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U.S. NUCLEAR REGULATORY COMMISSION

BRIEFING ON PART 35 MEDICAL EVENTS DEFINITIONS

PERMANENT IMPLANT BRACHYTHERAPY

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TRANSCRIPT OF PROCEEDINGS

Public Meeting

Before the U.S. Nuclear Regulatory Commission:

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William D. Magwood, IV, Commissioner

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P R O C E E D I N G S

CHAIRMAN JACZKO: Well, good morning, everyone. We are here today to discuss a very precise but very important issue, which is the definition for medical events for permanent implant brachytherapy. And we have a very good line-up today, with representatives from the Advisory Committee on the Medical Uses of Isotopes, the American Society for Radiation Oncology, the American Brachytherapy Society, the Organization of Agreement States, and then -- as well as another member of ACMUI.

So we have a very good group here to talk about what I think is a very -- been a very challenging issue for the NRC, to come up with a definition of medical events for permanent implant brachytherapy that is -- will work to ensure that this important medical practice can continue appropriately, but at the same time that we can take care of -- fulfill our responsibilities for patient protection. So we're here today because the staff directed -- or the Commission -- [laughs] if only.

[laughter]

The Commission directed the staff to develop a medical event definition that does exactly that standard that I said, that protects the interests of patients and allows doctors the flexibility to take actions that they believe are medically necessary. So I look forward to a very good briefing. I think we've had a number of meetings, stakeholder meetings that have led to this point, and so I'm very interested to hear directly from all of you as well, and offer my colleagues any comments they'd like to make.

Okay, we'll begin, then, with Dr. Welsh.

JAMES WELSH: Thank you, Mr. Chairman. Thank you,

Commissioners, for the opportunity once to once again discuss this complex and important subject. And I will start by saying, I believe that his truly is important, for, once again, in fiscal year 2011, we have encountered nearly 100 patients whose cases were described as medical events, specifically 30 medical events involving 94 patients. So, yes, this is an important subject, and, for the past several years, dozens of medical events have been reported in this particular category. But the question remains as to whether this definition is faulty, or are the practitioners faulty. I submit that we now have conclusive evidence that the definition itself is seriously flawed.

I have been talking, as others have been talking, about edema following prostate, as an example, implantation, and this edema reflects volume, which is related to dose, and therefore dose calculations could be erroneous, and the cases which might be perfectly acceptable could be inappropriately labeled as medical events. Has this ever happened, however? Is this purely hypothetical? Can this truly occur, or is it just my and other practitioners, trying to explain things away? Well, in fiscal year 2011, there were three medical events involving five patients in which this exact scenario did unfold. Cases were labeled as medical events, and upon reevaluation, including repeat imaging, the volume returned to its appropriate size, and calculations showed that the dose was indeed within 20 percent, and therefore the medical events were retracted. Therefore, the definition itself is, indeed, flawed.

ACMUI has proposed what we believe is an appropriate definition, and this definition combines source strength and dose-based criteria, along with written -- the concept of a written directive completion, authorized user attestation, and post-implant dosimetry. So, as far as the source strength-based

criteria, this is for the treatment site. If there are more than 20 percent of the sources falling outside of the treatment site, we would consider this a medical event. Next slide.

As far as the dose-based criteria, we suggest the use of this be reserved for normal tissue structures. For neighboring structures, such as the bladder or rectum and prostate case, for example, the dose to these structures should not exceed 150 percent of the dose prescribed to the treatment site, to five contiguous cubic centimeters. For intra-target structures such as the urethra, in a prostate example, the dose to at least five contiguous cubic centimeters should not exceed 150 percent of that particular structure's expected dose based on the approved pre-implant dose distribution.

Please note that, for these definitions to hold, a dose must be calculated ahead of time to these structures, and that post-implant dosimetry must be performed subsequently. Next slide.

The ACMUI recommends continuation of the other standard existing criteria, such as those listed here, including wrong isotope, wrong activity, wrong patient, et cetera, but note that the fourth bullet point, delivered directly to the wrong site or body part, means directly, so left breast instead of right, for example. We are exempting situations of seed migration, seed displacement, embolization of seeds to the lung, et cetera, so long as the 20 percent criteria is not exceeded. Next slide.

The ACMUI has recommended the concept of a written directive completion. The completion of the procedure is defined as once the patient is released from the authorized user's control. Just before that completion, it is recommended that the written directive be completed to include unusual aspects

such as anatomic limitations or patient-related interference. We believe that it should be documented and could be documented in this particular possibility.

Another component of the written directive completion has been the concept of authorized user attestation. This is a fairly controversial recommendation in which the authorized user can provide a statement within this written directive attesting that the seeds have been permanently implanted in accordance with the approved plan. As I mentioned, this component of our recommendation is somewhat controversial. Next slide.

But it is not the only controversial aspect of our overall report, because there is a significant dissenting opinion in the ACMUI and on the ACMUI permanent implant subcommittee, in fact, which is detailed in writing in the 2012 report as an addendum called the minority report. It is largely based on information contained in the 2011 report, and it includes -- it is concerned with items such as the ambiguity of the term "treatment site." It is concerned with a possible dissociation of harm to the patient, divorced from the definition of medical event. It is concerned with the lack of any distribution criteria. And of course it is concerned about the attestation. Next slide.

Nonetheless, the overall vote of the ACMUI was in favor of retaining the term treatment site. The treatment site, as defined in 10 CFR 35.2 is an anatomic description of tissue intended to receive a radiation dose as described within a written directive. We know that the concepts of GTV, CTV, and PTV, gross tumor volume, clinical target volume, and planning target volume, at one time were relatively new to practitioners and foreign concepts to the NRC. But after six years of discussion, that is no longer the case. The Commissioners are well-acquainted with this; the staff is well-acquainted with

these terms. And I and others do not believe that it is necessary for NRC to insist that practitioners use one of those three volumes in their written directive. The written directive concept of treatment site can remain sufficiently general, so that an authorized user can prescribe to any one of those freely. To insist on use of one of those three volumes could be interpreted as an encroachment on the practice of medicine. Next slide.

The concept of bunching has been brought up on many occasions, but in my opinion, is grossly over exaggerated, in terms of importance. I've seen one documented situation in the past seven years. But the concept of the attestation could address this. The ACMUI dissenting opinion came up with a more objective means of addressing this, specifically the use of octants and insisting on a seed distribution criteria. Either way, for these solutions to be implemented and to catch this rare situation of bunching, post-implant imaging must be performed. So last slide.

In summary, we feel that there is now strong evidence that the current definition is imperfect, especially for prostate, and therefore there is truly a need for a new definition. The 2012 ACMUI recommendations include a source strength based criteria for the treatment site; a dose-based criteria for normal neighboring and intratarget structures; the continued use of the existing standard criteria, such as wrong patient, wrong site, et cetera. We recommend no change to the definition of treatment site. We recommend the introduction of the concept of the completion of the written directive, along with the authorized user attestation, and we feel that post-implant imaging and dosimetry is necessary.

So the 2012 ACMUI report is simple, does not use the detested

D90 concept, and it provides appropriate guidelines and criteria for defining medical events while excluding unimportant variations. Thank you.

CHAIRMAN JACZKO: Well, thank you for that. We'll now here from Dr. Zietman, who is the Chairman of the Board of Directors of the American Society of Radiation Oncology.

ANTHONY ZIETMAN: Thank you so much. Chairman Jaczko, Commissioners, good morning. I'm speaking to you in my position as former president and chair of ASTRO. I'm also a practicing radiation oncologist with a large prostrate brachytherapy practice. And I've developed an academic career around the study of this disease and its treatment. I also had the privilege of sitting on the VA Blue Ribbon Committee that studied the events at the Philadelphia VA, and what we could learn from them. And I, like everyone else here, was traumatized by those events and learned a lot from them. I'm also now editor of our specialties major scientific journal, which has devoted a lot of print ink to exactly this subject.

I'll start, really, at the end. ASTRO, which represents 96 percent of America's radiation oncologists, is actually delighted with the ACMUI proposal and the modifications that the NRC staff have suggested regarding this definition. We believe the proposed rule is meaningful, it's practical, and it's enforceable, and we strongly support it. We have to look backwards at the problems of the current rule because it's from the problems that the new proposal stands out in stark contrast.

Permanent implant low-dose rate brachytherapy, which to all intents and purposes, really means prostrate, is unique in the world of brachytherapy. There are these multiple physical biological imaging

uncertainties. They're the presence that interacts in a dynamic and unpredictable fashion during the weeks and months after the implant, that sort of have undermined a dose-based definition of a medical event. As you all know and if you had the chance to see PRAT [spelled phonetically], the procedure we use, ultrasound to determine the size and shape of the prostrate, and to determine what out treatment site's going to be. We use ultrasound again during the procedure because it's a great way of seeing the prostate and a great way of seeing the needles.

Now after the procedure, we're got to image the -- again, to make sure we've done a good job. But now we can't use ultrasound, because ultrasound doesn't show us the seeds very well. They look like bright shining stars and it's impossible to localize. So we've got a few CT scans. The problem with CT is that it routinely shows the prostate as being larger than it actually is. And it's not by a predictable amount; it's by anything from 5 to 50 percent. So this makes an accurate calculation of the dose that's been delivered extremely difficult, with a tendency towards underestimation.

And as you've also heard, an additional problem is that the prostate does swell unpredictably, particularly in the first few weeks after the seed implant. It can swell anything from not at all to twice its original volume. This separates the seeds and reduces the appearance of -- estimates of radiation dose delivered. Again, this phenomenon is beyond the control of the physician, and it's completely unpredictable.

You know, these changes mean that an implant which may appear very hot on day one, if you image on day one, may be just perfect by day 30. Or one that is acceptable on day one could be cool by day 30. So where do we

measure? When do we measure? You know, a patient who's scheduled to have a post-implant CT scan to assess the dose at the 30-day mark, maybe they're off to Florida, they asked to have the CT scan a week early. They're a medical event now, but they wouldn't have been at 30 days. So it makes it very difficult.

And let's talk about these so-called dose metrics which we've use to define absorbed dose. We talk about the D90, but there's also the D100 and the V90. But these are mere approximations of reality, and what's more, they don't even necessarily move in tandem. The D90 became an early measure of quality because it seemed to have some connection with cancer outcome. Well, this hasn't really been validated; and so to hang a hard regulatory rule on so soft a measure really made little sense to practicing radiation oncologists. It made so little sense, indeed, that most of us practicing physicians were actually unaware that medical events could be determined after the D90.

And when Philadelphia broke, none of us actually believed that this was a measure that could come back to bite us. It turns out that a patient who has a D90 of 80 percent has an implant that's actually good enough to enter a National Cancer Institute-sponsored clinical trial. But it's also bad enough to be reportable as a medical event. So you have two government federal agencies that really are not working in tandem here.

And in the confusion after Philadelphia, there's been some very uneven interpretation of the existing rule, with geography playing a strangely fickle role. In some states, such as Wisconsin, it's been very rigidly interpreted; in others, it's not. I'm not going to go into the details of that, but this could come up in the question and answer. We've felt, only in a more widely agreed meaningful and easily interpretable rule can end the confusion. I mean, it's said

that no harm comes from setting a sensitive regulatory rule. You know, it's simply a warning that a near miss may have occurred. It turns out that's not true. Any event labeled as a medical event sets off alarms at institutions that -- with -- there's reporting to QA committees, mandatory warnings to patients. And these warnings cause distress and undermine patients' confidence in their physicians. Patients whose -- physicians who may well have actually done a perfectly good job. Indeed it seems the majority have. And worse still in our media oriented society these events can be blown into major storms and no physician wants to go out in that kind of weather, I can tell you.

Prostate brachytherapy which is really the most cost effective treatment in prostate cancer is now in sharp decline. There're about 40,000 cases a year in 2005; it's estimated there'll be less than 10,000 this year. Now there are several factors for this but the medical even definition is one of them. Why bother, physicians say, flirting with a state report, a QA investigation, and an unwelcome appearance in the local newspaper when we could do something that's less personally risky.

If one looks at the VA system, which is not subject to the market forces that may also have contributed to a decline in brachytherapy elsewhere, the number of centers still performing prostate brachytherapy is down from, I can be correct on this, I think it was around 15 pre-Philadelphia to about eight now.

So our feelings about the proposed rule, what Dr. Welsh has described I think is clear advantages to you. CT scans which we all use to assess the quality of our implants have several problems; however, they do answer certain quality questions particularly well. Are the seeds in the prostate? Are they in the immediately adjacent tissue that is part of the target as defined by

the authorized user? Or are they elsewhere and in non-target tissues? And these really are the metrics of the proposed rule.

The proposed rule takes into account the fact that the source strength implanted within and around the prostate is under the control of the authorized user and is measurable. But the subsequent prostate volume imaging some uncertainties and ultimately the guestimate of dose that's given to the prostate is not.

So the target base definition that ACMUI have proposed, I think will clearly capture the most egregious medical events in a reliable fashion. And it's already -- this definition has already been battle tested by the VA Blue Ribbon Group that reviewed the events at Philadelphia. At the end of the day, our group agreed fully with the NRC investigators who found a poorly overseen program with limited QA. We agreed that there were many medical events. Where we couldn't agree was on how many. And we looked at the day symmetry from 107 cases, of which either 56 or 62 were medical events by the old rule, simply depending upon who drew the volumes. Then if one corrected for prostate swelling, it was down to about 20 medical events. And if one uses a target based definition such as you've heard, it came down to about 11. Now that is a non-acceptable number of medical events from one institution. But these were -- the new rule does not fail to detect medical events and it still would have raised the alarm in Philadelphia, but at an appropriate level.

Are there any concerns that ASTRO has? We have one small concern. Those metric which, the proposed rule use of those metric, within the target volume limiting the urethra fact less than 150 percent of the prescribed dose. I don't have a major objection to this but there are some small risks.

Brachytherapy is by definition heterogeneous within the target, hotspots are a little unpredictable, and the other problem is that not all physicians measure the urethral dose. To do so you need to insert a catheter into the patient, you know, a tube through the penis approximately that thickness, and I don't necessarily measure a urethral dose in my patients. I don't want to have to put a catheter into the patient and say, this is from the government.

[laughter]

I don't think they'll appreciate that. So we believe that generally speaking this new definition is intuitive, it can be easily interpreted, reliably reproduced, and will be respected by physicians and by physicists. It makes it easier for us to report and for the NRC to enforce. It's not going to flood the inspection agencies with meaningless events, but it'll still capture those events that could cause serious injury or harm. ME should stand for medical event, not meaningless event and I think by this rule it will. So thank you so much for your time. I really appreciate the measured consideration that you've given to this particular issue. Thank you.

CHAIRMAN JACZKO: Well thank you very much for that description. We'll now turn to Dr. Lee, who is with the American Brachytherapy Society.

W. ROBERT LEE: Mr. Chairman, Commissioners, I want to thank you for the kind invitation and opportunity to speak with you today on behalf of the American Brachytherapy Society about this issue of medical events with permanent source brachytherapy.

I am Robert Lee, I'm a past president of the ABS and as my colleague Dr. Zietman, I'm a prostate cancer specialist. My clinical practice is

devoted almost entirely to caring for men with prostate cancer, whether they're treated with radiotherapy or active surveillance, which is a large part of my practice. I've been performing prostate brachytherapy since 1996.

In the interest of full disclosure, I think the Commissioners should know two things. One, I acted as an unpaid consultant to the VA OIG report; and second, I have contracted with the federal government to be an external contour for brachytherapy procedures at other VAs.

The American Brachytherapy Society was founded in 1978. It's a multidisciplinary society comprised of more than 1,300 members including radiation oncologists, physicists, dosimetrists, and other health professionals in related disciplines. The mission of the ABS is to serve its members by advancing the field of brachytherapy, by promoting excellence in education, research, and clinical practice, and by representing brachytherapy specialists and their patients.

In addition to an annual scientific meeting, the ABS holds multiple schools of brachytherapy throughout the year and I can tell you in the last few years that the definition of a medical event has been front and center at every single one of our meetings. There's been at least one panel on this issue and I can also tell you that the panelists that are experts in this area don't agree with one another. When we poll the panelists, we can't get a consistent answer. When we poll the audience, we can't get a consistent answer on what is a medical event. So the language is the language but the interpretation is not consistent. So I think that we do have a problem.

I do want to highlight two individuals on behalf of the ABS that have done most of the work with regard to the NRC staff. That is Dr. Brad Prestidge and Dr. Brian Davis [spelled phonetically], who have worked closely with NRC

staff over the last couple of years.

So the first -- second slide that I have is a slide that I use every year in the didactic presentation that I give to our residents at Duke. It's my attempt to distill the relevant regulatory language to the essentials. The first three bullet points are pretty straightforward and noncontroversial, and there's really no misunderstanding about what they mean. As you've already heard, it's the fourth bullet about which there's substantial disagreement. Next slide please.

This is the relevant language from the regulation and I want to take you on a little bit of a detour to try and describe for you the context of dose in permanent brachytherapy. So I'm a classical studies major as an undergraduate. I majored in Greek and Roman antiquities, so history is very important to me, in particular history of disciplines. And if you look at the history of brachytherapy, it's fascinating. From the very beginning you didn't hear about dose, primarily because we couldn't measure it. The way that patients were treated was with activity over time. X number of millicuries over X hours, days, whatever. And that's the way that brachytherapy evolved. My first written directive as a resident was an activity time written directive, milligram hours for cervix cancer. That's the way some practitioners still practice. It works very well.

So I want to highlight that in many contexts in permanent brachytherapy in particular when you can essentially exclude time, activity is dose, and dose is activity. And the NRC has felt this for years in their language; they make it very clear that prescribed dose can be activity. Next slide please.

So the root of the problem is absorbed dose and how difficult it is to calculate. You already heard about the problems with volume changes, the timing of the imaging, the modality of imaging. I want to focus on the fourth bullet

here, countering variation, and to illustrate this I'm going to show you a series of three images. Can we go to the next one?

So this is an image that I showed at the 2002 ABS Meeting. At that point and time the discipline was just beginning to integrate some of these dosimetric quantifiers into practice. And many of us, myself included, thought that this would be an excellent way to determine quality. This was right around the time when the Institute of Medicine Report came out in 1999, talking about the importance of quality, etcetera, measureable metrics. And I was guilty as some others of probably overly enthusiastically endorsing these dosimetric quantifiers, because when I did a simple project I took the same CT scans from 10 patients and asked my colleagues to contour the prostate. This is what they drew. This is two different reviewers contouring the same image set, and you can see that there are dramatic differences in the prostate volume that is contoured. More relevant to our discussion today, not only is the volume different, the calculated dosimetric quantifiers are very different. And depending on the contourer, a particular case was a medical event according to a strict dosimetric quantifier definition, in some cases it wasn't.

The other thing that's important that we found out in contouring differences is that the contouring differences are maximized at the top of the prostate and at the bottom of the prostate, where it's difficult on CT scan to see where the top and the bottom is. Since these are at the edge of the implant this is where the steepest dose gradient is. So prostate contouring really affects dosimetric quantifiers. Now the human element of contouring is we can never get rid of that. The definition proposed, which the ABS for the most part endorses, still requires the authorized user to define the target. You're not going

to be able to get rid of that, but it is much less finicky than dosimetric quantifiers in the sense that if a source is in or out it doesn't make a difference, but at the top or the bottom there's a lot of dose gradients there and depending on how you draw the contour the D90 or the V100, pick your metric, can be very different. Next image.

So I and a group of others once we discovered that there was this enormous variation, we decided to -- I'm an educator at heart, and we decided let's have a workshop where we'll bring in experts in diagnostic imaging, ultrasound imaging, MR imaging, we had some neurologists, and we basically sat in a room for a day hearing about prostate anatomy. And we did an exercise before and after this educational workshop, and what you see on that screen is after the workshop. These are our expert contourers contouring the top of the prostate. It doesn't probably project well in your book, but suffice it to say that there were 12 contourers on this image, I think four or five didn't even draw a contour because they didn't think the prostate was there, and the ones that did draw a contour were sort of all over the map. And given that this is at the edge of the implant, the dosimetric quantifiers resulting from the contours were very different.

The next, third and final image to try and highlight, this is something that's very personal. This is data taken from RTOG 0019, which is an NCI supported cooperative group study for which I'm the PI. And this is D90 post implant dosimetry. As PI, I reviewed all of the post implant CT scans and I contoured the prostate. So this is D90s based on my contour, not on the authorized user's contour, on my contour. And if you use a strict D90 definition, it doesn't show up here, but 35 percent of -- just advance it I think, 35 percent of

these cases would be classified as medical events. That sounds like a big number. It sounds like we should be concerned. I can tell you with nine years of follow up, these patients are doing remarkably well. They're indistinguishable from other institutional practices. The toxicity is not excessive. The efficacy is about what you'd expect. In fact the RTOG has taken this, the results of this study forward to a phase three, so that we feel comfortable that our practitioners across the country, this was from 27 different institutions, can do this in a consistent, safe way that highlights the problems with contouring and relying on dosimetric quantifiers. Next slide please.

So the proposed changes from the ACMUI and then translated by the staff, basically puts the onus on the authorized users for things that she or he can control, namely putting the sources where they should be. And not the things that they cannot control, prostate expansion, seed migration, etcetera, etcetera. Last slide, please.

So the ABS endorses for the most part the proposal. It's simple. We believe it's relevant. Since the secretary's letter has been published in the public domain I've heard from ABS members, two issues. One is trivial, I think, and it's a recommendation to replace the word seeds with sources. The second is, Dr. Zietman highlighted as well, and that relates to the use of an intra-target dose definition.

For years, in fact for better part of a century within brachytherapy, we really haven't paid any attention to what happens to dose inside of the target. Now part of that relates to the fact that we didn't use to be able to measure it. As we've highlighted today, we now think we can measure it, although I'm not sure that we can. And there has been a concern raised that intra-target definitions like

this are problematic, primarily because it's not at all clear that these sort of dose - brachytherapy is by definition the dose is heterogeneous. That is fundamental to brachytherapy and that may be why it works as well as it does. But, so there are going to be high dose spots within the target and in the proposed definition, there's really very little evidence to support the dose and volume that is used there that suggests that it's in any way related to medical harm. In fact, there's no information that I'm aware of that looks at the dosimetry for the urethra and can equate dose with toxicity. There's some very, very old papers from 25 years ago when dosimetry was very, very primitive that said if the dose was 400 percent then you may have problems. Nowadays hardly anyone gets anywhere close to 400 percent. And so recognize, I think the Commissioners should know that there is a concern amongst some very accomplished, experienced brachytherapists, who've had experience with the ACMUI, been on the ACMUI, that has concern about this intra-target definition of a dose for a medical event.

Big picture though, the ABS is very pleased that this issue is being looked at. We like the target activity definition, we believe that it will define those events that are truly outside of the standard of care and egregious and potential for patient harm and deserve to be acted upon, and it will not in the process lead to medical events that really are meaningless. Thank you for your time.

CHAIRMAN JACZKO: Thank you. We'll now turn to Chris Timmerman who is a Senior Nuclear Engineer at the Wisconsin Department of State Health Services and Radiation Protection Section and with the Organization of Agreement States. Thank you.

CHRIS TIMMERMAN: Thank you. Good morning. Good morning Chairman Jaczko and Commissioners. I am pleased to be here today

representing the Organization of Agreement States and briefing you on the Organization's position on the Part 35 Medical Definition as it pertains to permanent implant manual brachytherapy.

There are three primary areas that I will be focusing my time on today. First, I will describe the Organization of Agreement States' position on the recently submitted SECY paper 12-0053 on the Recommendations on Regulatory Changes for Permanent Implant Brachytherapy Programs.

Next, I will discuss what Wisconsin has done in the interim awaiting guidance for the NRC concerning these types of implants since the inspection of the VA Hospital. Finally, I will cover the work completed by a joint NRC/OAS Working Group tasked to create a supplement to the Inspection Manual Chapter 2800, "Manual Inspection Program" and the Inspection Procedure 87132, "Brachytherapy Programs" as based on current Part 35.

The Organization of Agreement States Executive Board has reviewed the SECY paper 12-0053 and supports the stated goal of the Commission, which was in SRM SECY paper 10-0062, to clarify the medical event definition to protect the interests of the patient, allow physicians to take actions as they deem medically necessary, while continuing to enable the NRC and Agreement States to detect failures in process, procedure, and training. However, the board does not support using only activity based medical event criteria as recommended in the SECY paper 12-0053. All other therapy treatments utilize dose based criteria, thus, it is inconsistent to have one radioactive material therapy treatment that does not utilize dose based criteria. OAS recommends retention of dose based criteria. If dose based criteria is not retained, the OAS requests that the Agreement States be allowed the flexibility to

utilize dose based criteria for these types of implants.

The OAS also performed a survey of the Agreement States concerning medical event criteria for prostate brachytherapy implants and 14 states have responded. The results of the survey were briefed at the stake-holder workshops which were held in New York City and Houston last year as well as at the Organization Agreement State's Annual meeting. All of the 14 states that have responded have the same “current” medical event definition as the NRC or a definition that is more restrictive than the NRC's.

Now I will discuss what Wisconsin has done. Wisconsin has inspected the majority of their medical licensees that perform manual brachytherapy implants and all of the licensees have established dose based criteria. These inspections were conducted utilizing the Wisconsin's Information Notice, issued in July 21, 2010 which reminded licensees that they are required to have written procedures to verify that each administration is performed in accordance with the provisions of the written directive.

Also, a Regulatory Information Summary was used that was issued February 18, 2011 which detailed additional guidance, also requested licensees to respond with the criteria currently used and provided some lessons learned from previous inspections. Additionally, during this time, Wisconsin completed 29 inspections and compiled the number of implants performed and the number of medical events reported. A retrospective review was conducted by the licensees to determine if any process improvements could be made to the licensees concerning their prostate manual brachytherapy programs. Out of 1,970 prostate implants performed since 2003, which when Wisconsin became an Agreement State, there have been only 35 reported medical events, which

comes out to 1.78 percent of all implants performed.

Many of the reported medical events could have easily been prevented. For example, some were planning errors; some were not documenting the correct number of seeds that were implanted due to pubic-arch interference or under other cases where the physician decided not to implant all the seeds. Therefore, as seen in Wisconsin, if licensees use a dose based medical event definition, there will not be a huge surge of medical events, as some people have projected.

Now moving on to the Joint NRC/OAS working group, it was established or assembled in August 2011. The working group was comprised of personnel from the Office of Federal and State Materials and Environmental Managements Programs, two Agreement States, all NRC Regions, the Office of General Counsel, the Office of Enforcement and the Division of Intergovernmental Liaison and Rulemaking.

As you may know the Inspection Procedure 87132 is in the final steps of the approval process and the training will be conducted for all NRC Regions and all Agreement States this Thursday, April 26 via webcast and webinar. The training will go over the changes made to the Inspection Procedure based on the “current” 10 CFR 35.40, “Written Directives” and 10 CFR 35.3045, “Report and Notification of Medical Events”. This Inspection Procedure will be used by NRC Regions and all the Agreement States until the new Part 35 is finalized.

As the co-chair of the Working Group, the group worked hard to find common ground that would only benefit not only the NRC Regions but also the Agreement States as pertaining to inspection guidance for manual

brachytherapy programs. In the NRC Regions as well as the Agreement States there is a big difference when it comes to licensees using dose based criteria or activity based criteria, or even how licensees are performing these implants.

In providing interim guidance for inspectors, we had to work within the constraints of the current rule. The revised rule should define key terms, for example, completion of procedure, prescribed dose, administered dose, and absorbed dose, just to name a few. And unlike the current Part 35, it should be used to defined terms consistently throughout the revised rule and associated guidance. One consistent message from the Working Group was that training and guidance needs to be given to the licensees and the inspectors on current and new medical event definition.

In closing, the Organization of Agreement States would also like to submit the following recommendations concerning the new Part 35 rulemaking process: Consider listing Authorized Medical Physicist on the license for Manual Brachytherapy based on Medical Physicist's involvement with treatment plans and post-treatment plans. This would be similar to the requirements for Strontium-90 eye applicators; also, incorporate treatment planning process; incorporate post treatment evaluation steps. Now in Wisconsin, most of the licensees are using a 30-day follow-up that was described earlier by Dr. Zietman and I believe Dr. Lee; and finally, do not remove "total dose" as an option for completion of the written directive or at a minimum allow the Agreement States flexibility in this area. Thank you again for allowing me to talk with you today. This concludes my remarks.

CHAIRMAN JACZKO: Well thank you very much for that information. We'll now turn to our final witness, which is Laura Weil, who is the

Patients' Rights Advocate for ACMUI as well.

LAURA WEIL: Good morning. Thank you very much for the opportunity to be here today. I would like to talk about, in very broad strokes, about principles of patient advocacy and how they apply to the question at hand. Can we move two slides up please? Thank you. There are two kinds of underpinning to the work of patient advocacy. The first is ethics and the second is rights. Let me talk briefly about ethics first.

Here I'm going to borrow from the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research's paper called "The Belmont Report." This is -- these three ethical concepts can be broadly applied to any medical encounter, and therefore, I find them very useful for talking about patient advocacy in broad strokes.

The first is the principle of beneficence. And very simply stated that is the concept of maximizing benefits and minimizing harms. That's not a surprise to any of us. The second, respect for persons, really refers to the fact that patients are autonomous beings with rights and preferences and person-specific values. And we'll return to this concept of autonomy for most of what I'm going to talk about. But the third principle of justice relates to equality. In the Belmont Report, it's specifically related to equality in terms of the burdens and the benefits of clinical research, but one could spread this out a bit to say there should be equality in access to medical services in general. Next slide please.

The next set of underpinning concepts to patient advocacy has to do with patients' rights or rights in a general sense. The patients' rights movement really was an outgrowth of the civil rights movement of the 1960s. It signaled a move away from a strongly paternalistic medical model to a more

collaborative and participatory model of shared physician-patient decision making, which is supported by open communication. Statutory rights are those rights that will be enforced by courts. So those can be legislated or they can be rights that are formed by substantial case law, which then influences further actions by the courts.

Normative rights, which one could consider the ethical underpinnings we were talking about earlier to be in this realm of normative rights. These are rights that reflect the prevailing ethos and values of a society. Normative rights affect statutory rights. They change the way we view things, and they are not consistent. They change over time. The third category of rights that I would like to talk about are implied rights. And I've labeled these rights that are conferred by codes of professional ethics, because I think it's pertinent to this particular discussion. So, professional ethics will prescribe how a particular professional, in this case a clinician, ought to behave. And the best example for this discussion would be the American Medical Association's Code of Medical Ethics that clearly states that patients have a right to know when a medical error or unexpected adverse event has occurred, whether or not the patient has actually been harmed.

Now we could question whether patients really want to know these things, but it's been fairly well demonstrated in the medical literature that patients generally do wish to know. They wish to be told when there's been a departure from the plan. They wish to be told what the implications of that might be, so that they can actively and autonomously make future medical decisions. It is important, of course, not to step on the rights of those who might prefer not to know, but that's a conversation that a physician and a patient can certainly have

the same way one has those conversations with patients at the end of life to know whether they'd like to know about a terminal diagnosis or whether they'd like to have the decision discussed with someone else. These are communication opportunities that we shouldn't be stepping on in our rush to define medical events and, therefore, define the physician's responsibility to disclose these things. Next slide please.

So if we go back to Belmont's respect for persons we can talk about autonomous choice and there are barriers to autonomous choice and enablers. Enablers obviously are full information and transparency and access to services, and the barriers would include geography, rural areas have very limited access to medical services. Provider payment issues are an enormous barrier, mostly insurance issues where folks are denied access to centers of excellence because their insurer simply won't pay for it or because they're uninsured and have very little choice about where they can receive care if at all.

The third barrier would be provider biased and that's something that we all run into. Perhaps it's a hidden kind of thing but certain providers will recommend certain kinds of services, and other providers will recommend other kinds of services. We all know the joke about if you go to a surgeon, of course a surgical intervention will be recommended because that's how that physician is trained. That's facetious but it certainly, it illustrates the kind of bias that different kinds of training will infer. But there's a subtler kind of bias which is gender and racial bias and we know that physicians will recommend treatment based on their preconceptions about what -- or their unconscious preferences for recommending treatment to women and men of color or not. So, next slide please.

So the current issues before the ACMUI, which have a patient advocacy focus, would be these three issues we've been discussing lately. The CardioGen Iodine 131 Patient Release and this permanent implant brachytherapy situation. What concerns me as a patient advocate most in this context is the question of communication and transparency. The question of whether patients will be informed about -- if the medical event definition is extremely strict and rigid and catches as Dr. Zietman said the most egregious medical events only, then will patients indeed be informed about other kinds of changes in the treatment that they've received? I think I can probably stop there, and thank you very much for the chance to present.

CHAIRMAN JACZKO: Well, thank you very much. We will turn to Commissioner Magwood for questions and comments.

COMMISSIONER MAGWOOD: Thank you, and thank all of you for your statements this morning and many of you have been before us before. Thank you for coming back, especially, you know, Dr. Welsh and Dr. Zietman. You both have participated quite extensively and Dr. Zietman has gone above and beyond by providing me a personal tour of his facilities at Mass General. I always greatly appreciate that education.

Let me start with you Ms. Weil. I -- this -- you know, I do see a lot of synergisms between some of what you're saying and some of what Dr. Zietman is saying, but I wonder if we're really on the same wavelength. Let me explore this a little bit because it seems to me that medical events are not a medical term; they're a regulatory term. And it's not clear to me that patients knowing, particularly at the current -- in the current definition of medical events, that the patients given that information doesn't necessarily as Dr. Lee indicated,

doesn't necessarily tell them anything because, just because the regulator thinks that something, there's a medical event. And don't forget we, even we use the term medical event; we're not necessarily saying something bad happened. We're just simply saying that something happened that requires us to look at, you know, what happened more, in further detail. So it's not clear to me that patients getting that information is giving them useful information because it's not telling them that something was wrong, it's telling them that the regulator wanted to look at this for whatever reason and it doesn't say that there's something wrong. It just simply says that we wanted to look at it. And I just wondered if that's something you've thought through as you've looked at this? There's good information, there's bad information, and I wonder if what we're -- if you're giving them bad information, is that?

LAURA WEIL: Constructive?

COMMISSIONER MAGWOOD: Is that constructive?

LAURA WEIL: Well, I'm a believer in transparency and I think that there's a contract between patient and clinician which the whole informed consent concept includes a description of things that may not have gone according to plan. Whether they're good or bad patients have a right to know about what the plan was, what the procedure was, and what the likely outcome might be. Those three things don't necessarily mean it's bad news. They simply are information for the patient about what happened. I think that's necessary. I think that it's well borne out by surveys of patients. I can quote one, I think it's Hobgood [spelled phonetically] who says that 76 percent of patients want to know specifically what happened if there was a departure from the planned intervention, in the Academy, Academic Emergency Medicine. I have the citation

in my last slide. And because patients want to know, I believe that that desire is well supported by rights and the ethical underpinnings of the contract between physician and patient. Doesn't mean something bad happened, simply means that it's full and transparent information.

COMMISSIONER MAGWOOD: Yeah, and I fully subscribe to giving patients full information. I just wonder if -- but I think the information is more useful if it's based on criteria that actually indicate that there's been a variance. I mean I think it was Dr. Lee that indicated that, you know, physicians have gone through these procedures, done exactly what they wanted to do, got the outcomes they wanted, were very pleased, and it was nine years later after looking at the results that things went well; but nevertheless some of those procedures could have been classified as medical events and, therefore, patients might become unnecessarily burdened with this -- now again, non-medical information but regulatory information. And I just think that's something we need to be very careful with, because, you know, we're not doctors here. You know, we don't even pretend to be doctors here. [laughs] So I think this is something to be conscious of.

LAURA WEIL: Absolutely.

COMMISSIONER MAGWOOD: Let me go on. Mr. Timmerman, I was actually -- I read some of the concerns that OAS has had about the direction this has taken. You do seem to be a little bit in isolation on this. The staff and the community seem to have astonishingly come to some agreement as to the direction, but the States seem to be unhappy with that. I wonder if you can give me a little bit more on this. I mean, you -- I think as I recall from previous Commission briefings the States indicated that they thought that the current

regime was flawed. And is that still the case?

CHRIS TIMMERMAN: Yes Commissioner. We, the Organization of Agreement States, feel that way. If given.

COMMISSIONER MAGWOOD: Go ahead.

CHRIS TIMMERMAN: Okay. Also, I mean for, I can't speak for the other States but for Wisconsin what we did, we had licensees establish those basic criteria and that came from a couple of inspections of very large facilities that did not have any procedures in place on how to do the post implant verification, which is required by our rules, the same as the 10 CFR. And so what we found there was they had -- could've made a process improvements if they were viewing their cases that wouldn't have been medical events but they would have prevented ones that -- occurring that happened later on, like not -- if they didn't -- they had a couple needles where they couldn't put in the prostate, for example. If they would have revised the written directive it would not have been a medical event. The patient got the exact treatment done, what the physician wanted to do, but the documentation was not there. Just one example. Or there was other steps they could have taken.

We had retracted some medical events in the past where they did -- they changed their procedure. They were doing a same-day CT and they changed to 30-day. They did a same-day and they said, "Well, can we wait and do 30-day," and we said, "Sure." And we retracted that medical event because of it -- we understand it was from edema, as some of the other panelists said earlier. So it's not -- we don't want to put out the face that we are very strict. We work with our licensees and whatever protocols -- they were following national protocols from the R2Gs or the AAPM. We said, "Okay, is -- this is what you're

following, this is in your procedure," then it says in there -- you know, recommends to do these areas and the way our current rule is written, it's all -- it's all -- it's dose-based and none of our licensees in our state were using activity-based so that's how we sent out the regulatory issue summary that I mentioned earlier and we moved forward from there.

COMMISSIONER MAGWOOD: A big part of your concern seems to be that using activity is at variance with the usual practice of any radio-therapy, which is to look at dose. Though this is substantially different from most radio-therapy. I mean, you're not simply exposing tissue to -- you know, or a beam or on a temporary basis a source. This is implant. Is -- does that -- I mean, the fact that it's very different in kind, does that not require a different regulatory approach than your -- I mean, obviously it doesn't but I'm just trying to understand the logic a little bit.

CHRIS TIMMERMAN: It does, but for -- I guess from our standpoint it's -- all the regulations should require consistency so there's not questions that come up. Obviously, the definition of why we're here is, you know, it's flawed in some way. We just don't -- we -- if -- the main point is if the activity-based will be used, we were -- the Agreement State requests that we're allowed flexibility to utilize those base criteria if that's what all of our licensees are using. What we don't want to happen specifically is -- they're all using dose-based criteria. Now they changed the medical event. Now they've got to retrain themselves theoretically on the medical event definition, not actually practicing medicine, but what we're going to be looking at. Our licensees are already onboard and they're working forward. We haven't had any medical events since everybody had got this in place and they corrected all their process improvement.

So if activity-based is used, the agreement states just want to have flexibility that they currently have now to utilize the dose-based criteria.

COMMISSIONER MAGWOOD: Okay, so the -- so basically the bad thing that happens if you don't get the flexibility is that your licensees have to go back and train.

CHRIS TIMMERMAN: They wouldn't have to go back to train, necessarily. They would have to train their documentation on how to document it. And that may be an issue; it may not be an issue. At this time, we don't know.

COMMISSIONER MAGWOOD: Okay. I appreciate that. Yes, I have a minute left. Let me -- just generally to Drs. Lee and Zietman that you've indicated -- I think you used the word "delighted," which we don't hear very often -- delighted with the outcome of the -- with the staff's position is -- there do seem to be some issues on the borders of this, such as the definition of treatment site. That seems to be still a little bit at-play and I think there's still some process left on that. But one aspect I was hoping one of you could speak to is, make sure my understanding is correct, we're extending the closure of the written directives. You know, we're not -- the written directive is not completed before the procedure. It actually has some tentacles that continue after the procedure's completed as you go through the CT scans later. When is the thing close? When is it done?

W. ROBERT LEE: I'm sure Anthony will have an answer, so I think -- I can't remember the specific language, but it was basically when it's out of the authorized -- when the patient is out of the authorized user's control, and I think this is a very good thing going forward. You -- as you make changes you almost want to think about what's going to happen 10 years down the road. I

think, 10 years down the road, our ability to come up with an accurate, reliable dosimetric judgment on the implant will be able to take place in the operating room almost routinely. It's happening in a few places now and it allows people who are doing that sort of thing the opportunity to do the case, do some sort of quick dosimetric assessment, and then maybe add a few sources if it's a little light in a particular place. Sort of before the patient is let go. The inter-op people that do real-time treatment planning are enthusiastic about this clarification, making it clear that they can, you know, improve their implant after. Not everyone does this, but it does allow, you know, folks to sort of touchup implants to get them perfect, perhaps, without having the patient to come back on another day to put sources in.

COMMISSIONER MAGWOOD: But theoretically this is something that could go on for years? Is that --

W. ROBERT LEE: No, I think that --

COMMISSIONER MAGWOOD: -- possible?

W. ROBERT LEE: You know, and this is where the written directive -- it would be incumbent on the authorized user to basically describe sort of what happens. I wouldn't think it could go on for years. I mean --

COMMISSIONER MAGWOOD: Months?

W. ROBERT LEE: No.

COMMISSIONER MAGWOOD: Okay. Okay. I just want to make sure.

W. ROBERT LEE: Hours.

COMMISSIONER MAGWOOD: Okay, I just want to make sure I understand where you thought that was that --

W. ROBERT LEE: Yeah, no.

COMMISSIONER MAGWOOD: Okay.

W. ROBERT LEE: It's at the --

COMMISSIONER MAGWOOD: Okay.

W. ROBERT LEE: The whole idea is to allow so that the patient doesn't have to come back and get -- say, in the circumstance -- even though this wouldn't count as a medical event, if you have source migration and on the 30-day CT scan you find that they're, you know, the sources of the anterior part of the gland went off into the pelvis, then, you know, many users will actually bring the patient back and re-implant that area. The idea here is that you sort of discover that sooner and can do it. But, yeah, no, it would be hours --

COMMISSIONER MAGWOOD: Okay.

W. ROBERT LEE: -- for it.

COMMISSIONER MAGWOOD: Appreciate that. Just wanted to thank Dr. Welsh and the ACMUI for the work they've done on this. It's been, you know, truly of tremendous importance for the Agency and appreciate the effort you put into this. With that, Chairman, my time is up. Thank you.

CHAIRMAN JACZKO: Commissioner Ostendorff.

COMMISSIONER OSTENDORFF: Thank you, Mr. Chairman. Thank you all for being here today, and it's interesting to see the different perspectives from different organizations and I think it's actually a real strength of the process here at the NRC, a strength to bring in disparate -- different viewpoints together to see how is it synthesized into something that's workable at the end of the day. You know, I know there's some differences of opinion on certain aspects but I think this is a good new story, that we're moving in the

direction we've moved. Just my personal opinion.

For the sake of continuity I want to go back to Mr. Timmerman just for a minute here with some of the question that Mr. Magwood was pursuing with you. And I guess I can appreciate the need for some consistency and for being able to explain to people, "Well, this is a special case but it's not like this other procedure," and I can -- I do understand the challenges associated with the consistency piece. But let's just hypothetically assume that the only treatment that we were considering that required any kind of a dose-based or activity-based definition was the permanent implant brachytherapy, that we're not talking about any other forms of treatment. Does the OAS have any substantive concerns with the activity-based approach?

CHRIS TIMMERMAN: Just from the survey that we sent out, there are some States that are still waiting for NRC guidance, there are some States that, you know, are still going along as they normally have. For -- to answer your question, I can't really say what the other States have done, I just know what our -- in Wisconsin.

COMMISSIONER OSTENDORFF: Because it seems like the volume, the prostate volumetric change during procedure, the swelling issue, that seems to be pretty well accepted by -- two years I've been on the Commission, I've been hearing about that for two years. And I've not heard any medical evidence to suggest that that's not a concern during prostate treatment, so that really was a key factor in trying to get away from the dose-based approach. I'm just trying to figure out if there's any substantive disagreement with that medical issue on swelling and then dose to this volume.

CHRIS TIMMERMAN: No, the agreement states understand the

edema occurs during this type of very invasive procedure. We just like to have more structure to it.

COMMISSIONER OSTENDORFF: Okay.

CHRIS TIMMERMAN: Yeah, I guess that would be why they recommended to involve the treatment process or even the post-treatment plans, because right now that's pretty much moot on current 10 CFR, I believe. So if there's some kind of robustness there or working with ASTRO -- if that can be addressed somehow, we're all for that, just to have -- make sure it's laid out and out there in the open so everybody knows what we as regulators expect and also what the medical community is trying to do.

COMMISSIONER OSTENDORFF: Okay. Thank you. Dr. Welsh, I'm going to go to you for a minute. I want to add my thanks to that of Commissioner Magwood here. I think the ACMUI involvement has been very helpful. I know that there's been an existing rule and then the draft ACMUI report, final report, dissenting opinion, and looks like we're looking at a Supreme Court case here with the different legal views. But I think that's actually a healthy part of the process, so I commend ACMUI for having the process in place to allow other voices to be heard, which I think's really important.

Because I may have some things confused here, help me out. I think the most significant -- correct me if I'm wrong but I think the most significant delta between where our NRC staff is with the proposed changes to the medical event definition and where ACMUI was is the staff did not include the attestation requirement. Is that the most significant difference between ACMUI's position and the staff position?

JAMES WELSH: Currently it is. It's perhaps the only significant

deviation from the ACMUI 2012 report. And as I mentioned, the inclusion of the authorized user attestation was controversial and the vote was perhaps more divided on that particular issue than on all the others.

COMMISSIONER OSTENDORFF: Okay.

JAMES WELSH: And after reading the staff SECY paper, the concern about the attestation may not be as much of a concern after all, because the staff did explain fairly clearly the rationale for no need for the attestation.

COMMISSIONER OSTENDORFF: Okay. Does anybody else have anything to add on the attestation issue? That -- no one to provide opportunity if you had anything to add. Okay. Let me go on to another issue. Substantively, in the 150-percent criteria for doses to normal tissue, and I like -- kind of go down the line. I'm not sure I've seen a whole lot of scientific or medical evidence to suggest that that's an appropriate standard or not. I'm not disagreeing with it, but I just am not personally seeing a lot of -- it's less than conservative than the current rule, certainly. Is the medical community pretty supportive of this 150-percent criteria?

JAMES WELSH: I can say that overdosing normal tissues can cause harm. And as Dr. Lee pointed, in the older literature, where we had cases where there might be a 400-percent deviation, the urethra could have been harmed. Therefore, the concept of overdosed normal tissue as justification for medical event definition has a sound basis, but the challenge is to construct an acceptable or appropriate definition. And as we have heard, measuring the urethral dose can be a little bit cumbersome, it can be challenging, and it can be very difficult on post-implant dosimetry. Coming up with intra-target dose definitions is a bit challenging. Therefore, this particular number of 150 percent

is perhaps a moving target because it is not entirely soundly based on science, it is something that was just put forth initially as a concept of overdosed normal tissue is a sound reason for using dose in a definition. But for the target, the treatment volume, the use of dose is very, very difficult and is opposed.

COMMISSIONER OSTENDORFF: Dr. Zietman, you have anything to add on the 150-percent?

ANTHONY ZIETMAN: No. I would agree that there isn't really strong science behind it. We're all -- I suspect, as commissions, we all know that we wish to avoid high doses to normal tissues, period. These suggestions I think are a little bit arbitrary but they do provide some parameters within which we can work. The only distinction I personally would like to make, and has been raised by some ASTRO members, is that -- to draw a distinction between intra-target normal tissues, like the urethra runs right through the middle of the prostate, which will inevitably get a high dose, and those outside which should be getting relatively low doses.

COMMISSIONER OSTENDORFF: Okay.

ANTHONY ZIETMAN: And I think the intra-target normal tissue is a very difficult one to regulate.

COMMISSIONER OSTENDORFF: Yeah. Dr. Lee, do you have any comments or anything you want to add on the 150-percent criteria?

W. ROBERT LEE: So, I think you've got it right. There's limited in science. I think, as clinicians who are interested in doing well by their patients, we are all taught from a very early age to minimize dose to normal tissue, and I make the distinction between those things that are outside the target and those things that are inside the target. The urethra can probably tolerate very, very

high doses based on the fact that, you know, the urethral injury rate is very low, other than urethral strictures which is farther down, and that's probably that the sources are too low. So, you know, it's -- I understand what the committee is trying to do, is trying to be cognizant of trying to minimize hotspots but the history of the discipline, in many different contexts, is within the target volume that doses are sometimes astronomically high and patients seem to do okay.

COMMISSIONER OSTENDORFF: Okay.

W. ROBERT LEE: It's the doses outside the target that we can be -- you know, really emphasize.

COMMISSIONER OSTENDORFF: Okay. Thank you. Ms. Weil, I'd like to back to you, and I appreciate having a patient rights advocate here, I think that's very helpful for us. Just a very simple question, do you think the proposed revised definition is understandable by most patients?

LAURA WEIL: By patients. Well, English-speaking patients, yes. Patients with a reasonable level of health literacy or ordinary literacy, yes. I think, in general, we have a hard time communicating well to patients when we take into account the various barriers that there are to understanding, not the least of which is their emotional state at the time --

COMMISSIONER OSTENDORFF: Sure.

LAURA WEIL: -- the explanations are given. I have concerns in general, not specifically with this medical event definition. Yes, perhaps specifically with this medical event definition. As a layperson, I find it challenging to understand. Takes several readings through to get to the pith of what it's about. And I doubt the patients would bother. I'm not sure that it is of interest to patients at this point, at the point of treatment, what the definition might mean. I

think they simply want to know whether they've been harmed, whether they've not been harmed, and what the implications are for their futures.

COMMISSIONER OSTENDORFF: Just -- Chairman, if I can have another 30 seconds there I'd appreciate it. I know -- I think the diagrams you have about the contours, I thought that was very helpful and instructive, looking at the different interpretations by experts in the field. And so, Dr. Lee, I really appreciate you bringing those. And I'm just curious, do diagrams such as that help people that have your position elsewhere explain to patients these -- or why there are uncertainties? I mean, "Let's look at some diagrams of different prostate situations"?

LAURA WEIL: Well those conversations should really be had by the physician with the patient, rather than a patient advocate who is usually a non-clinician, and that's a clinical conversation.

COMMISSIONER OSTENDORFF: Okay.

LAURA WEIL: But they're interesting. They're certainly very illustrative.

COMMISSIONER OSTENDORFF: Yeah.

W. ROBERT LEE: If I could just add, one of the -- and I'm very interested in patient communication and education. One of the -- I think a broad theme that is associated with lack of perfect communication is this notion of uncertainty. Patients have this expectation that we as physicians are certain about certain things and that this is good, this is bad. The gray area, which is probably 80-percent of what we do, they have some difficulty understanding. That's where it takes time to -- I see this with medical students in residence as we teach them. They think that the answer is clear. It's -- they are programmed

to take multiple choice questions. "The answer is B." Sometimes the answer is -- you know, we don't know, and that's where --

COMMISSIONER OSTENDORFF: Good point. Thank you, both. Thank you, Mr. Chairman.

CHAIRMAN JACZKO: Well, thank you all for your -- for being here. I just have a number of questions, but maybe make some comments first. I think -- I'm certainly sympathetic I think, Mr. Timmerman, to your concerns. We are a nuclear radiation regulatory organization, so our unit of conversation is dose. Activity doesn't mean so much; it's the impact of that on human tissue that matters, which is effectively dosed. So I have sympathies for you. I appreciate the challenges and I think, having talked to Dr. Zietman many times about this, of the difficulties, and I think, Dr. Lee, your pictures were quite helpful in trying to determine where the prostate is. We can't really calculate a dose if we don't know what the volume is. I mean, that's really the challenge we find ourselves with. So it may be that to some extent we're not necessarily talking about different things. What I tend to think of this is more of a -- perhaps it's the -- it's just the state of the art is very crude, and what dose means here is nothing more than activity in the target volume, and that is in effect a dose. It's a very crude estimate of dose, it's a very gross estimate of dose, and a very simplistic view of what the target volume is and the tissue is and the distribution and uniformity of dose within the tissue, which is not very accurate given the type of procedure. But it may be the best that we can ultimately get in this case.

So I'd like to try to think in the end we are doing some kind of dose work here, it's just not as sophisticated as we'd like. And perhaps in the future we will have far more sophisticated ways to do this and then I think this gets to

be the same as all the other procedures we do here, where we can have a 20-percent variance and it's straightforward and we know how to do that.

So -- but I -- you know, so I can see both sides of this. The one thing that I do continue to find interesting though, and I think slightly new information, Mr. Timmerman, and that was the incident reporting rate. And I'm not sure what to make of that. And -- because -- and I think you even used the phrase, "If we go to a dose-based," but we do have a -- I mean, the current definition is the 20-percent variance by dose, largely I think based on the D90 value. And you're shaking your head, Dr. Lee. Or --

W. ROBERT LEE: Well, I don't mean to interrupt you but --

CHAIRMAN JACZKO: Yeah.

W. ROBERT LEE: -- the thing that struck me about the OAS survey was that different States are interpreting --

CHAIRMAN JACZKO: No, no, I'm not talking about the survey. I'm talking about his -- in Wisconsin, the rates of --

W. ROBERT LEE: Sir, I will tell you I have never used D90; I never intend to use D90; I never hope to use D90 except as a sort of internal quality improvement.

CHAIRMAN JACZKO: And I'm not -- that's not the point I want to say. If I could finish.

W. ROBERT LEE: I just want to make sure you understand that it is --

CHAIRMAN JACZKO: No, I'm not -- let me --

W. ROBERT LEE: -- uniform that everyone uses D90.

CHAIRMAN JACZKO: That's not the --

W. ROBERT LEE: Okay.

CHAIRMAN JACZKO: That's not the point, if you could let me finish. The point is, and this is an issue of concern, that what we are being told is with this definition there will be a tremendous amount of medical events reported. The dose-based definition is the current definition and there is a disconnect here because we're not seeing large numbers of medical events being reported. Now, regardless, the rule does not specify D90 as the methodology for calculation of dose. I mean, that is generally -- or used because that is, to some extent, an industry standard, so it's one that could be used but there could be other methodologies for determination of dose. But, regardless of what the dose methodology is, we're not seeing large numbers of medical events reported. So that is a bit of an enigma. I'm not sure what the explanation is, I'm not sure if physicians are all drawing their contours such that whatever they use for their dose, they're not seeing. And I have to be honest that that's perhaps not a laughing matter for a regulator. I mean, that is a real issue that we have to confront, that there may be things that are currently medical events that are not being properly reported.

So, you know, I don't know where that leaves us, you know, with the rule. So, on the one hand, there clearly are ways within the existing construct of a dose-based rule to not have large numbers of medical events reported. Now, that -- again, that may be because that's how physicians are drawing the contours. Now, I don't know that as a regulator and an inspector and, you know, your experience in Wisconsin seems to indicate that that's not something that, as inspectors, we're going to get in and start drawing our own contours of where the prostate is and arguing over contours in terms of our capturing the medical event.

So -- you know, to some extent the practical -- you know, if we truly look at the data, this actually -- you know, we're not seeing the large number of medical events being reported, nor do I see us taking enforcement action for people improperly not reporting medical events, if you will.

So on the one hand, I -- and I'm not sure where I'm going here because I'm just thinking off the top of my head. On the one hand, you know, I'm not sure where the, you know, issues really are, but, you know, that's just one of those realities of -- I don't know, maybe you can help clarify some of this for me, doctor --

JAMES WELSH: Mr. Chairman, I respectfully disagree somewhat with your assertion that we're not seeing a large number of medical events because we are seeing approximately 100 per year. The vast majority, at least 60 percent of those, are due to D90-based deviations. And in Wisconsin --

CHAIRMAN JACZKO: But if people -- I mean, is there -- what -- if you don't use D90, what do you use?

JAMES WELSH: If we use the activity-based the numbers would be much less.

W. ROBERT LEE: -- the point I was trying to make. You keep calling it that the existing regulation is a dose-based rule. The NRC for years has allowed dose to be defined in the brachytherapy setting as activity. So --

CHAIRMAN JACZKO: So it's not a --

W. ROBERT LEE: -- it's activity.

CHAIRMAN JACZKO: Yeah.

JAMES WELSH: That's the way I define --

CHAIRMAN JACZKO: Well, it's dose.

JAMES WELSH: For a regulatory --

CHAIRMAN JACZKO: Yeah.

JAMES WELSH: -- unless I put in 20 percent more activity than I said I was going to, or 20 percent less.

CHAIRMAN JACZKO: So why do we need to change the definition then?

JAMES WELSH: Because --

CHAIRMAN JACZKO: I mean, why do we need to change the rule? If that's under guidance an acceptable dose definition then what's the need for the rule change?

W. ROBERT LEE: There is currently lack of clarity, people don't understand.

CHAIRMAN JACZKO: I mean that could be clarified in guidance.

W. ROBERT LEE: Potentially.

CHAIRMAN JACZKO: Yeah.

W. ROBERT LEE: I think we've already seen that places are just closing. They're just not offering the service anymore.

CHAIRMAN JACZKO: No, I mean -- you know, again -- I mean, I'm sympathetic to the concerns you have but what I'm not seeing the big issue that everybody claims is going to happen with the new rule. And in the new rule, all -- well, not the new rule, but the existing rule doesn't require D90. I don't know, maybe the staff can help clarify this. So -- and somebody just said it was true. I don't know who said --

W. ROBERT LEE: But what has happened is that the VA has interpreted -- the VA has made D90 as the metric.

CHAIRMAN JACZKO: Okay, well the VA is not the NRC.

W. ROBERT LEE: I understand that.

CHAIRMAN JACZKO: So -- but --

W. ROBERT LEE: But practically everyone else, or a lot of people, have taken that to be the rule.

CHAIRMAN JACZKO: Well this is helpful. I mean, again, I don't know that it's the right answer, to do it this way. I mean, you know, from a -- you know, from a transparency perspective we probably want the rule to be as clear as possible, but it doesn't seem that the rule as it is now is as -- it's the use of D90, which the rule doesn't dictate, which seems to be the issue more than anything.

W. ROBERT LEE: So I'll give you a concrete example. At a VA across the street from where I work, at which I'm credentialed, the administrator at that hospital went behind the authorized user's back to the physicist and demanded to know the D90 of the patient 20 minutes after the procedure was completed, okay? And so the administrator's just chasing after a member that doesn't understand the complexity and you have medical physicists who are trying to do the best by the patients who are fixated on a number and then will blow the whistle on something that is, you know --

CHAIRMAN JACZKO: Right, but that's not -- you know -- and, again, I think that, you know, part of this -- you know, that -- and I can appreciate confusion and I think that's an important point, that we need to clarify what the actual meaning of the rule is. But, I mean, an administrator can take that action regardless of what -- I mean, an administrator could take that action even if the rule said it's a source-based. An administrator could come in and say, "I would

like to know what the D90 value is because I've heard that that's another way to measure this and I'd like to know a perspective on the D90." We can't stop that, necessarily. So that -- I'm not sure that that's necessarily relevant to our discussion, but --

ANTHONY ZIETMAN: Well, I would say that the proposed rule brings with it clarity and reproducibility and no time dependence. So if that hospital administrator, 20 minutes after a procedure, wanted to know whether 20 percent of the activity was outside the prostate, we could find that. And I'm sure it's in the patients' interests for firstly responding to a hospital administrator in that way, but --

CHAIRMAN JACZKO: But -- again, I guess what I'm trying to go back to is this may be a guidance change, not a rule change because it doesn't -- it sounds like the -- as I'm understanding it, and again stop if you can clarify this, that we don't need a rule change here, which is a little bit, I think, new to me. That if the issue is whether we will accept some concept for activity as the dose measurement, that should be acceptable under the current rule. Again, maybe stop me if you can clarify that for me. Again, speaking strictly from the regulatory perspective, that seems to be the problem, is D90 seems to be the problem. Not necessarily the fact that we have a dose-based rule, it's the fact that D90 is the way we measure the dose. And -- yeah.

LAURA WEIL: If the goal of rulemaking is to protect patients then the best rule would be the clearest and the most universally applicable in order to protect patients.

CHAIRMAN JACZKO: So that would argue for changing the rule to prevent the use of D90.

W. ROBERT LEE: Well, no, I think you can -- if institutions or States want to incorporate that into the process, I think that's fine.

CHAIRMAN JACZKO: Incorporate what into the process?

W. ROBERT LEE: Dosimetric quantifiers. But the rule itself, that's the problem. The rule is -- the language is what the language is, but if you go to institution A and institution B, how it's interpreted is completely different.

CHAIRMAN JACZKO: Yeah. Well -- and again -- and that --

W. ROBERT LEE: Be that a medical event in Illinois, the same thing is not a medical event in Indiana.

CHAIRMAN JACZKO: Yeah.

W. ROBERT LEE: And that's the --

CHAIRMAN JACZKO: No, and I appreciate that. I'm just -- from -- perhaps this is from a legal perspective, whether that really requires us changing the rule -- and, again, we can argue whether that's a good policy but I'd probably lean to the fact that is a good probably policy choice to actually make the rule as clear as we can. But it may be something that we can specify because the rule change will take time -- that we can make some clarifying guidance ahead of time to at least get clarity now on what the situation is and on -- you wanted to say something?

RONALD ZELAC: Mr. Chairman --

CHAIRMAN JACZKO: Yeah.

RONALD ZELAC: -- I can add some words. This may provide a little bit of clarity to the situation. The rule that we're operating under now for brachytherapy is all-inclusive of all brachytherapy.

CHAIRMAN JACZKO: Right.

RONALD ZELAC: Temporary and permanent. The use of activity and time was put into the rule intending to be employed for temporary implants, how much activity are you putting into place, and how long is it staying there as the surrogate of dose.

CHAIRMAN JACZKO: So the current rule does not envision that being used for permanent brachytherapy?

RONALD ZELAC: That's correct.

CHAIRMAN JACZKO: Okay.

RONALD ZELAC: And the metric used for permanent implant brachytherapy would traditionally be looked at more towards absorbed dose as it is for the other modalities that are used for therapy than it would activity and time. Although the way the rule is written, activity, time can be used for permanent, as well.

CHAIRMAN JACZKO: Okay. Okay, thank you, that's helpful. I guess it shows that it's not clear. Well, anyway -- again, I'm not -- I think -- you know, this is a difficult situation. I mean, I do, you know, fundamentally believe as a regulator our job is dose. I mean, that's what we're here for. But it is clear to me that this is not something which can be easily measured for the prostate and so we have -- you know, we -- what I think, in my mind, I'll have to convince myself of is that in the end that we're not relinquishing our responsibility for radiation safety to, what I would not necessarily call patients, but to members of the public, and that's really where our responsibility lies and -- you know, and I think that is -- will always be a difficult area here where we are specifically dosing tissue for medical benefit and where we do have a degree of deference, where we have to give to the judgment of the medical community, and I think that's

often where we find ourselves here.

So I probably talked long enough. So, again, I appreciate all of you being here and your presentations. I think it's very, very helpful and we'll take a quick break and then hear from the staff. Thanks.

[break]

CHAIRMAN JACZKO: Want to get -- can you get started?

BILL BORCHARDT: Yeah.

CHAIRMAN JACZKO: Okay. Okay, great.

BILL BORCHARDT: Okay. Thank you, Chairman. Since 2010, following the Commission direction the staff's been actively engaged with the stakeholders and, as you saw from the first panel, there's a lot of very good information that we benefit from as we developed the position and the recommendation that's in the paper before the Commission now. Brian's going to provide some background on the issue, then Dr. Zelac is going to give the details of the various perspectives that have been brought before the NRC staff and then the staff's recommendations. So I'll turn to Brian.

BRIAN MCDERMOTT: Thanks, Bill. Good morning, Chairman and Commissioners. Since joining FSME last October I've really come to appreciate the importance of having appropriate criteria for medical events. Medical events may indicate potential problems with the facility's use of radioactive materials, but not necessarily result in harm to the patient. I think the general medical event recording criteria in Part 35, as you've heard, is not considered to apply well for permanent implant brachytherapy by either the user community or the NRC staff. As a result, we've had a considerable amount of effort put into improving the medical event reporting criteria for permanent implant brachytherapy. And I'd

like to go over just a brief history of the efforts to make these changes before we get into the details.

In 2005, the Commission directed the staff to develop a proposed rule that would modify both the written directive requirements and the medical event reporting requirements to be activity-based rather than dose-based as was recommended at the time by the ACMUI. In 2008, the Commission approved the publication of a proposed rule to amend the pertinent sections of Part 35 and the vast majority of the comments received on the proposed rule offered no objections to the conversion to a dose-based, permanent dose-based to an activity-based medical event criteria.

However, it was during this summer and fall of 2008 that there were a substantial number of medical events involving permanent implant brachytherapy that caused us to pause, and then we had a number of reviews of those events, and based on those reviews, we believe that the number of them would not be categorized as medical events under the proposed rule.

In ’09, the Commission sought further information from the ACMUI and directed the staff to work with the committee to provide recommendations on regulatory changes.

In 2010, proposed rule language and rationale were modified to reflect the new information gained from the review of those 2008 events. However, the Commission disapproved publishing that reproposed rule, and as Bill mentioned earlier, directed the staff to work closely with the ACMUI, and that broader medical and stakeholder community, to develop revised medical event definitions, and you heard mentioned that earlier, about the public workshops that were held in the summer of 2011.

In October of ’11, the staff received the ACMUI’s final report on prostate brachytherapy regulations. There was a response to that report from interested parties in the medical community, and I was very pleased that the ACMUI revisited its final report, and actually provided a revision to the staff in February of ’12, that better incorporated some of those stakeholder community views.

Most recently, on April 4th, the staff provided the recommendations to the Commission for amendments to the regulatory requirements for permanent implant brachytherapy programs that appear in 35, 40 written directives, and in 35.3045 medical event reporting. As directed by the Commission, staff has worked closely with the ACMUI and the broader stakeholder community in developing these recommendations. The recommendations include changing from a dose-based criterion for assessing whether a medical event has occurred, to a hybrid definition, using dose-based criteria for normal tissue and source strength base criteria for the treatment site. This approach was, and is, consistent with the February, 2011 recommendation from the ACMUI, and most of the input from our stakeholders. At this point, I’d like to turn the presentation to Dr. Ronald Zelac, my staff, who’s going to talk to the recommendations more detail.

RONALD ZELAC: Good morning. My presentation is focused on staff’s recommendations, their objectives, the reasons for change, their basis, and their content. I’ll also discuss how and why the recommendations differ in some respects from recommendations offered by stakeholders, and finally, I will provide some staff positions about the recommendations. Next slide.

I think you’re one ahead of me. Yes, thank you. The main

objectives of the recommendations were first and foremost to change the treatment site medical event criterion from dose- based to source strength based, and secondarily, to remove ambiguity from the written directive as well as from the medical event requirements.

For the first bullet there, the nearly unanimous position of stakeholders is that a dose based criterion for the treatment site limits the physician's authorization -- authorized user's ability to provide optimum patient care without resulting in inappropriately identified medical events. Next.

Reasons for the change, authorized users can't control, as you have heard, patient related factors and use of the available absorbed dose metric causes much concern, and finally, the current rule is worded towards temporary implants. For the first bullet, an example, a patient related factor as you've heard, is edema and swelling of the treatment site that's created during the implant procedure itself, but physicians can control where and how many seeds are implanted. For the second bullet, the absorbed dose metric variances, the trigger of medical event don't relate to patient harm or potential harm, and that's an issue. Suitable absorbed dose metric, in fact, does not exist. Next.

The recommendations which appear in the paper that has been provided are based on recommendations that we staff have received from the ACMUI's revised final report, from stakeholder input that we received from the workshops which have been mentioned, as well as from public meetings, which preceded and followed those workshops. We have also included consideration of ASTRO's recommendations, and the recommendations from the Organization of Agreement states. Next.

This slide and the next several slides are going to speak to the

recommendations themselves. The first recommendation is that we define separate medical event criteria or permanent implant brachytherapy utilizing radioactive seeds, or sources. This medical event criteria would differ from those used for other medical uses, which are primarily dose-based, and accordingly, separate criteria are recommended for this use.

With respect to the second recommendation, it's here, the treatment site medical event, if 20 percent or more of the implanted seeds are outside of the intended implant location. Here, source strength and positioning is the measurable metric or surrogate for dose, as related to harm or potential harm. With respect to the 20 percent that appears there, 20 percent is the variance limit from physician intention that was approved by the Commission on the recommendation of the ACMUI, for all medical uses of byproduct material. Next.

I was asked to include a couple of pictures before we begin speaking about nearby and neighboring structures. This particular diagram gives you the locations, if you will, of the primary target for this procedure, which is the prostate as well as the nearby, neighboring normal tissue structures of the urinary bladder, and the rectum. Nearby normal tissues and structures are, in fact, the organs at risk that limit the magnitude of the dose to the treatment site, because dose is delivered as well to those tissues which are nearby. Next.

This gives a graphical appearance, rather than pictures of post implant, post imaging treatment assessment, is shown here with the seed positions defined and the projected absorbed doses. The seeds, or course, are the dashes that you see, and the treatment site target itself, the prostate. Next. Slide.

So, we are talking now not about the treatment site, but about the normal tissues and nearby, neighboring organs or structures. For normal tissue and neighboring structures, a medical event will have occurred if dose to the contiguous greater than five cc's or more exceeds 150 percent of the absorbed dose prescribed for the treatment site. This is because nearby tissues and structures will generally be receiving essentially the same dose as at least portions of them, to the tissue that is the principle target. Absorb dose determinations for this criterion are to be made within 60 days of the implant, unless a longer time is justified in writing, and because of this criterion, the fact that doses need to be determined, there is an implicit operational requirement for post-implant imaging, as strongly recommended during the public workshops and, in fact, as practiced in most clinical facilities.

The other thing, which needs to be, I think, at least mentioned, the five cc's. If you want to picture it, something the size of a large grape, or a large olive, and the 50 percent excess dose, which is listed there, is, in fact, what appears in the current rule for normal tissue. So, it's simply been carried over to this new recommendation. Next.

Now, for normal tissue structures within the treatment site, medical event, if the dose to a contiguous five cc's or more exceeds 150 percent of the expected absorbed dose for that tissue, as you have heard. The absorbed dose determinations, again, are to be made within 60 days of the implant, unless a longer time is justified in writing. I will also note that staff is seeking further stakeholder input on the size normal tissue contiguous volume being highly irradiated, that would trigger a medical event, as there are some differences in opinion. In other words, I'm talking about the five cc's as the criterion. Next.

Again, we're still talking about medical event definitions. A medical event, if treatment is administered using the wrong radionuclide, using the wrong source strength as specified in the written directorate, or with delivery, of course, to the wrong patient. Next slide.

Again, medical event would have occurred if treatment is administered and if implantation directly into the wrong site or body part, with delivery using the wrong modality, or if leaking sources are used. Now, the first item there is implantation directly into the wrong site or body part applies to other distant from the treatment site locations, not to neighboring structures. Next.

Just a general comment about these recommendations for the treatment site, and normal tissues, all of them, all of these proposed medical event criteria reflect circumstances in which there is, in fact, actual, or at least potential harm to the patients being treated. This characteristic is consistent with ACMUI recommendations and stakeholder input that has been received, with all the interactions that we have had. Next slide.

This slide is to now speak to the written directive definition. There are a few modifications from our current written directive definition, and they are listed here; first, to define separate criteria for permanent implant brachytherapy, second, to delete total dose as an option for completing the written directive, again, this applies to permanent implant brachytherapy only. And finally, replace the phrase that appears now, before completion of the procedure.

For this second item, deletion of total dose, if total dose is deleted, what it would leave is total source strength and exposure time, as the required entry field, along with the other entry fields that are already there, like radionuclide treatment site and the number of sources utilized.

For the third item, the third bullet there, before completion of the procedure, this would be replaced with before the patient is released and the authorized users control, and leaves the post-procedure recovery area, in other words, at the conclusion of the implantation itself. The wording reflects the ACMUI's position and this recommendation is being offered to remove the uncertainty that has been encountered in interpretation of the existing requirement. Next.

This slide and the next two are going to speak to variances between the recommendations that had been provided and recommendations that we as staff, have received from the various organizations that I mentioned previously. The first of these deals with the ACMUI's revised final report, the February 2012 report. The difference here of our recommendations from their report is there's no requirement for an authorized user at that station on source distribution. Now, this concern involves a possible bunching of implanted seeds in the treatment site, instead of being distributed as the authorized user had planned before the start of the procedure.

Staff believes that the existing requirements in our current 10 CFR 35.40, dealing with written directives, and 35.41 procedures when written directives are required, plus the recommended medical event criteria on absorbed-dosed to normal tissue structures that has been offered here provide patient protection from undeclared or unrecognized bunching, and provide opportunity for the authorized user physician to initiate follow-up medical remediation, if deemed appropriate. Next.

With respect to ASTRO's recommendations, we clearly have included a source -- a dose-based medical event criteria for normal tissues and

structures had been received directly in writing as a recommendation, did only deal with the treatment site itself, without making mention of anything relating to normal tissues and structures. However, as you heard, there isn't apparently any objection on the part of ASTRO to the inclusion of these. There has been no ASTRO objection to the dose-based elements that the ACMUI's revised final report, upon which our recommendations are based. Next.

With respect to the Organization of Agreement State recommendations, the first variance is not having the dose-based medical event criterion for the treatment site. The OAS rationale and desiring this, as you have heard, was that dose-based criteria exists for all other medical uses. However, dose-based criteria for the treatment site have been opposed by other stakeholders from whom NRC has received input.

The second variation from OAS recommendations is having a set dose threshold medical event criterion for normal tissues and structures. Part of the recommendation that we received was that the doses that would trigger an event should be defined by the authorized user, individually for each treatment being provided. The intended doses, in fact, are under the control of the authorized user, as OAS had recommended, and I will note that OAS is the only stakeholder that has objected to us, including preset percentages of 50 percent approach, or the values recommended. Next.

This and the next slide are simply providing some overall summary statements from staff on our position with respect to these recommendations. We certainly feel that patient's interest would be protected by these changes and the physicians would be able to take medically necessary actions. Next.

We also believe that NRC would continue to be able to detect

failures in process, procedures, and training, plus misapplications by authorized users, and finally, we want to make it very clear that we have been listening to the stakeholders and we've had many opportunities to hear from them, and we have tried to, as best to our ability, to reflect their input in these recommendations, and that concludes my presentation.

CHAIRMAN JACZKO: Great, well thank you. We'll turn to Commissioner Magwood.

COMMISSIONER MAGWOOD: Thank you and thank you for the presentation today. This is, obviously, this has been an issue that's been around for a long time, but it seems like it's been a long, around since I joined the Commission, and Dr. Zelac and I have had several discussions about this, and I do appreciate the fact that staff's worked so hard to try to bring the community together on this. I know it's been a very difficult subject, but, you know, Dr. Zelac, in particular, I think even though you've worked personally a lot on this, so I appreciate your efforts in this. The work is certainly shown here.

One area, and you mentioned it towards the end, one area that does seem to be a bit of an issue is the view of the States, and I think you heard the previous panel. The States would like to have flexibility to continue using dose-based approaches. I wonder if the staff can talk a bit about this. What are the -- what are your thoughts about the States requesting that direction, and I'd also like to hear any thoughts you have about what hospital downsize could exist if we go the other direction, don't provide that flexibility. Just give us some thoughts on your view on that.

RONALD ZELAC: Currently, the section 35.3045 is considered to be a compatibility C, meaning that as long as the essential objectives of the

regulation that NRC provides are included in State requirements, we're satisfied. There is not a limitation currently, nor frankly, at least at this point, do I envision there being such a limitation placed on any modified definitions that might come forth. So, if a State wished to include a dose-based criterion that should be satisfactory from our perspective, as long as the activity base is included as well, source strength-based.

COMMISSIONER MAGWOOD: You clarified towards the end, this question about whether licenses to use activity now, in the permanent brachytherapy, and that obviously some of them are, and it sounds like that there's enough ambiguity in the current rule that licensees have been able to go in different directions on this, and that's obviously created some inconsistencies. Do you feel that the new rule would eliminate a lot of those inconsistencies?

RONALD ZELAC: I certainly do. I think the time is overdue for us to have something which is easily understood and easily implemented by the practitioners, not just with respect to what constitutes a medical event, but the timing associated with making these determinations, which is now extremely difficult problem with much variation from one facility to another. In one case, the day after the procedure is done, the dose determinations are made. In another case, the dose determinations are made a couple of months later, or somewhere in between, and the question is when is the procedure completed. Is it when the implant is done or is it when the dose determination has been made?

COMMISSIONER MAGWOOD: There still seems to be a few pieces of this that have to be wrestled to the ground. One is this issue about the size of normal tissue contiguous volume; I guess you're going to have some more interactions, stakeholders. Can you talk about that specifically, what you

plan to do to try to resolve that, and are there any other remaining issues that you think need to be resolved before this rule goes final?

RONALD ZELAC: The size of the volume of normal tissue, which would constitute a criterion for a medical event, is something that is definitely in need of further input from the user community, whether this is accomplished when the proposed rule would be published, asking specifically a question for this, or whether we could glean out in advance of that, something that would be more definitive to, perhaps modify, or feel more comfortable with it as it is. You know, that's not completely clear that we could, but we will certainly make an attempt to. I participated in the American Brachytherapy Society meeting about two weeks ago, where these questions were being raised, and discussion was ensuing. So, we're trying to keep our avenues of input to this question open.

COMMISSIONER MAGWOOD: Is it the sort of thing that lends itself to workshops, something like that?

RONALD ZELAC: It could. It could.

COMMISSIONER MAGWOOD: Are there any other issues of that nature that were made, unresolved?

RONALD ZELAC: Well, we've just heard one today, with respect to normal tissue that's located within the treatment site. However, it's really important to keep in mind that when we're writing this, it's for all permanent implant brachytherapy utilizing sealed sources. Now, the principal utilization today certainly is prostate, but there are other tissues involved too, and if having a normal tissue within the treatment site criterion is not particularly appropriate for prostate, it may well be appropriate for other organs in which implants are done.

COMMISSIONER MAGWOOD: Okay, great. Well, thank you, and again, you know, thank you for the hard work and I know a lot has gone into this. Bill, did you want to --

BILL BORCHARDT: Yeah, commissioner. I just wanted to bring up one aspect of the question you asked about State and the compatibility issue. What -- just thinking about this very broadly, one of the reasons we have medical events and all reportable events, is so that we can learn generically to the extent that there's a variation between States and NRC requirements for medical events. That makes that more problematic, right? We don't have medical events to be a punitive act. We do it so that we can learn and make safety improvements, or regulatory improvements where warranted. So, that's a counterbalance there, one of the factors, I would say, that we would need to take into consideration before we decide how much variability is appropriate.

COMMISSIONER MAGWOOD: So, in your mind, the issue capability is still somewhat --

BILL BORCHARDT: Sill needed to be evaluated, I think.

COMMISSIONER MAGWOOD: Okay. That's fair. I look forward to the staff's views on that. All right. Thank you. Thank you, Chairman.

CHAIRMAN JACZKO: Commissioner Ostendorff.

COMMISSIONER OSTENDORFF: Thanks, Chairman, and thank you all for your presentations today. I want to start out with our -- with Ron here. If the current -- if the proposed revised definition were in place at the time of the Veterans Administration problems here, two years ago, or two plus years ago, would the revised definition, if that had been in place, that has significantly changed to how the NRC reviewed the VA prostate situation?

RONALD ZELAC: If the criteria that we are proposing here for medical event reporting with the treatment site, were in place at the time, we would have found that we had a practitioner who either was not competent or was ignoring what he knew should be done with the very first case, and this goes back to, like, I believe 2003, or 2005, somewhere in that area, or in that -- the particulars of that occurrence were that a significant number of seeds which had been implanted wound up in the bladder, and they were subsequently relatively soon removed, and the numbers of seeds that remained in the prostate or near the prostate itself, was only about half of what had been implanted and had been intended. That would have clearly triggered a medical event and we would have been able to at that point, ask the licensee as well as ourselves, to take a very careful look at how these procedures were being carried out at that particular facility. So, yes, it would have had an impact on what occurred and came to light later, in 2008.

COMMISSIONER OSTENDORFF: But would it have resulted in there being significantly less number of medical events?

RONALD ZELAC: Absolutely, because it would have occurred that much earlier.

COMMISSIONER OSTENDORFF: Okay. One of the things I remember Commissioner Magwood had highlighted when he and I both joined the Commission around the same time, that this has been an issue every since we've been here and Chairman Jaczko's been dealing with this for a longer period of time.

CHAIRMAN JACZKO: I think since I first joined the Commission, too [laughs], so…

COMMISSIONER OSTENDORFF: And there's been an evolutionary nature of some of the discussions, and some of the positions, but one of the issues that appear to be the case back in 2010 was that the existing definition for Part 35 did not provide physicians with significant -- enough flexibility to in situ during a procedure, make changes as the situation dictated. Is it your sense that the revised definition of medical event reporting from the stakeholder meetings and the feedback you got, and that concern has been resolved?

RONALD ZELAC: I think it has and if these recommendations were enacted, it would be totally resolved in its entirety. The written directive requirement now, the pre-implantation written directive requirement calls for the practitioner to indicate first, clearly, who the patient is, second, what the treatment site is, where are the seeds going to be implanted, third, the radionuclide to be used, and fourth, because it's always included anyway, what dose are you intending to deliver to the treatment site. That's all they need to state before the procedure begins.

Now, if there's a treatment plan associated with this written directive, all the better. They can certainly incorporate that. They can incorporate whatever further and explanatory information they'd like to include about the treatment site description, or any problems they encounter, or anything else, but that's all at this point that they're being held to, in terms of providing information. Then, when the implantation is done, again, what radionuclide was used? How much total source strength did you implant? How many sources did you implant? And of course, the treatment site itself? That simply reflects what had been accomplished during the procedure, but not being held to having any

match to what had been planned initially. So in that sense, the physicians will have full and complete ability to modify as appropriate, during the procedure of what they intend to be doing.

COMMISSIONER OSTENDORFF: Okay. I'm going to stay on the same theme with you, but it's in a little different direction, a question that deals with the perception or the reality that physicians who perform these procedures face. I think we heard at the first panel, a comment, I believe it may have been Dr. Zietman that stated that there had been a deterrent effect that the VA event and the current definition of medical even had served to deter physicians from offering these treatments, and we heard some statistics about how many clinics were offering it now, compared to what had been the case. Does that match up with the NRC staff's views as to how the medical community has viewed the definition of medical event, and perhaps has it precluded the availability of this treatment?

RONALD ZELAC: It's our position, having received input on this and knowing what's been going on about it for these many years, that in fact, there is a hesitancy on the part of some practitioners to get engaged in this at all, because of the uncertainties that are associated with it, relative to regulatory outcome. The mere fact that we're only seeing in the United States now, 25 percent of the cases being done in this way, as compared to just a few years ago, is an indication that clearly there's a reluctance to be implying this. Granted, there are other reasons that this number has declined, but certainly in many respects, this is the principal one.

COMMISSIONER OSTENDORFF: And I'll ask just one follow-up question on that, and I perhaps should have asked this of the prior panel, I just

didn't think about it, but from your stakeholder meetings, engagements, public meetings, et cetera, was the notion of medical malpractice insurance premiums, malpractice claims associated with prostate cancer treatment? Was that an element of the discussions?

RONALD ZELAC: I don't have a recollection of that being an issue. I think it was more of the concern of the practitioners about how they would be treated from a regulatory point of view.

COMMISSIONER OSTENDORFF: Okay.

RONALD ZELAC: That was the focus of the interactions.

COMMISSIONER OSTENDORFF: Okay. Thank you. Thank you all. Thank you, Mr. Chairman.

CHAIRMAN JACZKO: I thought I'd just make a comment on the compatibility issue. I think perhaps more in line where Bill is. I'm skeptical that this is something where we can have a wide latitude of compatibility. I mean I think if we're going to go to a new definition of the whole reason is because there isn't consistency in the application, and it would seem that that would lend itself towards a more restrictive compatibility designation, whether that's B or, you know, I don't know if we went to a source, how you could have a State have both a source and a dose-based activity, so it may be one of those things that we don't really have a real option here if what we're trying to do is clarify, otherwise, it seems we could just work under the existing rule as it stands, but that's just my thoughts on that.

I had a couple of questions, and again, this is probably something I should have asked the earlier panel, but I didn't. In terms of the 50 percent deviation or increase for the tissue internal to the prostate, in this case the

urethra, is the rule intended that that needs to be -- that you need those dosimetry to measure that, or can that be determined by analysis, by, you know, CT scan, and then some measurement of the placement of the sources, and then a calculated dose, or is intended to be a measured dose?

RONALD ZELAC: It -- and I'd look to any of the panelists that preceded ours to add, but it's my understanding that what's really being done is to determine where the urethra is located.

CHAIRMAN JACZKO: Yeah.

RONALD ZELAC: And on the basis of it plus the array of seeds, then a dose assessment can be made for it.

CHAIRMAN JACZKO: So, it's not necessarily needing --

RONALD ZELAC: If it's not measured to the extent that you have a dosimeter, you know, in the urethra during a procedure, and, or anything like that --

CHAIRMAN JACZKO: Or after…

RONALD ZELAC: Or after.

CHAIRMAN JACZKO: Okay, because I think there were some insinuation that that would be necessary to do the dosimetry, which may be uncomfortable for the patient.

RONALD ZELAC: Well, again, I think that was relating to being able to know precisely --

CHAIRMAN JACZKO: Yeah.

RONALD ZELAC: -- or within reason of the imaging technique used, where, in fact, the urethra is located, relative to the seed distribution.

CHAIRMAN JACZKO: Okay. Okay. So, in fact there may need to

be some invasive procedure to do that or --

RONALD ZELAC: No.

CHAIRMAN JACZKO: -- or, but would under the rule, the staff would accept or in guidance, you know, a contour for the urethra much in the same way we do a contour for the prostate. That would be your understanding of the rule?

RONALD ZELAC: Yeah.

CHAIRMAN JACZKO: Okay, I think that's maybe a helpful thing that we could clarify as we go forward. On the issue of just in terms of process of where we are, we, at this point, have I believe, I'm not sure, but have issued, at one point, a proposed rule, which was withdrawn, or did we not get to the point of issuing a proposed rule? Where --

RONALD ZELAC: We had issued a proposed rule in 2008.

CHAIRMAN JACZKO: Okay.

RONALD ZELAC: We received comments on the proposed rule and then we had the VA occurrence, and it was taking all of what had been received in comment, plus the learning experience from the VA, that was the basis for the reproposed rule in 2010, now which of course, was not published.

CHAIRMAN JACZKO: So at this point, do we need to renotice a brand new rule or is the thinking that we would repropose the proposed rule, or what's the process, assuming the Commission, you know, would vote one way, do something with the recommendations here, but and then what's the next step?

BRIAN MCDERMOTT: Well, we're back at the point where we're planning to incorporate this rulemaking, if the Commission approves, in a larger

Part 35 medical rulemaking. So…

CHAIRMAN JACZKO: Where does that one stand?

BRIAN MCDERMOTT: I think the proposed rule would come to the Commission somewhere in the end of calendar year ’12, first quarter of ’13.

CHAIRMAN JACZKO: Okay. In the interim, on one of the discussions perhaps we had earlier was the possibility of some type of clarificatory guidance in the interim, to at least have a consistent application under the existing rule, albeit not the most perhaps preferred way to do it, but what’s your sense of the ability to do something like that if the Commission were to say move to an activity -- or the source base standard, at least for that, could that be done under the existing rule with some guidance pending the rule change?

RONALD ZELAC: As Mr. Timmerman pointed out, there’s been a combined effort of the Agreement States and NRC to create guidance for the current rule, so that it can be more easily understood and implemented in the timeframe from now until such time as, in fact, the final rule is published.

CHAIRMAN JACZKO: Okay.

RONALD ZELAC: So yeah, that clearly has in part been accomplished in terms of creation of a revised inspection procedure, which is -- as was noted, going to be discussed or tutored, if you will, both for Agreement State people as well as NRC people, this very Thursday.

CHAIRMAN JACZKO: And that would allow for a source based reconstruction of dose, or not? It would essentially be, and again, just talking about the, you know, the target volume here, would essentially the staff proposal under the new approach, be acceptable from a guidance perspective as a way to

satisfy the current rule?

BRIAN MCDERMOTT: I think what the staff tried to do with the revised inspection guidance was certainly, be mindful of the fact that our current regulations are what they are. So, you know, no inspection guidance can alter that, but what they did try to do was ensure that the focus of the inspectors was on the broader picture of the program. I think this was mentioned earlier regarding the VA case. There were a number of those examples that would clearly demonstrate there was a problem with the program, without going to --

CHAIRMAN JACZKO: I mean I'm -- I mean I think to me, this is an important question and I am not asking this right. I mean if we have a proposed rule that comes in 2012, late 2012, early 2013, that's going to take, you know, Commission acting at its fastest will be done within 30 days. That's got to go out then for 75 days for public comment. You will then get another flurry of comments and this would be a part of a larger rule packet. So, there'll be other issues as well in the Part 35 revisions, none of which ever seem to be uncontroversial. So, we are talking maybe the earliest 2014 to have a final rule to the Commission. So, we're talking about a long time from now, and if what we're hearing is the practice, is the current rule is having impact on medical practice, then we may want to think about a different way forward. If under the current rule we couldn't provide some clarity, and I'm not talking about inspection guidance; I'm talking about, I mean, rule guidance on -- or regulatory guidance on what the rule really means.

BILL BORCHARDT: I think I'd rather take a look up and get back to the Commission on the various options that could be presented, but just off the top of my head, I mean there's enforcement discretion. There's a lot of different

tools that we have available. We could issue orders right?

CHAIRMAN JACZKO: Yeah.

BILL BORCHARDT: -- that superimpose over the existing regulations, if in fact, there was a conflict, but I'd rather study this and get back to the Commission.

CHAIRMAN JACZKO: I guess what I'm taking away is that right now we probably would have to take some action to --

BILL BORCHARDT: That would be my best guess.

CHAIRMAN JACZKO: Okay, thanks. The last question, and again, this just goes back to the issue with the written directive. We did have, I think, Dr. Zelac, you mentioned the 2003 incidents, and I think that was what drove some of this, and one of them was in fact an incident that involved a modification to the written directives such that, and I think it's one that probably certainly under the current definition would have shown up as a medical event. I think the incident involved the implementation of 34 seeds instead of 74 into the prostate. So, that would meet the -- it would meet the 20 percent deviation, and it did not exceed the 50 percent dose to the expected, or to the -- oh, I guess it was 50 percent at that time, but in any case, part of what -- it was not reported because the written directive was changed at that time.

Under the new rule, would that, again, and I have had trouble following the changes to the written directive requirements, so, under the new rule, would the written directive be allowed to be changed in such a way that this particular event would -- let me say this another way. Would the current rule ensure that this is considered to be a medical event? I mean if you want to go back and look at it, you can always get back --

RONALD ZELAC: No, no. As I was trying to explain before, under the current requirements, the practitioner provides some information prior to the implantation procedure, and additional information at conclusion, and if the practitioner were to utilize source strength and time as the criterion, then they could easily report that 44 seeds were implanted, period, as long as they had very promptly removed from the bladder those seeds which were misplaced. So, under the --

CHAIRMAN JACZKO: So, under the new proposed definition, this event would not have been a medical event?

RONALD ZELAC: It would to the -- it depends on your interpretation. If placing the seeds -- the seeds were implanted, to the fact that they wound up in the bladder rather than the target meant that they were implanted in the wrong place.

CHAIRMAN JACZKO: Right.

RONALD ZELAC: So, even though they were removed promptly, since they didn't have residual [unintelligible] dose contribution to the bladder wall, still in all, they had been misplaced when the implantation took place, and on that basis it would be a reportable medical event.

CHAIRMAN JACZKO: And the ability to modify the written directive won't change that?

RONALD ZELAC: No. No. In fact, it's not modification. It's simply completion, if you will.

CHAIRMAN JACZKO: Completion, yeah. Okay, and previously were they allowed to modify the written directive?

RONALD ZELAC: Once the procedure begins the written directive

information that has been provided remains. At the conclusion, there is a need to enter what is called for now, and --

CHAIRMAN JACZKO: Yeah, I mean I know, obviously where we are now. I guess I was trying to go back and make sure that we don't re-unlearn the lessons we learned in 2003, and that was in the 2003 incident, that as I understand, drove the definition or the requirements on the written directive, but I think you've given me a pretty good answer, and I can follow up a little bit later, after just -- on this particular one, because I think I'm not asking the question in the right way here. So, but if you wanted to say anything…

RONALD ZELAC: I don't know what else to say at this point.

CHAIRMAN JACZKO: Okay. Well, again, I didn't have any other questions at this point then, and I want to thank all of you for your comments.

COMMISSIONER MAGWOOD: Chairman, I just wanted to follow up on your point about finding a way to move a little faster on this. I'd like to support you on that. So, if we can get maybe either a Commission notice or a CA notice, something as a result of the meeting, we can constructive plan something.

CHAIRMAN JACZKO: Yeah, if you could send us up some options for how we would proceed, you know, assuming -- I mean the Commission will adopt something. In regards to what is, what would the options for proceeding. I think that would be helpful for all of us. I think last time we had this meeting, I think we probably did the opposite and told you to combine it into the Part 35 rule, and probably now we're going to tell you to do it different. [laughs] So, anyhow, okay, good. Thanks, everybody.

[Whereupon, the proceedings were concluded]