most of the other

brachytherapy procedures to the extent that I and some others on the ACMUI are not opposed to having separate categories.

But if we come up with an ideal medical event definition, it should be able to encompass both subcategories of permanent implant brachytherapy. And I believe that the activity-based metric may be capable of doing that.

So although, in principle, it might be appealing intellectually to distinguish prostate from non-prostate for the reasons I have elucidated, in practice, if we come up with an appropriate definition -- and I believe that the ASTRO definition, the ACMUI definition, which are activity- or source strength-based, would satisfy both categories.

MS. SALTER: Would anyone else like to comment on this issue of combining prostate implant brachytherapy with other permanent implant brachytherapy? Because I think Mr. Walter said that they -- he was under the impression that there was a sense that they had to be combined. I think this is your opportunity here to tell the NRC, you know, what you feel about that, what your thoughts are.

Dr. Welsh has done so. I don't know if anyone else has a similar or different opinion, either

on the panel or in the audience? Dr. Mower?

DR. MOWER: If I would pay attention to what my slides are -- and I never listen to what I'm saying -- I believe my second slide said that the AAPM endorses having one system instead of having multiple systems.

MS. SALTER: I'm sorry. Mr. Walter?

MR. WALTER: My statements aren't based on -- the statement that I have made twice today about one rule isn't based on anything that the states have commented on. It's based on the comments that I have seen that have come back to the NRC.

I have not seen a comment that says anything other than one rule. That's the only reason I say what I said.

MS. SALTER: So now is -- we have an opinion to keep them combined, an opinion that maybe it makes sense to separate them. However, if a medical event definition can come up that adequately addresses the needs of both, that would be okay. Dr. Welsh?

DR. WELSH: I think you have just said it. If we can come up with the appropriate medical definition, medical event definition, there is no need to break out the categories. If we adhere to

something that is dose-based, I think we are going to have problems and we might have to bring out the subcategorization, which is something that I don't advocate.

MS. SMITH: Can I ask a question?

MS. SALTER: Ms. Smith?

MS. SMITH: So question -- when there is post-implant dosimetry done, either 30 days down the road, 60 days down the road, 100 days down the road, what in fact are we measuring then? Are we still measuring placement of seed, or are we back to dose? What does that measurement accomplish?

MS. SALTER: Dr. Mower?

DR. MOWER: Yes, both.

MS. SMITH: Both.

DR. MOWER: Both. We check the number of seeds, we count the number of seeds, make sure that they are all where they are supposed to be, what not, and then we also look at what the dose is.

MS. SMITH: Okay. So with that background, I would say we are trying to rush medicine, and maybe we don't need to rush it. That in the end, what we are ultimately looking at here is a combination of dose moving to activity, moving back to dose in the long run, if in fact we do get data from a

significant number of patients on dosimetry somewhere down the road.

So, you know, that's one reason I'm still on the combined dose and activity parameters, because it sounds like in the short term, yes, we are looking at activity, but in the long term down the road we circle right back to dose, which is where we were this morning, but --

MS. SALTER: Anybody -- Dr. Zelac?

DR. ZELAC: I think it's important to point out, as most of us I'm sure appreciate anyway, that the determination of dose after the procedure has been completed is for purposes of determining what, if anything, additional needs to be done for the appropriate treatment of that patient. If the dose is less than had been originally planned, for whatever reason, extra dose can be --

MS. SALTER: Ron, can you pull the microphone -- kind of lean it over? It's hard to hear.

DR. ZELAC: Yes. If the dose that in fact results from an implant procedure is less than what had been anticipated and planned, then additional radiation can be given by a number of different techniques to make up for that, to get to where the

physician had originally intended. If the dose is greater than had been intended, for whatever reasons, again, there are things that the physician can take into account and do for the betterment of that patient's overall response and outcome.

So the determination of dose is not simply for its own sake, to have a number to put on a piece of paper, but also to determine what, if anything, needs to be done for the appropriate care of that patient at that point in time.

MS. SALTER: We'll go back to Ms. Smith, and then we'll go to Dr. Mower.

MS. SMITH: Which is -- you know, is actually exactly my point is it accomplishes multiple things to put in that second dosimetry, that later dosimetry measure. But I think it enriches the data that we have, because it does give us dose and it does give us the ability to look further into treatment.

MS. SALTER: Dr. Mower?

DR. MOWER: For those who may not be aware of all of the things that a lonely physicist does, one thing that we do any place in radiation therapy, as a part of a good quality assurance program, is to do a second independent check of all calculations, and what not, that are made.

So the CT scan, or whatever that is followed by doing a second plan, and what not, and certainly in my institution, you know, whoa to that physicist who happened to be the one who did the first plan who then tries to sneak by me and do the second plan, he or she will get knuckles rapped severely. It is an independent check to make sure that everything that was done at the time of the procedure was done the way the physician intended for it to be done.

So a second check does other things besides those things we have talked about today, and it is standard operating procedure throughout all of radiation oncology -- external beam, gamma knife if you're doing it, whatever. It's done with everything.

MS. SALTER: Dr. Welsh?

DR. WELSH: I'll take a stab at answering Ms. Smith's question about, what do we measure with post-implant dosimetry? What's the reason for it?

I would say that Dr. Mower is right. We are measuring the seed distribution, and we are measuring the dose. However, for the reasons that we have discussed many times during today's workshop, measuring the dose may or may not be the smart thing to do, because what are we going to do with that information?

As Dr. Zelac said, well, if we find that we have grossly underdosed the patient, maybe we can supplement it with some external beam radiation therapy. But I can tell you that any experienced prostate brachytherapist who has calculated an underdosage will probably have that patient come back on at least one further occasion to validate that estimation of dose, because that's all it is. It's an estimation of dose at a particular point in time, because of the volumetric changes in the prostate.

So as an example, if I did post-implant dosimetry at day five, and the prostate was 50 percent larger than it was during my procedure, there is going to be a significant underdose. Well, I certainly wouldn't rush into planning to supplement this patient with external beam radiation therapy. I would bring that patient back on at least one occasion to do post-implant dosimetry at a time when the edema has resolved to see if there truly was a discrepancy in the dose administered versus the dose planned.

So the post-implant dosimetry really does measure the seed distribution, and it does measure the dose. But what to do with that dose estimation is somewhat problematic. For the reasons I just discussed, I wouldn't rush into supplementing external

beam for an initial assessment that suggested an underdosing.

Similarly, in clinical trials, or in single institution retrospective analyses, series, if the post-implant dosimetry is not done at exactly the same point in time following the procedure, you are not going to be able to use that dose-based parameter for the purposes that you think you are using it for.

If you are analyzing the past 500 patients, and you have done post-implant dosimetry anywhere from day one to day 60, and you are trying to correlate your D90 with biochemical control or urinary adverse effects, you are not going to be able to draw the conclusions that you might think that you are going to draw simply because dose, as measured on post-implant dosimetry, is not as objective as we want it to be.

And, therefore, although we do the post-implant dosimetry, and we do measure the dose, and we do measure the seed distribution, we probably shouldn't be relying too much or putting too much faith or stock in that number that we get when we calculate the dose from our post-implant dosimetry. And certainly it should not be used for regulatory purposes.

MS. SALTER: Okay. Sue Langhorst, do you want to come up to the mic?

DR. LANGHORST: I would like to suggest a change in verb in what you're saying. Rather than the dose being measured, it's calculated. And that's -- it's an important factor for that therapy and knowing that the patient got the right therapy. It's just not good to measure regulatory compliance, because of its inexactness between physicians, even between the same physician, on going back and trying to redo a plan.

So it's an important measure -- not a measure, an important calculation, but not so great when you are trying to make these regulatory judgments of compliance.

MS. SALTER: Dr. Welsh?

DR. WELSH: Yes. Dr. Langhorst is right. This is nothing more than an estimation of the dose. And I think that many practicing radiation oncologists who perform brachytherapy realize that on the very same day, if you were to calculate the dose -- the dose -- or, I'm sorry, measure the dose or estimate the dose, whichever verb we choose, we might come up with very different numbers, because of the imprecision of using a mouse to contour the estimated volume of the prostate based on a CT, which is very

difficult to -- which makes it very difficult to delineate the prostate boundaries in the first place, and what Dr. Hagan showed in one of his slides where a couple millimeters difference leads to a tremendous difference in estimated dose, so that one might even be a medical event and the other one is considered a good implant.

And, in fact, I'm talking about the exact same -- same set of images, done by the same physician on the same day, I'd be willing to bet that you might come up with some surprisingly different calculations in dose or estimations in dose.

And that's why Sue's point is well taken. This is not a calculation of real dose. This is an estimation or measurement that is variable and subjective.

MS. SALTER: All right. I think we have a comment from the webinar, so let me go to Gretchen.

MS. RIVERA-CAPELLA: Okay. So our first comment/question is from Timothy Gao from Southern Advanced Medical Physicists, Inc. And he is saying, "The source strength-based definition should be preferred, because it is directly related to delivered dose but eliminating the quality volume in D90 or V100."

That is subjective and varies significantly between individuals contouring the prostate, depending on the timing and modality of the post-implant and possibly the algorithm used by a specific planning system in computing the volume.

Consider gynecological applications -- tandem and ovoids. It is common that the applicator is not at the desired location. Similarly, in HDR prostate application, sub-optimal needle placement has no regulatory consequence as long as the computer plan is done and delivered correctly by the computer-controlled machine.

These poor temporary implants could be because of authorized users' experience, skill, or patient conditions such as bone interference or movement.

Then, the question is why suboptimal needle placement is permanent -- in permanent implant due to identical causes will have to be regulated?

MS. SALTER: Did you all get that? What was the question part? Oh, why suboptimal needle placement in permanent implant, due to identical causes, will have to be regulated?

So I think he is asking why that would need to be regulated. Does that make sense? No? All

right. Who gave that comment again? Timothy Gao. You may want to resubmit the question. But as far as the comment, did anyone want to speak to that or would that -- does that kind of explain itself?

(No response.)

Okay. Timothy, if you can just resubmit your question part, because I think there is a word missing in there.

And I think we have another comment?

MS. RIVERA-CAPELLA: The next comment is from David Lightfoot from Grand View Hospital, and he is saying except for shipping requirements, the activity usually used for prostate seed implants is the apparent activity based on the measured air kerma rate of the encapsulated source.

The dose rate in tissue at one centimeter from the source is influenced by the source construction. Should not a better measure of whether a medical event occurred be related to the total implanted apparent activity? The measure -- volume at the time of implant, the method of measure, the nominal prescribed dose, and ranges of expected tolerances that account for the likely agreement of the post-implant dosimetry with the nominal prescribed dose for prostate seed implants?

The next one is from Daren Perrero. He is from Illinois Emergency Management Agency, and he is asking, how will an activity-based metric address instances of unintended doses to the rectum and prostate urethra or perineum or penile bulb?

How will -- I'm going to read it again. How will an activity-based metric address instances of unintended doses to the rectum or prostate urethra or perineum or penile bulb?

MS. SALTER: I think we had some discussion on this this morning. Did -- how will an activity-based metric address instances of unintended doses to the rectum or prostate urethra or penile bulb? Does anybody want to talk to that? No?

DR. PRESTIDGE: I'm not sure that it will or that that's the idea here. I think what we are talking about is defining a medical event, and we have been having this debate about a single seed. For example, it might be somewhere where it is not supposed to be.

Those kind of, you know, areas where maybe it's something that is unintended, but is not going to do direct harm to the patient necessarily, is not the argument we would make from ASTRO, is not in the purview of the NRC to regulate, to call it a medical

event or not. That is something more for -- to look at in terms of quality of the implant and for the individual practitioner and for the societies who do the training, and so forth, to help to prevent those sorts of things.

And as I stated, in terms of the patient safety organizations becoming involved in helping to identify those kind of maybe gray areas, those practices where a practitioner is maybe doing implants that aren't as good as they should be, but yet they are not in the realm of being a medical event.

MS. SALTER: Ms. Smith?

MS. SMITH: So that's exactly the arena that really concerns me, because I think the profession of medicine has frequently shot itself in the foot over exactly this kind of issue. I think if there is something that occurs in the process of a procedure, it -- while it is good medical practice for the clinician to talk to their patient/consumer about it, I think we also need a requirement that it be discussed beyond the clinician's best practices inclination to do so.

I just think, from a public perspective, we need to know that that's a mandated disclosure, because I, as the public, have gone in and had a

procedure where something has not worked the way that we thought it was going to work. And I have a right to know about that.

So it shouldn't be at the physician's option to disclose or not disclose. Again, I think we have to regulate to the lowest level of performance that we see out there in the medical community, acknowledging that most physicians do way, way better than that.

MS. SALTER: Dr. Welsh?

DR. WELSH: I might reply to the question from the webinar that the ASTRO-suggested medical event definition states that the physician must attest that the seed distribution is in accordance to the plan. And, therefore, nobody would plan to overdose the urethra, rectum, bladder. And even if the seed distribution is within 20 percent of the treatment target site, or treatment site, it might be possible that there could be a little bit higher dose than anticipated or wanted to the sensitive adjacent structures.

So this is where the ASTRO definition is going to be important, that the physician must attest that these seeds were placed in accordance to the planned placement. And as I stated earlier, there can

be some way that regulators could validate this attestation by comparing the actual seed distributions that are obtained on the post-implant dosimetry study to the plan that was done either prior to the implant or intraoperatively.

So that might be one way of addressing unwanted doses or excessive doses to these sensitive structures. If the physician does not intend to put seeds in the perimeter of the prostate and peripherally load these -- the prostate and the particular implant -- there should be no reason for excess dose, then, to the rectum, bladder. And if there is, that's not in accordance to the patient's -- the physician's plan.

So that might be one way that the ASTRO proposed definition can solve this potential challenge.

As far as the matter of disclosure to the patient or consumer about the results of the post-implant dosimetry, I personally do agree with that wholeheartedly. If my patient is coming in for a post-implant dosimetry procedure, at day 30 or whenever I have asked him to come in, and he comes in, he deserves to have a discussion about what the results of that study are.

Just as anybody who comes in for any kind of procedure -- a biopsy -- you are going to have followup discussion about the results of the biopsy. If a patient comes in for a post-implant dosimetry test procedure, of course we would want to disclose those results with the patient. So I do agree that it's appropriate to disclose what the analysis has shown.

MS. SALTER: Dr. Zelac?

DR. ZELAC: I would just like to raise an issue here with respect to what has been suggested several times as a regulatory method for determining if a medical event has occurred based on the attestation of the authorized user after the procedure is done.

From my perspective -- and I would like to be convinced otherwise by anyone -- this is getting inspectors for the regulatory agencies too far into medical practice in terms of having the ability to look at a dose distribution and compare it to another dose distribution and decide if they are close enough.

Unless you've got something that is patently and grossly different, you are making it, I think, difficult through that approach to have good regulation.

MS. SALTER: Let me go to the webinar. I think we have one last comment.

MS. RIVERA-CAPELLA: Okay. From Jeff Michalski. He is from Washington University again, and he is saying that Sue is correct when she was talking in the microphone. The CT scan doesn't measure anything. It is a tool that allows us to assess the implant.

MS. SALTER: Okay. Dr. Langhorst? Again, if anyone else would like to jump in here, I just -- fill out a blue card if you haven't done so already and raise your hand.

DR. LANGHORST: Yes. Sue Langhorst. I just wanted to ask a question that maybe you all can be pondering during the break. I know we are all interested in the break.

(Laughter.)

And then, maybe we can come back and discuss it after.

So I'm going to one of Dr. Zelac's slides, but this isn't necessarily a question just for Dr. Zelac. In your challenge slide you say, "How do we appropriately balance between the general medical community's desire to define a medical event in terms of clinical significance with NRC's need to have

mistakes in the process reported, even if there is no actual negative consequence to the patient?"

My question is: why aren't these the same thing? I mean, to me I think these can very well be the same thing. And from my point of view, me to have mistakes in the process reported, if they have no clinical significance, it seems like it may waste resources in evaluating them as a medical event.

So I pose that question for you to conjure, because I think it may be a little bit of discussion.

MS. SALTER: Very good, and I actually was going to throw out a couple of other ideas for folks to think about on the break and then -- but we don't have a lot of time to get into any discussion on this. So, like Sue said, that's one topic that I think we can discuss when we get back.

Another topic is the issue of training to identify a medical event. I know we heard some information from, you know, perspectives on that during the presentations, but we haven't really had a chance to discuss, you know, how -- who should be trained, should that be something that the NRC requires in the regulation.

The other issue has to do with, how do we

determine when an implant procedure has been completed. And then, I think this might be related to what Sue is saying is that, you know, what is the appropriate risk threshold for defining a medical event of nuclear safety significance? And is there enough of a body of scientific knowledge to evaluate that risk?

So just a couple of things that I think the NRC would like to hear perspectives on. Again, you are welcome to bring up any issue related to the medical event definition.

And then, finally, there was one other issue I know we had some discussion on in New York. Dr. Welsh had brought this up earlier, is, you know, is the term "medical event" perhaps scaring people, preventing or causing providers to decide not to do this type of treatment, causing patients not to want to get this type of treatment? And so is that something that the NRC should consider as the term "medical event"?

So a bunch of things for everyone to think about over the break. There are some refreshments out there. I'm going to get us started on the break a little bit early, but we will come back at 3:15. Is that okay? At 3:15, and we will continue this

discussion on those topics and anything else that you'd like to discuss.

If you want to speak, please do fill out a blue card for me, and you can hand that to me at this point.

(Whereupon, the proceedings in the foregoing matter went off the record at 2:58 p.m. and went back on the record at 3:23 p.m.)

MS. SALTER: Okay. Well, as some of you can see, we are trying to be able to put the webinar questions up on the big screen so you can see them, but the font is so small I don't think you'll be able to read them. But we will continue to try to work to make this a little easier to understand what the folks are saying on the webinar, and we thought if you could read along with it it might be a little helpful.

And we'll see what we can do with that. A work in progress there.

Are we missing someone? We're missing Dr. Welsh.

Okay. So before the break we kind of threw out some areas that the NRC was hoping to get some feedback on, that we hadn't really discussed in depth yet. And, again, I don't think I got any new blue cards, but at any time during this afternoon, if

you would like to comment, just fill out a blue card and hold it up, and I'll come pick that up and either bring you the mic or you can go up to the standup mic.

Folks on the webinar, just a reminder to type your question in and include -- your name should be there, but include your affiliation as well.

So to get us started, I'm going to pitch it to Dr. Zelac and ask him to elaborate a little bit on Dr. Langhorst's issue as well as the issue we talked about as far as defining a medical event of nuclear safety significance and try to get us started on some discussion in that area.

Dr. Zelac? And pull it close and talk into the mic.

(Laughter.)

DR. ZELAC: If it was any closer, it would be in my mouth.

(Laughter.)

One of the slides that I had presented at the beginning of this has been brought up again, and I think the question in fact is still with us. But part of the answer is relatively apparent, at least it's apparent to me. I mean, I try not to ask questions for which I don't have at least a reasonable response and thought about the answer.

So the question, again, was how do we appropriately balance between the general medical community's desire to define an ME -- medical event -- in terms of clinical significance with NRC's need to have mistakes in the process reported, even if there is no actual negative consequence to the patient.

My position, not necessarily the agency's, my position -- it has been said to us several times at NRC that medical events should in fact have clinical significance. There should be harm to the patient before you start calling something a medical event, because it has negative connotations and because it needs to be reported to the patient under our current rules.

And that's what we think the medical community would want us to call a medical event, something that in fact was negative, definitely harm to the patient.

Whereas, from our perspective, NRC's perspective, our intent is to become aware of things associated with the process of delivering care such that the outcome isn't exactly -- and is at some difference, significant difference in fact, from what the physician had intended.

Why would we want to know that rather than

just being aware of situations where the patient actually was harmed? It's so that we can have the licensee in particular take a look at their processes to see what went not the way it was intended. So they can prevent occurrences where in fact it might result in harm to the patient.

Similarly, when we become aware of situations where there has been one of these -- noncongruity between what had been intended and what was achieved, if it has any kind of a generic nature to it at all, if it's related to a piece of equipment or a particular generally used procedure, we can make our other licensees, and the agreement states, aware of this to possibly prevent harm to someone else in another setting at another institution.

So that's kind of the rationale that we have in wanting to have medical events reported even if there is not a direct definite harm to the individual involved.

Now, if you -- as was suggested in New York at the public meeting, I think that those kinds of occurrences should be called something different than a medical event. Perhaps be recorded and not reported. That's -- you know, that's something we can discuss as a group and with the audience.

But there is, from a regulatory point of view, from protection of patient point of view, which is part of our medical policy statement objectives, to know about situations where there is a decided significant difference between what a physician had intended and what the patient received.

MS. SALTER: Dr. Mower?

DR. MOWER: I agree that certainly if something is labeled as a medical event, it should be something substantial, something which has happened to the patient. For those who are old like myself and possibly the person to my left -- but I won't say that too loud, because he will smack me -- we used to have two categories. There used to be a recordable event and a misadministration, of which one was the "please sue me" letter and the other was to let everybody in the community know that there was a potential problem.

Certainly, as we look into things like the culture of safety guidelines, which are coming along now, we want to identify those things which are not just a random blip in the curve that didn't hurt someone, but something that could happen in other institutions, something that happened in the current institution, and escalate into a serious event that these be known by other people, so that they can make

sure they don't fall into the same trap or pitfall and end up with something which then does become something which truly harms the patient.

The other problem I have with the term "medical event" and what we do now is if there is no harm, no chance of harm to the patient, but yet we go and we start telling all of these things to the patient, and what not, what psychological harm are we doing to the patient?

And does that far outweigh any physical harm that was done in this thing? Which might be a minor thing and is probably not going to have any future consequences, medical consequences for the patient, those things which are borderline or just under the radar or just over the radar as a medical event, but which are not going to hurt the patient, but with what we're doing and the way we handle a medical event, may psychologically bring a lot of grief to the patient.

And we don't seem to be addressing that issue at all as we look at harm to the patient, and this is another avenue of harm to the patient.

MS. SALTER: Mr. Walter?

MR. WALTER: Being one of the dinosaurs, I do remember the times when there were two different

levels. We now have one level in our state. It's called misadministration. It's not called medical event.

Medical event is take two Tylenol and call me in the morning -- is a medical event as well. It's all in the head. Okay?

The fact of the matter is, we could call it a -- we can call it whatever we want. You can just pick up a medical tool and say what it is, and it's going to scare somebody, because of the name.

But when it comes to coming up with the lower level that you were discussing before, yes, it was reportable. We used to have investigational levels of exposure. Perhaps the term "investigational" would be something that you would want to use. I don't know on that, but that's just another idea, another piece of terminology out there.

MS. SALTER: Dr. Welsh?

DR. WELSH: I think what Dr. Mower said is brilliant. It's important to consider that psychological harm that can accompany all the investigations surrounding a so-called medical event is something that is often ignored or underestimated. And I do believe that the psychological harm can be quite significant and real and has not been factored

in at all in many of our discussions.

Just because something is old doesn't mean it's not good. So if --

(Laughter.)

In years past, there were different categories, different terminologies. That might not be a bad thing to resurrect, because today, as I mentioned earlier, the term "medical event" is used synonymously with the previous very alarming term "misadministration."

I think almost any patient who hears that he or she has been subject to a misadministration is going to be quite alarmed, and may seek legal counsel, recourse, and go down a path that could be of significant psychological harm.

So we've gotten rid of the term "misadministration," replaced it with "medical event," which sounds friendlier. But as we know, the patients are savvy consumers these days. And it's not going to take long before patients realize that there is no such thing as a misadministration. It has just been renamed something that sounds friendlier, and that is medical event, but it is still what it is. And it is going to cause some alarm and perhaps unnecessary anxiety.

So I would be in favor of resurrecting different tiers of terminology so that maybe medical event would be something that could potentially cause direct harm to a patient, be of genuine clinical significance in some form or fashion, whereas things that are more like a written directive that was incomplete or not written or post-implant dosimetry that was done on day 61 would fall into a category with a more friendly terminology that would not alarm patients quite as much.

Recordable event I'm not sure would be unintimidating. Perhaps policy violation would be something that would clearly resonate with the patient that it was not something of medical consequence but it was something of policy -- a break from standard procedure that is going to be investigated, and the patient perhaps would be more amenable to the idea that this is going to be investigated further without being alarmed that something serious has gone wrong.

And that could be one way in which this unintended psychological harm, which has largely been ignored, could be averted.

MS. SALTER: Ms. Smith?

MS. SMITH: So I have two words for everybody: shared decisionmaking. So the world of

the consumer is changing, and the world of people that are now the Gen Xers and the Gen Yers and how they are looking at medical care is very different.

So where older generations now looked at physicians as a paternalistic/maternalistic figure in their lives, and they came to them and basically said, "Doctor, tell me what to do," and that is a very valid model, and some of the clients I work with now, that's exactly what they want to hear is, "Tell me what to do."

But what is being taught in medical school now, and what is being asked for by younger generations, is shared decisionmaking in medical care. And that definitely pertains to what we have been talking about today.

Those people are going to look for more disclosure, not less, of what has happened and what the parameters are of what has happened to them. I would say different terminology would be fine, and I would even make it more benign perhaps and call it just Step 1 and Step 2 events, where there is no -- I have to say, when I told people that I was coming to this particular workshop and we were going to be talking about medical events, they all said, "What is a medical event?"

So that's not a term in the general public, but we could put -- pick something very benign like a Step 1 or a Step 2 event, some of which would be very serious, perhaps that's the Step 2. The Step 1 would be the ones that we're monitoring. Maybe they got reported to the NRC under guidelines that the physicians follow.

MS. SALTER: Anyone in the audience want to make a comment on that? Dr. Welsh?

DR. WELSH: I might just reply to Ms. Smith's comments by saying that, yes, during the informed consent procedure and the decision-making process it really does need to be more than just the physical paternalistically telling the patient how it's going to be.

And so a discussion during the informed consent procedure that includes conversation about the current terminology, medical event, etcetera, as well as disclosure of what that might really mean, such as maybe it's not necessarily of harm to the patient, would be good for the patient. But the reality is that when a patient is diagnosed with cancer, they are weighing so many things in their mind at the same time.

Should I get this prostate cancer treated

at all? Should I have surgery? Should I have external beam radiation? Can I afford to be out of work for this long a period of time? What about the brachytherapy? That might be the quickest and most efficient procedure.

So they are really going to be focusing primarily on a small subset of the information. And as we said earlier, maybe patients remember 20 percent of what is discussed in the patient's office during the consultation.

So while I advocate full disclosure of what "medical event" means, I am not optimistic that that conversation will really stick in the patient's memory, and the patient will remember six months later when the post-implant dosimetry is being further analyzed by the state and the NRC and it's possibly a medical event or not a medical event. I think that it's still going to provoke some anxiety.

But I do like the idea that events that could lead to potential harm be named differently from those that are more regulational policy violations. The patients are going to realize that a medical event or misadministration is something that -- that sounds serious.

Policy violation, I think most patients

would understand, is not necessarily something that is going to be of medical consequence. Calling something Step 1 or Step 2 I fear would cloud things in too much secrecy, and patients would start to wonder, is this a broken arrow or a bent spear? Or what exactly is a Step 1 here?

And I think that maybe the clearer things are the better for our patients.

MS. SALTER: So we had some discussion on different levels and different terminologies, and we have talked a lot about defining a medical event that has clinical significance. But if we were to have different categories, what would the risk threshold be for defining a medical event, or whatever you call it, in terms of nuclear safety significance, so that the NRC can continue to track trends and identify potential problems or mistakes? Would it be the same? Would it be different? No? Dr. Welsh?

DR. WELSH: I'm not sure exactly what you're asking. But if you're asking what would be a preferred recommendation for a medical event, the ACMUI's initial definition, which coincides with the currently proposed ASTRO definition, is the one that I think I personally endorse, and many of us who practice prostate brachytherapy also favor.

So if you are looking for a definition for "medical event" that is appropriate, you have that in the ASTRO proposition.

MS. SALTER: Okay. So, and that would be something that would have a clinical significance. But you wouldn't have something different if you were just looking at it from strictly the NRC's perspective of identifying trends or --

DR. WELSH: Well, I would --

MS. SALTER: -- from the nuclear safety perspective versus the clinical perspective.

DR. WELSH: -- respond that I personally think that the term "medical event" should be reserved for something that is of medical potential consequence, and that another term, whatever may be voted as most appropriate, would be appropriate or usable for those events that are not necessarily of clinical significance but are valid for the purposes of identifying trends, so that the NRC can have some instrument in which to continue to assess programs, practices across the country, to see if an event might be on its way. I think that's very valuable, but I do think that different terminology is also valuable in this context.

So no written directive, post-implant

dosimetry at an inappropriate time, I don't think should be medical event. I know that most are not considering calling it a medical event. But if this is consistently done in an inappropriate fashion, it should be flagged by the NRC as perhaps some kind of recorded event or violation or policy violation of some sort, but not medical event.

MS. SALTER: Mr. Walter, did you have a comment on that?

MR. WALTER: Yes. I think, you know, what I've heard today so far regarding the problems that we are having with prostate seed implant therapies is that everything is subjective the way it is right now, and it's not very -- you just -- you cannot look at it objectively and determine whether or not there has been a medical event under the current rules.

I see subjectivity all over the clinical determinations as to whether or not it becomes a medical event or not. And unless you have some very well-defined terms that make it objective -- and I don't think there is going to be an easy way to do that -- we could be here another 15 or 20 years before we figure that out.

That is going to be extremely difficult to define, and as a rule-writer, licensing person, and

inspector, almost impossible to really inspect.

MS. SALTER: Anyone else want to get in on this discussion? Okay. Mr. Lieto, I have your card. So I will go to you and then -- let me get Ralph up here first. I'm going to make you go up there.

DR. LIETO: I'm going to take sort of the devil's advocate position here about changing reporting criterias and levels. It has been out on the NRC website and been their criteria for a number of years that medical events and the reason that they changed the term was because that these events do not necessarily indicate harm to the patient.

I think Ron pointed this out a little bit earlier, that medical events were reporting to indicate that there was a deviation, potentially serious deviation, from the licensee's practice that might indicate potential for more harmful things to occur.

That is one I guess bullet point that I want to make. The other point is -- and I think Dr. Welsh probably can supplement this -- is the --

DR. MOWER: Your mic is doing strange things. Either that or you are.

(Laughter.)

DR. LIETO: This is being recorded, so I

will not say anything in response.

(Laughter.)

DR. MOWER: It's the same thing. That one is not doing any better.

DR. LIETO: It's not?

DR. MOWER: No.

DR. LIETO: I'm getting kind of little bit -- kind of a fuzzy -- can you -- well, I'll try to hold it a little bit closer.

The other point that I wanted to make was regarding the medical events that have been reported to date almost are -- have always been overwhelmingly human error causes of events. I think to look at these, to trend these, even though they are very uncommon and rare events, to trend this for future use, I think we already know what the causes of these are.

And not that they still shouldn't be reported, but I think to establish another reporting level to gather more data on something that we know the causes of already, I'm not really quite sure of the added benefit for this.

The other bullet point that I want to make is that when medical events are reported, we need to remember that these have to be reported within 24

hours of determination, gets reported into a national office which then is publicly -- if it's a patient medical event with patient identification information stripped, but still is reported in a public venue within 24 hours.

So it is not a very, you know, shall we say agreeable thing for a licensee to have to report. So I think if we are going to increase the number of things that we are reporting at different levels that have potentially no significance, I just don't see the added benefit for that when I think that the medical event terminology was changed to try to remove the onerous designation -- even though some people still use misadministration, was to try to remove that connotation, and that it was an event involving a medical application of radiation. And I personally think it is still a good term.

MS. SALTER: Would anyone -- is it working for me? It's working for me. I think it's just you, Ralph.

(Laughter.)

Anyone like to comment on -- can't hear? Turn me up. Okay. We're having some trouble with the speakers. I can talk loud for the folks that are here, but on the webinar you might have a little bit

of trouble until we resolve the problem. Sorry about that. Hopefully, the microphone is working at the front table.

Is there anybody that wants to chime in on that, or should we move to another topic? Mr. Walter?

MR. WALTER: I am not going to say this just because -- just as a way of trying to stand up for what we are still doing in Alabama. We also have a much lower level that needs to be reported that is called a misadministration.

Now, I have had half a dozen licensees call me over the first part of this year telling me that they thought they had a misadministration. When I have gone over it with them, they haven't been. They haven't met the criteria of a misadministration. And while that makes them feel very good, I'm proud of them for being willing to call me and talk to me about it.

I guess states in general have had a different way of handling reports of misadministrations -- medical events, excuse me. We do know that we have to, though, report to the NRC those that meet their criteria. Many of us have criteria that are well below that that we require reporting from our licensees.

But it doesn't matter what level they are. It does not mean that we are immediately going to run out and do a reactive inspection. The very first thing we do is expect that licensee to be a licensee and do an internal investigation and figure out what happened, why it happened, and what they are going to do to keep it from happening again, and give that to us within 15 days.

If we don't like what they're saying, then we will talk to them on the phone a little bit and see why they didn't choose some other pathway. But more often than not -- and I would say probably 98 percent of the times that we have reports -- we never go out to the licensee. We go to the licensee for our next regularly scheduled inspection. Yes, they will get cited for it, but they will also be told that they have already addressed it and no response is necessary.

So there are some differences in the way states handle things that might make a difference in the way licensees react to that rule or terminology that I'm not saying that either one is absolutely right or wrong, but they are different.

So we need to bear that in mind, too. Remember, we do have 87 percent of the licensees in

the country, and so we are doing things differently than what the NRC is doing. And, yes, we do use NRC rules -- and you will see us fighting a lot on compatibility, but it is because -- and I'll tell you right now, I don't have enough people to write rules all the time. And I'm not going to reinvent the wheel.

If there's a good rule out there, I don't need it to be a compatibility A or B or C to make me adopt it. I'm going to adopt it because it makes sense, and I'm going to write it the same as the NRC.

But we decided that the term "misadministration," while it may have bad connotations, well, maybe that's what we want them to understand.

Now, one other thing that was talked about here was human error, that so many of these are human error. Everything is human error. If you take a root cause and analysis class you are going to know that everything is -- ultimately could just be thrown out there as human error just about 99 percent of the time.

But why did that human error occur is what you have to go through and analyze. Is it because of not having enough training? Because they're

overworked? Because they're underpaid and they want to get back at you? There is a number of different things that are ultimately the reason, so that you can cut down on the number that you can just say are human error. So --

MS. SALTER: Dr. Zelac, did you --

DR. ZELAC: Just wanted to make one thing clear. Can you hear me out there?

PARTICIPANT: Yes.

DR. ZELAC: Okay. Medical events to NRC are not violations. There might be some underlying reason, which in fact is associated with a violation, but the reporting of a medical event does not equate to getting a violation. And I think that has to be made very clear.

MS. SALTER: Dr. Welsh?

DR. WELSH: So I will just try to respond a little bit to Mr. Lieto's comments. Ralph Lieto is almost always correct, but today I think I am going to disagree with our devil's advocate.

And what I'm disagreeing with is my contention that maybe two or more than one category of terms would be appropriate. And I think Ralph's contention was that medical event is good enough.

So having just heard what Mr. Walter said

about a half dozen cases in Alabama that were turned in that were suspected of being misadministration, but upon evaluation they were not, what do you call those?

So if the only word we have is "misadministration" or "medical event" or just one term, then we don't record those. And this might be an instance in which it would be valuable for there to be an alternative term, which would serve NRC and the states to identify trends that could be going on and ultimately lead to the real thing if that trend is not identified and nipped in the bud.

So I think that having a different set of terminology, a different term in addition to "medical event" or "misadministration," could be valuable in this specific instance, because it seems like there might be a trend that is going on in those particular practices that had those half dozen procedures that were questionable, and it sounds like they are an honest team of clinicians that want to have things investigated, evaluated, and hopefully they will learn from their experience and not have a real medical event or misadministration in the future.

But by not having any term or not recording this in any way, that educational lesson could be lost, and that's why I do advocate a two-

terminology system, and one term that is significant enough to cause patient harm, potential harm, be it medical event or misadministration, and the other one be a more benign-sounding one that is less likely to cause psychological harm for a patient.

MS. SALTER: Mr. Walter? And I would just ask -- the handheld mics, the wireless mics, seem to be having more trouble than the wired mics. So if you can reach a wired mic, that would be the preferable system to use.

MR. WALTER: Okay. We do actually assign a name to that. It's called an incident. And what we ask all of our licensees that go into this situation, finding out that it's really not a misadministration, we ask them to -- if they have a committee, a safety committee, to take it before the safety committee, to explain to them what happened, why it happened, and what they put into place to make sure it doesn't escalate.

If they don't have a safety committee, then it's the safety officer's responsibility to do that, and that is what we look at during our next inspection is we take -- we ask them -- one of the questions we ask is: have you had any incidents that have occurred? And that would be something we would

expect them to let us know about, even though we have written it up in their file, and I'm sure our inspectors already know about it.

But we would expect them to do that, and we would just evaluate it at that point and see how things are going with them, because we are working as a partnership with our licensees to try and maintain health and safety.

DR. WELSH: So if I could ask, is that Alabama only or is that nationwide?

MR. WALTER: I don't know if we have any other states other than maybe Texas that is here today. But, you know, I don't know what other states are doing as far as medical event criteria and levels of criteria are concerned. But I do know that states in general do work with their licensees very similarly to what we do.

MS. SALTER: Dr. Welsh?

DR. WELSH: That's my point, that you have a system that seems to be working well in Alabama, and it uses different terminologies, and different things are done for followup in terms of -- different things are done in terms of following up that medical event or that misadministration or whichever other term was used.

But if you have only one term, and you either meet that criteria or you don't, it is possible that some trends will be missed. And, therefore, maybe NRC should follow Alabama's lead in this regard.

MS. SALTER: Mr. Lieto, did you want to follow on to this discussion? Can you -- I can't reach you. My arm -- you have to come out, sorry. Actually, that's fine. Go and grab --

DR. LIETO: Is this working?

MS. SALTER: Yes.

DR. LIETO: Okay. My point was about reporting two levels to the NRC, of having to report two levels to a regulatory agency.

What Mr. Walter described I think -- well, I can't say I speak for all licensees, but I know in a hospital setting that if you administer something to someone that is different from what was prescribed or not according to the clinician's intentions, that did not meet a medical event recording criteria, that is a deviation that has to be reported within the internal medical safety structure as Mr. Walter pointed out.

An example that I would like to give would be, in the case of nuclear medicine, if a patient was supposed to get an MDP for a bone scan, and was injected with DTPA, which is a renal agent, they got

the wrong -- they were injected with the wrong pharmaceutical. That's a pharmacy error and has to be reported, and those avenues occur on -- I mean, those avenues are followed as to followup investigation, and so forth, and corrective measures.

And that's -- and I have no problem with that type of secondary level reporting. I just think that if the medical event -- if we change things with the medical event criteria -- and I think we are getting a little bit off track, because this is going to affect all the regulatory uses. And I think that if we have just a one threshold -- and if you want to call it a medical event or a misadministration or a goober, or whatever, that has occurred, that's fine. I don't think there is a problem with that.

But I don't think we want to convey whatever -- or name that we give it that necessarily harm has occurred to the patient, because, as has been pointed out, there are a lot of things that do exceed medical event reporting in which patient harm has not occurred. And so, you know, that's kind of my point.

So I think we are on the same wavelength, Dr. Welsh. I just -- my concern is this lower level of reporting going into the NRC, you know, toll-free number reporting mechanism that gets reported

nationally. That's my concern.

MS. SALTER: Dr. Zelac?

DR. ZELAC: Just to make one quick comment, we are talking about, in the course of one year, including not only NRC licensees but all of the agreement state licensees as well, something like 40 medical events typically, not a large number at all. And it's very difficult with such a small number of events on an annual basis to start looking at trends per se.

What we are really interested in, from my perspective, is the fact that something has occurred at a particular facility which was a deviation from their procedures, that met certain criteria which are published and readily seen, so that that particular facility can look at its procedures to see the why and the what they are going to do to prevent it from occurring again, and this is all before potentially -- although there are exceptions, this is all before there has been any harm to anyone, including the patient.

MS. SALTER: All right. We have a couple of comments on the webinar. And we're going to try to put these on the screen, but it's really tiny. It's even tiny on this screen, but -- so maybe you can see

them as Gretchen reads them.

MS. RIVERA-CAPELLA: So the first one is from Mary Moore. Mary is from Philadelphia VA Medical Center, and she is asking, how do panel members view their role of peer review in determining medical events?

MS. SALTER: All right. Any of our panelists want to respond to Mary's question? Anybody in the audience want to respond to Mary's question? Dr. Zelac?

DR. ZELAC: I'll give a quick response. I think peer review is a good thing. Period. If a facility is operating and there isn't a second set of eyes to look at what has been done, things can be missed, and it's just helpful in general.

Now, if the question has to do with whether or not there should be a requirement for peer review, you know, that's something that is a little more indepth that we would have to really discuss. But in terms of peer review, who would not want peer review of what has been done?

MS. SALTER: All right. We will move to the next comment.

MS. RIVERA-CAPELLA: This is from Jeff Michalski or Mihalkey. He is from Washington

University. And he is saying that, "While I appreciate the comments of Mrs. Smith, the idea of having two levels of reporting have potential for abuse. I think we should strictly reserve medical events, or whatever the term becomes, for issues related to the regulatory aspects of the medical use of radioactive materials. I fear that a lower second tier of reporting gets to the practice of medicine.

"We need to avoid the slippery slope of government intervention in our clinical practice. ASTRO and other professional societies can address the need for quality improvement through a national registry."

MS. SALTER: Okay. Not so much a question as a comment. I don't see anyone wanting to follow up on that, so we will move to the next comment.

MS. RIVERA-CAPELLA: Jeff Michalski again. "The 10 most dangerous words in the English language are, 'Hi, I'm from the government, and I'm here to help.' Ronald Reagan, remarks to Future Farmers of America, July 28, 1988.

"I disagree with Dr. Welsh on his point. Our government shouldn't oversee medical practice at this level. Our professional societies should do this."

MS. SALTER: Okay. And is there a comment? Dr. Prestidge?

DR. PRESTIDGE: Yes. Just I think those are good comments by Dr. Michalski, and, you know, unfortunately, we are a little bit late to the table on this. There is no formal certification for brachytherapy. Other than, you know, board certification in the specialty of radiation oncology, there is no other subspecialty certification.

Up until now, the American College of Radiology and the American Brachytherapy Society are now working on putting criteria together, so we can start to establish that, so there is now going to be a focused certification on brachytherapy, and there may be different types.

There may be for certain types of brachytherapy and then for general brachytherapy. And I think that's a very good thing. That gets to some of these questions about having peer review involved in one's implants and having certain criteria to adhere to, having to put patients on a registry doing your own research and projects to try and improve your technique and your quality of your implants.

So I think we are getting to that point, and we are really I think figuring out that that's

needed, not only by the patients want it, we physicians want it, the payers want it. So I think that's a good thing, and it's maybe a little bit later than it should have been, but it is happening now.

MS. SMITH: Can I comment on that?

MS. SALTER: Ms. Smith, and then we will go to Dr. Welsh.

MS. SMITH: Okay. So I think, you know, the goal I would see here in terms of the discussion on medical events and other steps or gradation we might put in is that I think we are at the stage where we have to be proactive. How do we, in the future, identify what goes wrong? It's by a compilation of these little pieces that happen along the way.

If we don't get that information, if the NRC doesn't get that information, how are we going to look proactively at what needs to happen down the line? In terms of peer review, I think we start walking down a really dangerous track when we start talking about peer review as a solution to this process.

Yes, I agree there should be peer review. I'm all for that. But in terms of peer review taking over any of the responsibilities of actually doing the regulation, no, no. Peer review is to enhance

performance, it's to identify mistakes that have happened, to look at alternate ways, but it does not carry regulatory guidelines into the future.

Whereas, if they were events that were also reported to the NRC, even if they were low-level events, we could look proactively at, how can we prevent that happening on a nationwide basis in the future?

MS. SALTER: Dr. Welsh, I think you had a comment?

DR. WELSH: Is this working? Regarding Dr. Michalski's comment, I'm not sure that -- maybe I didn't make myself clear earlier. While I do think that having more than one term might be appropriate, such as the two-tier system of having a term "medical event" and "policy violation," the reason why I think that this is good is because it actually intrudes less into the practice of medicine.

If we have less governmental oversight, intrusion into medicine, I think we are better off, and too much oversight of course is a bad thing. So if we have only one term, and it's "misadministration" or "medical event," and it encompasses everything from a minor violation, such as something is not proper within the written directive, all the way to a gross

overdose during a brachytherapy procedure -- and we have only one term for that -- then I think that's more governmental intrusion into the practice of medicine than is necessary, because in one case -- the overdose -- it is clear that the term "medical event" or "misadministration," whichever is chosen, is connotating -- appropriately in this example -- a very negative occurrence.

But if we use the exact same term for a written directive that has -- is missing a comma or something, that is going to lead to the psychological harm that Dr. Mower brought up that is really unnecessary. A patient will perhaps have heard about a misadministration or a medical event in which something horrible happened to a patient, and then learn from his doctor that his procedure was also termed a medical event, and he is not going to be able to distinguish, in all cases, the difference between the two, which is why I personally advocate the multi-tier terminology system.

MS. SALTER: All right. With our last half an hour or so, I'm going to turn your attention to some issues that we really haven't discussed in depth here, and, again, welcome members of the audience to make any comments that they would like as

well as individuals on the webinar.

And the first topic I'll throw out to the panel and the audience is, when would you consider an implant procedure to have been completed? Dr. Zelac?

DR. ZELAC: I'll just add to that, would it be when the patient leaves the post-implantation recovery area? If not that, when?

DR. PRESTIDGE: I think I stated in the ASTRO position on that that it's when the patient leaves the care of the authorized user. So that would be as the patient leaves the operating room or the procedure area.

MS. SALTER: Dr. Welsh?

DR. WELSH: I would expand on this a little bit, understanding that there are some nuances that make this a complicated question. When is the procedure completed is a very difficult question, because is it when the procedure is physically done? Is it when the patient has left the control of the authorized user in the recovery room? Or is it when the post-implant dosimetry has been completed and analyzed? All three of those could be the answer.

But from a regulatory perspective, a more important question I believe is: when can the written directive be completed? And I think that the ASTRO

statement and others have pointed this out clearly, that in practice the most appropriate time for the written directive to be deemed completed is after completion of the implantation, but before the patient leaves the control of the authorized user in the recovery room.

And I think that's an important point for regulators to perhaps seize on and be able to use rather than this broader question about, when is the procedure itself technically completed?

MS. SALTER: Well, we were talking about from a regulatory perspective, for the NRC, when should they consider the procedure to have been completed? So I think you answered that.

Dr. Mower?

DR. MOWER: But I think Dr. Welsh is right. Why are you asking the question? Are you asking the question relative to when the written directive should be completed, or are you asking the question for another purpose?

If it's for when the written directive should be completed, his answer is, I believe, correct. If there is some other reason for asking it, then we need to know that reason because that could go into a whole bunch of other things, so that when the

patient leaves the recovery at that point, if there are anticipated complications, is it when the radiation oncologist finally turns that patient over to another MD? Is it after the first follow up that the radiation oncologist no longer has the control of the patient?

So I think we need to know the reason why you are asking that question in order to give a realistic answer to that question.

MS. SALTER: Dr. Zelac?

DR. ZELAC: The current regulation calls for completion of the written directive before completion of the procedure. That is why, because there is very unspecified nature to completion of the procedure. Some physicians would take it as when the implantation is done; others will take it as when the dosimetry has been finalized in terms of nothing more is planned, which could be a year down the road.

So we are trying to pin it down somewhat, and the thought was that when the patient is out of the direct control, if you will, of the authorized user, is an appropriate time.

MS. SALTER: Does that change anyone's -- Mr. Walter?

MR. WALTER: I agree that -- I believe

that what we need to look at here is the written directive. And I realize that there are -- each type of brachytherapy implant therapy brings its own complications into play, but the -- for instance, pubic bone can be a problem occasionally for you to be able to get the dose distribution, because you can't get the seeds exactly where you'd like to have them. That's just a for instance.

And I would advocate that there should be a chance for the authorized user to review what has happened post-implantation, to verify clinically this is what is good enough to work for what they are going to do, because those complications, if we are going to -- if we are going to do that, then we might as well cite the patient, because they're the problem, not the surgery.

So, you know, I know we have no regulatory authority over the patient, but the fact of the matter is that's the root cause. So I would advocate that there should be something involved in after or post-implant for permanent seed implant therapies.

MS. SALTER: Any other comments on -- Dr. Prestidge?

DR. PRESTIDGE: Yes, I think that maybe we are all talking about the same thing. I think there

is that opportunity between if it's allowed -- as I think I stated in the ASTRO statement, if the brachytherapist is allowed to finalize or do his final attestation of the written directive. So there's a period of time between when you complete, you take off your gloves, and you start to do your paperwork before the patient leaves that operative suite, procedure suite. You have that period of time, would allow for that.

You know, there is other analogies and other specialties where, for example, a surgeon who resects a tumor in a certain instance, in breast cancer for example, positive margin rates come back as a surprise. But it happens maybe 10 to 20 percent of the time.

Most of the time that patient is then taken back a second time to the operating room to clear those margins, you know, but that's a second procedure, so that's, you know, another thing to keep in mind. There are occasions where an implant is thought to be acceptable, and then found subsequently to be not as acceptable, as we have talked about here. And one of the solutions to that is to take the patient back in and to place additional seeds.

So, you know, that's kind of the thought

that occurred to me, whether that complicates what we are discussing here in terms of the definition of when the procedure is complete. In my mind, that constitutes two separate procedures, but it's something that is correctable, is being corrected, and shouldn't necessarily be considered a medical event.

MS. SALTER: Okay. Dr. Welsh?

DR. WELSH: So I think that Dr. Mower framed the question appropriately, because it was a little confusing at the start of this conversation, but he was able to clarify what the question is, and Dr. Zelac was able to provide a rationale for why we are asking this question.

If our question is, when is the written directive to be considered completed, and the answer is, before completion of the procedure, we must have a better definition of when the procedure is completed.

And, therefore, if there are multiple ways of defining the procedure -- as soon as the last seed is put in, when the patient leaves the recovery room and control of the authorized user, or when the post-implant dosimetry has been performed and analyzed -- well, if those are different definitions of when the procedure is ended, then you are going to have different interpretations of what time the written

directive could be completed by.

Therefore, we either have to change the -- we need a better definition of when the procedure is completed, which is what I think the original question was aiming to ask, or we need to change the wording all together. And I would propose the latter, because the former -- when is the procedure completed -- I think we are going to have some internal discussion about, does the "procedure" include the post-implant dosimetry analysis or does it not?

So to avoid that controversy, which is a completely separate subject in my opinion, I would prefer to focus on, when is the appropriate time for the written directive to be completed? And, as I stated earlier, I think that the ASTRO suggestion is the way to go, where the -- I'm not going to use the term "procedure," because that's going to be confusing here -- but when the implant is completed, and the patient is leaving the control of the authorized user in the recovery room, that's when the written directive needs to have been completed by.

MS. SALTER: Dr. Mower?

DR. MOWER: Getting into an area which I know nothing about, but which might give some additional guidance to this. When a surgeon completes

the surgery in the OR, what is the normal anticipated timeframe for him or her to have written the OR procedure note? That might give us some guidance on this, and it's -- I haven't any idea.

DR. PRESTIDGE: That's usually regulated by the hospital, the work, and generally, you know, they want it done by the time the patient goes into recovery, because they have to have their orders, and so forth. But usually, you know, we're allowed 24 hours, if it's a dictated note, or something like that, 24 hours for it to appear in the chart.

MS. SALTER: All right. I don't see anyone else looking to make a comment on this issue, so I'm going to throw out another topic that was one of the questions in the Federal Register, I believe. And it has to do with training and the requirement for training everyone involved in the process on how to define a medical event. And so I throw that topic out.

And see, I know, Dr. Mower, you had stated in your presentation that you did not feel that the NRC should require that. I don't know if you wanted to elaborate on that or if anyone else has any other ideas on that topic.

DR. MOWER: Sure. If we look at what's in

the NRC rules and regulations in Parts 19, 20, 35, and whatever else might relate to us, and what not, those things just come from the states. If you're in an agreement state which comes down through them, the radiation safety officer, as part of the training program in the hospital, has to make sure that all pertinent points are covered by a responsible person who can do that.

Do we need some additional training from the NRC on one point? Number one. Number two, how good is that training going to be, and how long is it going to be before it comes into effect? I'm thinking about when we started talking about TEDEs and TODEs and other little creatures that crawled around out of Parts 19 and 20, and we contacted the NRC and said, "What on earth do you mean by all of this stuff?" then the basic answer was, "Go figure it out for yourself, sonny." And they didn't want to provide any training.

And, finally, they did provide training. And I'm not sure if the person from Region I is still here or not, but Region I hid the notice about the training, never let the stakeholders know about it, and then said, "You guys didn't show up for it."

And the person high up in Region I had to admit at an AAPM summer school when some obnoxious

physicist by the name of Herb Mower said, "But we never got notification about it," and a higher up from the headquarters said, "Didn't you notify people?" He said, "We had training." "Didn't you notify people?" "We had training."

I said, "Did you notify people?" "No."

So I don't have much faith in NRC coming through in a reasonable time period with reasonable training to all of us and think that when something new comes along either they have to set up a real good training program on how to train on everything, or else they should leave it to the people who train at the institutions.

MS. SALTER: And I'm not sure -- and, Ron, maybe you can clarify -- if the question had to do with the NRC providing the training or just a requirement that training would be provided. And so I'm just tossing it out to you, Dr. Zelac, to maybe clarify that.

DR. ZELAC: The question specifically is a requirement for licensees to go over all of the appropriate procedures involved with medical events and the reporting of them, and be sure that that is part of the training that would be provided to all of the involved individuals in these procedures.

The rationale for doing this is that we have had cases where there has been a claim by the involved individuals -- physicians, physicists, technologists -- that they had not received any such training and didn't know that a medical event had even occurred at their facility, although they were clearly conducting procedures and activities in a way that did involve medical events.

MS. SALTER: Mr. Walter?

MR. WALTER: This is where I get a little bit fuzzy thinking about our regulations and Part 35, because I know they are not 100 percent the same. So our rules just say that everyone who is working with radioactivity, under the supervision of an authorized user, is required to receive training commensurate with their duties. And just stops right there.

Now, if knowing what an event is is commensurate with their duties, and they don't know what it is, cite them and be done with it. And get them to get the training done.

I don't know why we need to do anything more than what we already have.

MS. SALTER: Dr. Zelac?

DR. ZELAC: The fact that there was a question doesn't mean that necessarily we intended or

wanted to go in this direction, but it was being put out there to get opinions from stakeholders about this question.

MS. SALTER: Dr. Welsh?

DR. WELSH: So when this session began, I was in agreement with Dr. Mower and the AAPM's sentiment that maybe nothing beyond the local institution, hospital, or RSOs, training of individuals at that institution is required.

Having listened to the conversation, and seen what is unfolding here, I am changing my opinion slightly, because I think Dr. Mower pointed out something about standardization of that training. And I started to think that if you allow this training education on definition of "medical events" to vary from one institution to another, and one hospital, one RSO, to another, you are going to have nothing that even closely resembles standardization.

So while it might be not NRC's aim to provide this training, which is what I think some of us were thinking the question was originally surrounding, it sounds like NRC does not wish to provide the training.

I feel that the training is something that is important, obviously, but I think that it should be

mandated, because what I knew about medical event definitions 10 years ago when I got training in residency, or whatever, is very, very different from what it is today. It's different today from what it was five years ago, and it's different -- it's going to be different next year from today because of the results of our workshops.

So it's an ongoing process of education, and I would say that, yes, it is something that should be required. And that it should perhaps not be left to the individual institutions, because that's not going to provide standardization. Although it's a solution, it's, in my opinion, not the optimal solution.

We have representatives from the two largest organizations that are involved in radiation therapy -- ASTRO and AAPM -- and I would think that we have no better venue than those two organizations to provide such education, which in my opinion, because it is changing, the definition of "medical event" is changing so frequently, that it is important to be up to date and shouldn't be left in the hands of the individual institutions, and probably is beyond the purview of the NRC to provide that education.

MS. SALTER: All right. With our last 15

minutes, I am going to go one final time to the webinar to get those comments from participants on the webinar. And then, with the last few minutes, I am going to take the liberty of asking Ron if there was any particular question that he had that he would like to pose to the panel as we close this portion of the program devoted to discussing how to define a medical event.

So with that, I am going to turn it over to Gretchen to read our final comments from the webinar.

MS. RIVERA-CAPELLA: Thank you, Susan. The question is from Mary Moore, and she is asking -- the question is for Dr. Ron Zelac. Is the NRC considering requiring licensees to have peer review and/or expanding training and experience regulations for brachytherapy authorized users to include training in reading ultrasound and CT scans, performing a minimum number of procedures under personal supervision, etcetera, or is the NRC looking at partnering with professional organizations to address these and other relevant issues?

MS. SALTER: Okay. We have that question on our screen, so I'm just going to give Ron a minute to read through it, digest it.

DR. ZELAC: I think the answer that I would offer to this question is a repeat of what I said previously. The idea of having peer review is great. I don't think anyone should be, and would be, opposed to that occurring. The question of having peer review as a regulatory requirement is another matter entirely.

We are open here, and that's the whole point of these public meetings is to gather public opinion, stakeholder opinion, as to what we should be doing, the direction that we should be going. This would be a significant additional step in our regulatory process, but it's one that could be considered were there support from the regulated community and others to us going there.

MS. SALTER: Thank you, Dr. Zelac. And I'm going to turn it right back to you and give you an opportunity to raise any issue or ask any question of the panelists that you would like. Dr. Welsh wants to make a comment.

DR. WELSH: I'm simply going to comment, because, Ron, as the NRC, you are looking for opinions rather than providing the answers yourself. So what I will do is say that I agree with what you just said, and I will state it as a representative of the ACMUI

who says that peer review is good.

But should the NRC intrude into the practice of medicine to the extent of saying that it's mandatory? I don't think so. I don't think that NRC should put in the regulations that peer review is mandatory or else a medical event has occurred or some type of violation has occurred.

I think it's common sense to have peer review, and it should be done, and like I've stated before, practice that doesn't do post-implant dosimetry or doesn't have peer review is not a practice that I am going to refer my patients to. And I think most clinicians feel the same way. But for the NRC to be seizing upon this for regulatory purposes would be a mistake.

And as far as that particular question on the board, on the screen, should -- to what extent should the NRC be involved in insisting upon this additional training? I would say the NRC, as a Federal Government agency, should steer far clear of getting involved in being very prescriptive about this in terms of the specifics of training and education and leave those specifics to the boards and the professional organizations.

MS. SALTER: Thank you, Dr. Welsh. I am

going to go now to Dr. Zelac and let him pose the final question or topic to the panelists.

DR. ZELAC: First, I'd like to comment on this question that was raised by Mary Moore. Specifically, I think it's important to point out that NRC's position with its medical use regulation has been, since 2002 when the regulations were modified, to be as performance-based as possible, and to not have prescription in the regulations except where it was felt necessary based on the potential risk associated with errors that might occur were there not prescriptive requirements existing.

So please keep in mind that as we move forward, at least my position is that that is not going to change. We will continue to remain as looking for results, looking for adequate performance, and, again, we are dealing with radiation safety, not with medical use in terms of medical practice.

Since I have been given an opportunity to ask a question, I will take advantage of that. We had several things in the earlier rulemaking groups that had been brought up and had been commented on, and I would like to get a bit of feedback from the assembled group here, as well as the webinar people.

As had been pointed out earlier, there is

a written directive requirement for the authorized user. Part of it -- the written directive -- is completed before the procedure, and part of it is completed after the procedure.

One of the things that is in that requirement, and will I'm sure remain, is identification of the treatment site. So the question is: as the regulator's descriptor for the location -- regulation's descriptor for the location of implantation, does treatment site provide adequate flexibility to the authorized user?

There have been some people saying that our regulation should be more prescriptive and get down to the level of talking about gross tumor volumes and clinical treatment volumes and planned treatment volumes, as opposed to leaving it as it is, simply saying "treatment site" and leaving it up to the individual physician as to define that in the written directive to begin with and then be held to it at the conclusion.

MS. SALTER: Dr. Welsh?

DR. WELSH: I will try to answer that question about treatment site. And the -- I can't say that the ACMUI or the subcommittee as a whole is changing its perspective, but I can tell you that I

personally have changed my perspective on this matter over the past few years.

A few years back, I was a staunch advocate of abandoning the term "treatment site," because it was so loosely defined, and there was a lot of confusion -- controversy about what "treatment site" really represented. Was it the prostate gland? Was it our using more modern terminology -- GTV, CTV, or PTV? At that time, it was not clear, and many of us believed that NRC did not have a clear understanding of the modern terminology used in clinical radiation therapy.

But those days are gone. The NRC is well versed in this terminology, and knows full well what we clinicians mean when we say gross tumor volume, clinical target volume, planning target volume. And, therefore, in the spirit of being less prescriptive, I would suggest that NRC leave the original term "treatment site," which can be interpreted in whichever one of those three definitions the individual authorized user chooses to define the treatment site as, rather than saying, "We want our medical event definition described and defined in terms of a clinical target volume or planning target volume." I think that being less prescriptive here

might be better, and treatment site allows that latitude.

DR. ZELAC: Any other comments on that issue from anyone?

(No response.)

Okay.

MS. SALTER: Okay.

DR. ZELAC: I will, then, move on to another question.

MS. SALTER: Okay.

DR. ZELAC: As I mentioned earlier, there is two parts to the written directive -- pre-implantation, post-implantation. At the post-implantation entry, if we are going the direction that has been discussed of having total source strength being the requirement for completion of the written directive, 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, is that an appropriate basis to consider that whatever we call it -- an event, an occurrence -- has taken place?

In other words, the physician, to complete the written directive, puts in a number. This is the total source strength that was used in this procedure.

If it turns out, on examination later, that there is a significant difference between what that number says and what the actual implanted source strength was, is that -- should that be considered one of these reportable events? A medical event in the current terminology?

Such things can occur -- the wrong isotope was used, the wrong source strength was used, unbeknownst to the clinician at the time of the procedure but discovered later, as examples.

Anybody -- any opinions?

MS. SALTER: Dr. Welsh, and then we can go to Ralph Lieto.

DR. WELSH: I'll provide a quick answer that, yes, from -- if I understand your scenario correctly, I would say that if the authorized user has signed a post-procedure/post-implant written directive that provides a specific number, and it is subsequently found that that specific number is wrong, we have a medical event.

If it's caused by putting in more seeds than was called for, if it's because the wrong isotope was used, or for whatever reason, if it differs by that percentage from the final -- and that's the important point -- the final post-implant written

directive, then I think it could qualify as a medical event.

MS. SALTER: Mr. Lieto, did you want to --

DR. LIETO: I agree.

MS. SALTER: Okay. Dr. Mower?

DR. MOWER: I think, here again, we need to look at what has happened. Wrong isotope was used, certainly medical event. Wrong activity procedure was used, certainly medical event. The physician just received a call from his wife that the daughter was in an automobile accident and is hanging on for dear life and happens to reverse two numbers in what he dictates, but what was put into the patient was correct, that is not, in my opinion, a medical event, and yet we have just clarified that as being a medical event.

So I think we need to be careful if it's -- he made a goof in his dictation or writing relative to what was really intended, and what was intended was really done, if it's something that somebody's knuckles should be rapped for, but it should not go through the medical event process.

Yes, wrong patient, yes, wrong site, yes, wrong isotope, yes, wrong activity of seeds, I'll agree to all of that. But where I just screwed up

because of something else that happened right at that time, I'm not sure that should be a medical event.

MS. SALTER: Dr. Prestidge?

DR. PRESTIDGE: The only exception, I may say, to what you just said is maybe the activity. If the activity was different by five percent, for example, you know, and the implant ended up being, you know, five percent high or low, I don't think that would qualify, do you?

DR. MOWER: I think you're well within your 20 percent kind of variation.

DR. PRESTIDGE: Yes. So if it's off by more than 20 percent, yes.

MS. SALTER: Okay. Dr. Welsh?

DR. WELSH: So Dr. Mower brings up an interesting point. I, frankly, hadn't thought of this one before, but I suppose it's a legitimate scenario in which basically there is a typo in the written directive. And, therefore, if the written directive differs from what was intended and what was actually performed, but what was actually performed was what was intended, and it can be proven that the written directive has a typo in it, I would certainly not want that called a medical event.

I would hope there would be some latitude

so that the written directive could be corrected, because there would be documentation from the notes, from the computer-generated plan that, "Here is what we intended, and here is what we did," and the written directive has an obvious typographic error in it. But that does raise an interesting question that few of us have thought of before. I wonder if there is latitude already present or not.

DR. ZELAC: I am not sure if anyone from the region would care to comment, or anyone at all. But I think that certainly is within the latitude of an inspector's prerogative, to take a look at what available information is there, and if what was done is in fact what was intended, we don't have certainly a medical event, and certainly, I wouldn't think, a violation either.

MS. SALTER: Mr. Lieto?

DR. LIETO: Well, I hate to burst everybody's bubble, but the NRC is already on record of an event where a nuclear medicine physician prescribed an iodine therapy, told the technologist it was an iodine therapy, wrote 10 microcuries in the written directive. The technologist "knew" it was a therapy, ordered 10 millicuries, the patient got 10 millicuries, and it was cited as a medical event when

it was reported.

So you have already got a history of the type of scenario that you are talking about where the patient got what was intended, the physician wrote the written directive improperly, not under the duress that you were describing, Herb, but -- and this was determined to be a medical event.

MS. SALTER: Okay. We are at that time where we are going to -- we are scheduled to start closing remarks. But we have 15 minutes for that, and I know Mike Fuller only needs about five, so I am going to let Ron, if he would like, pose one final question, since this is -- you're done. You got everything in?

DR. ZELAC: Yes.

MS. SALTER: Okay. Very good.

All right. Well, that closes this part of the program. And before Mike gives some closing remarks, I just want to once again thank our panelists for sitting at the front all day. I think we had some really good discussion. I want to remind everyone that there are evaluation forms in your folder for today and tomorrow.

So if you could fill the one out for today and leave that at the registration desk in the front,

that would be great.

We are going to get started again tomorrow at 8:30 here in this room. And I'm going to ask Mike maybe to go over a little bit about tomorrow's agenda and close our meeting for today.

(Applause.)

MR. FULLER: Okay. Thank you, Susan. I want to thank everyone who participated today, who came and -- use this one? Can you hear me? This one is not working.

Okay. Yes, that is much better.

I just want to thank everyone who came today and participated or listened, or what have you. I mean, everyone is very busy -- I know that and we all know that -- and this has been very important to us, and so we just appreciate it.

And also, to echo the earlier sentiments, I want to thank our panelists. This has been extremely fruitful for us. As I said this morning, you know, we had a very successful -- we felt like a very successful workshop in New York City at the end of June, and it was going to be interesting to see if we heard anything different. And I think we have heard some things that are somewhat different, and, again, that's very valuable to us.

To give you a little idea about what to expect for tomorrow, I will be getting together with other folks who are here in attendance from NRC this evening, and we will be comparing notes and making sure that we are able to clearly articulate what we heard today.

So tomorrow morning I will do just that. I will be sort of reporting back, if you will, on what we heard. And, again, it's just another opportunity to give folks -- another opportunity for folks to give us more feedback and let us know if we actually heard what we thought we heard.

It's important to us to get this -- to capture this information correctly. Again, it's very important to us.

And with that being said, as I said this morning, we did provide the summary from the meeting in New York. So I would ask, if you had some time this evening, this afternoon, to take a look at that and see if there is anything there that you would like for us to review, if you think -- if you disagree, if you think we didn't quite get it right, I'd like to have that feedback.

Now, tomorrow we are going to be talking about some different subjects, some things that are

currently part of our expanded rulemaking activities, and so if you do have something that you want to share with me, catch me on a break or send me an email. And I'll make sure everybody has my email address.

So, again, thank you all. It has been a very good day, it has been a very informative day, and it is going to be very helpful to us as we move forward. So thank you. Have a great evening.

MS. SALTER: Just one other -- the evaluation forms, actually it's one form for today and tomorrow. So if you are coming back tomorrow, please keep the form. You can fill it out and hand it in. But if you're not planning on coming back tomorrow, then please fill it out for today and leave it at the registration desk. Thanks.

So we'll see you tomorrow, 8:30.

(Whereupon, at 4:53 p.m., the proceedings in the foregoing matter were adjourned, to reconvene at 8:30 a.m., the following day.)