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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

OPEN SESSION

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MEETING

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TUESDAY,

SEPTEMBER 30, 2014

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The meeting was convened in room T2-B3 of Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, at 8:00 a.m., Bruce R. Thomadsen, Ph.D., ACMUI Chairman, presiding.

MEMBERS PRESENT:

BRUCE R. THOMADSEN, Ph.D., Chairman

MILTON J. GUIBERTEAU, M.D., Vice Chairman

PHILIP O. ALDERSON, M.D., Health Care Administrator

FRANCIS M. COSTELLO, Agreement State Representative

VASKEN DILSIZIAN, M.D., Nuclear Cardiologist

SUSAN M. LANGHORST, Ph.D., Radiation Safety Officer

STEVEN R. MATTMULLER, Nuclear Pharmacist

CHRISTOPHER J. PALESTRO, M.D., Nuclear Medicine Physician

JOHN J. SUH, M.D., Radiation Oncologist

ORHAN H. SULEIMAN, Ph.D., FDA Representative

LAURA M. WEIL, Patients' Rights Advocate

JAMES S. WELSH, M.D., Radiation Oncologist

PAT B. ZANZONICO, Ph.D., Nuclear Medicine Physicist

NRC STAFF PRESENT:

RAYMOND LORSON, Acting Deputy Director, Office of Federal and State Materials and Environmental Management Programs
LAURA DUDES, Director, Division of Materials Safety and State Agreements
SUSAN ABRAHAM, Acting Deputy Director, Division of Materials Safety and State Agreements
MICHAEL FULLER, Designated Federal Officer
SOPHIE HOLIDAY, Alternate Designated Federal Officer, ACMUI Coordinator
MARYANN ABOGUNDE, FSME/MSSA/RMSB
LUIS BENEVIDES, Ph.D., RES/DSA/RPB
DOUGLAS BOLLOCK, FSME/MSSA/RMSB
SUSAN CHIDAKEL, OGC/GCLR/RMR
JACKIE COOK, RIV/DNMS/NMSB-B
SAID DAIBES, Ph.D., FSME/MSSA/RMSB
GINA DAVIS, FSME/MSSA/RMSB
SARA FORSTER, RIII/DNMS/MLB
CASSANDRA FRAZIER, RIII/DNMS/MLB
SANDRA GABRIEL, Ph.D., FSME/MSSA/RMSB
LATISCHA HANSON, RIV/DNMS/NMSB-A
MICHELLE HAMMOND, RIV/DNMS/NMSB-B
VINCENT HOLAHAN, Ph.D, FSME/MSSA
DONNA-BETH HOWE, Ph.D., FSME/MSSA/RMSB

ANGELA McINTOSH, FMSE/MSSA/RMSB

KEVIN NULL, RIII/DNMS/MLB

PATTY PELKE, RIII/DNMS/MLB

GRETCHEN RIVERA-CAPELLA, FSME/MSSA/RMSB

KATIE TAPP, Ph.D, RES/DSA/RPB

ALSO PRESENT:

JENNIFER ELEE, Conference for Radiation Control Program Directors

RONALD ENNIS, M.D., American Society for Radiation Oncology

LYNNE FAIROBENT, American Association for Physicists in Medicine

DEBBIE GILLEY, *presenting on behalf of* International Atomic Energy Agency *

STEVEN J. GOETSCH, Ph.D., Dade Moeller Health

CAITLIN KUBLER, Society of Nuclear Medicine and Molecular Imaging

MICHAEL PETERS, American College of Radiology

GLORIA ROMANELLI, American College of Radiology

CINDY TOMLINSON, American Society for Radiation Oncology

C. GIBB VINSON, Illinois Emergency Management Agency

MARK WILLIAMS, Tripler Army Medical Center

PAUL YURKO, Veterans Health Administration

* Present by teleconference

A G E N D A

P R O C E E D I N G S

8:01 a.m.

CHAIRMAN THOMADSEN: Good morning and welcome to the second day. We're going to be starting off this morning talking about reporting mechanisms for events. We have presentations from four organizations that we'll be listening to, and then we will have discussions after all four of the -- after the presentations.

We will have first a description of the RO-ILS system that's run by ASTRO and AAPM. That will be given by our member-to-be soon, Ron Ennis. Then we'll be having the CRCPD by Jennifer Elee. We'll be having the SAFRON system by Debbie Gilley, and somewhere in there, I guess between the CRCPD and SAFRON, I will be giving a presentation on the CARS system. With that, we'll start with Dr. Ennis.

DR. ENNIS: Good morning, everyone. Certainly it's a little easier, having met everyone yesterday, but I'm now wearing an ASTRO hat, if you would, and presenting on something I'm actually very excited about, and the Society is very excited about. And it is a new initiative for the Society but dovetails very well with the interests of this Committee in terms of radiation safety. And it is a systemwide -- a

specialty-wide national system for reporting medical events or near medical events going by the acronym RO-ILS. And the mission of this is to help facilitate safer and high quality care, while providing a mechanism for shared learning in a secure and non-punitive environment. And of the two ranges there, the most important is shared learning and secure and non-punitive environment.

Shared learning, obviously, has tremendous value, instead of each department discovering errors on their own, and not being able to share with others, this will allow us to learn from group events, and some of the prior events that have occurred that have gotten some note may have been able to be prevented based on anecdotes if we had had a system which had been able to share information back in the '90s and early 2000s.

And to get information that is complete and honest, the secure non-punitive environment is essential.

So, this is the only medical specialty sponsor incident learning system radiation oncology, and as you heard sponsored both by ASTRO and AAPM. It's web-based, and it's collecting information about actual errors and also near misses. And it's, like I said before, also a national system where each institution

will enter their information.

There's a diagram here at the local facility that joins the system will have their own database, and then send it on to the patient safety organization; and they could do what they want with their own local data, but the national data will be analyzed by a committee and reports will be generated, and information will be shared with everyone.

It's to collect incidents, meaning some type of harm, even the minor, the vast majority of incidents are really extremely minor as well, but nevertheless are incidents that could have been worse. Even near misses are encouraged to be included. In fact, it's really crucial that they're included because there are more of them, and they could translate into incidents, if not something else after them, and then the unsafe condition also that increases the possibility of an event.

So, the local data is seen only by their own institution, and then it's uploaded to the national system it’s anonymized so no one will know that it was Roosevelt Hospital that had that event, for example, it will be anonymized which, again, encourages people to be able to send in the data and contribute in an honest way.

And this is kind of -- it's a web-based entry system, and what it looks like. You will be able to pick the event type, so it could external beam, it could be brachytherapy, it could be radiopharmacy, whatever the options are, and various information about the event, who's reporting it, so there's the options, for example, what type of event it was. And, obviously, for this Committee particularly interested in the brachytherapy, radiopharmaceutical, although external beam would also be of interest to this Committee. And just, again, more information. It's just a bunch of, you know, so I'll try to make it easy and straightforward, but also just for text because there are certain things about any event that are not easily clickable because they are unique to that event and require some free text.

But the particular things that are going to be asked for in the different pages are, you know, what kind of dose deviation there was, how much under/over dose, whatever the issue was, what kind of technique was used, the patterns and techniques, especially the newer techniques as they come out, are we seeing something in this new technique that is, you know, an issue. And, again, having the national view will be really helpful. Imaging is crucial now, radiation oncology in terms of using -- so, obviously, it's something in the type of

imaging that's being done, the kind of equipment that's being done, and then some kind of measure of how bad this is in terms of likelihood to perform, severity scales, toxicity scales, it was a toxicity, and whatever the people entering it think might have been contributing factors.

So, it was beta tested beginning about a year ago, and open for more general -- for general people to sign up as of June 19th. Already, 19 contracts were signed covering 46 treatment sites with another 29 contracts and more sites working their way through their respective processes within their institutions, getting them to sign a contract with the vendor, who has been contracted, Clarity, there are 120 reports in there. That'll give you a snapshot of what that looks like. It's not meaningful data yet, all 120 reports. I don't think there is anything that has jumped out in these reports, and the committee is starting to kind of figure out how they're going to analyze this data.

Just to give you a flavor, so 42 percent of what's been reported so far were actually incidents, and 31 percent were near misses, and 26 percent unsafe conditions, so that's kind of a nice spread, and kind of justifies looking at all three of these aspects, being recorded by the physicist or the therapist, but

even by administrators occasionally, as well, which is also I think a positive that within the institutions that are doing this, people from a variety of places, if you will, people are comfortable entering the data which is part of the idea that anyone can be able to enter the data, or anyone at least the institution designates.

The vast majority are external beam so far, which I guess is maybe a little less interesting to this Committee. Although I'm thinking about ViewRay™ and other things like that, some of that comes under the purview of this Committee, a couple of brachytherapy, no radiopharmaceutical events yet. And this is kind of more to the -- you know, what type of treatments, so most of it is 3D reflecting practiced, IMRT, again in terms of issues that the Committee will look at, when they share them, wanting to capture events. I don't know how there's no brachy, so some data entry issues there. But, basically, a big spread in terms of what we do.

And this is an interesting question, whether the event that's being reported had occurred to anyone else, so what is a single patient event and, you know, vast majority is a single patient, as I think you'd expect, but there were a few that are multiple, so already raising the flag that this is a significant issue, potentially.

And that's the overview of the system. As we get more data and we make more findings I suspect we'll be able to share that, as well. You probably all know Cindy who is in the back, and if you want to find out more, she's our ASTRO native analyst.

VICE CHAIRMAN GUIBERTEAU: Okay. Are there any questions at the moment? Yes?

MEMBER ZANZONICO: Just looking through the handouts of the slides and these four topics, these four presentations, including this one, they seem to be external therapy, and to a lesser extent brachytherapy centric. And I'm just wondering what kind of outreach, if that's the right word, to say nuclear medicine and radiopharmaceutical diagnosis or therapy, because it just doesn't seem -- these sort of databases don't seem to be as high profile an issue say than SNM and the Molecular Imaging Society as they are in the therapy societies. I'm just wondering what kind of outreach there is to those disciplines.

DR. ENNIS: All right. So, I can't --

CHAIRMAN THOMADSEN: I can answer that, in that one of the frequent questions we get when we're talking with potential clients is will we also log imaging events. And the problems with doing that is for the therapy, the AAPM led an effort which was joined by

ASTRO, all of the professional radiotherapy societies, several government agencies to come up with a data set that would capture the essence of radiotherapy events. And both the AAPM and we use that data set.

There is no data set for imaging events, and the AAPM is in the process of trying to establish a task group to do exactly the same thing for imaging right now. But at the moment, there is no agreed upon data set, so we couldn't capture the events officially.

VICE CHAIRMAN GUIBERTEAU: Dr. Suleiman.

MEMBER SULEIMAN: This is an area, I'm really glad you brought it up, Pat, because it's an area that I've had concern with in nuclear medicine events. Mainly, you've seen hair loss, and you've seen erythema, and you've seen skin necrosis, and the reason for that is the skin gets the highest dose. With nuclear medicine, the source is internal.

I've seen in clinical trials, but these are public events, but there have been cases in clinical trials where the wrong organ has been destroyed because of -- for a number of reasons and faults that the investigators admitted to after the fact. But what you don't see, you're not going to report. And then there's the inherent bias of not reporting it in the first place.

Most of my experience with x-ray

fluoroscopy years ago was when people were getting erythema, the dermatologist gave them some cream. I mean, they didn't recognize that as a radiation event. And I'm going to share this story with you, because I've raised this question.

If you go through the numbers and you see -- I'm not saying you're going to see a single nuclear medicine event that's going to cause a serious biological event, but there have been lots of presentations where some people in health care systems have undergone 10 to 15 imaging systems.

Let's say for cardiac, if these people are ill, they undergo multiple procedures, they may be nuclear, they may be fluoro, they may be whatever. Well, the body doesn't care where it's getting the radiation, so I've always wondered how is that -- you know, is that a hidden concern that we haven't -- that hasn't really surfaced, though some people have raised that.

But I raised this question in a meeting at the Agency, and somebody who headed up a major institutional nuclear medicine clinic said we've seen it. I said what are you talking about? We've seen patients after a procedure where the skin gets red, but it goes away. So, that was the extent of our communication, so in the back of my mind I'm saying well,

did this patient possibly receive some radiation from other procedures, and then along comes the cardiac scan and puts it over some conceptual threshold, and then it resulted in a mild erythema and it went away, but it's suggestive. And I'm concerned, and I -- but how would you capture that? How would you capture that? You don't want to start calling false alarms if you have a lot of other skin diseases or reactions that basically are not attributable to radiation.

VICE CHAIRMAN GUIBERTEAU: Dr. Dilsizian.

MEMBER DILSIZIAN: You know I'm clinically doing nuclear medicine to cardiology. There are a lot of patients that have CT scans followed up with nuclear medicine diagnostic studies and therapeutics. If you really do the accumulated dose, it's never going to be what you are proposing. It's really not that concerning.

And, again, what we're trying to do here is make sure the patients get proper clinical care and benefit versus risk. And this comes up all the time. I think that the concern of radiation is important if it's done in all volunteers and some research protocol. If someone has a brain tumor, or would have breast cancer and we need to CT scans, or PET imaging, and appropriate brain scans, and you're talking about accumulated dose, it's really insignificant compared to the patient care.

So, I wouldn't want to minimize what you're saying. I think that whatever you're saying is very rare, it's not the common, and I don't think that's a real concern.

If it's a misadministration, that's fine, but for patients who are getting multiple studies it's always clinically indicated. No one is doing it just for fun.

MEMBER SULEIMAN: I'll agree with you on the one hand, and I'll disagree with you on the other. I'm not saying -- the risk from any single exam is never justification to not do that exam. These are all patients, I understand that. But by being aware that these doses can add up, it ought to put pressure on the entire community to get the doses as low as reasonably achievable. So, I think from that point of view maybe -- and when mistakes happen it's not the mainstream people, it's the tail end of the distribution, so if those are occurring we can't just say they're not really occurring, or they're infrequent. It's just that maybe they are occurring, but it would be nice to find some and then sort of trace the case history. Why did this person --

MEMBER DILSIZIAN: But none of us -- I mean, all of the things that we do are FDA-approved package insert guidelines. The doses we use are as low as

possible. We've been all very sensitive to image wisely. We are giving the lowest doses possible, and I don't think can avoid patients having multiple studies, patients, not volunteers, who are going to have several nuclear studies, plus CT, plus contrast. And that's always going to be for the patient care.

And I can tell you that there was a particular occasion that was being referred to a sixth PET-CT within three months, and the patient brought up the concern "am I getting a lot of radiation", which was a reasonable question. So, the oncologist came to me and said what will I tell the patient? So, I said very nicely that you give 10 millicurie dose of FDG. The incremental risk over what naturally would occur for cancerous is 25 percent. It would be 25.0027, so is that really a concern for patient management in three months for breast cancer, or is this something that we should be worried about? See, so we have to put this in context of what is incremental risk for any procedure given what the disease condition is.

MEMBER SULEIMAN: I didn't mean to drag us off into that area. I mean --

VICE CHAIRMAN GUIBERTEAU: Dr. Palestro.

MEMBER PALESTRO: Yes, just really two comments. One, in response to what Orhan just said. The

fact that someone's skin turns red in a particular area and someone has seen it after an injection of a radionuclide doesn't necessary apply cause and effect. That could be due to any one of a number of things. It could be due to an allergy to a compound that has nothing to do with radioactivity, to the materials that we just to inject and so forth. So, I think these sorts of anecdotal observations sometimes create more problems than they solve. So, that's my comment on that.

And then, Ron, I have a question for you. In terms of this system, which actually seems very intriguing, you either said or I understood that there's a cost involved to participate in this. Am I correct?

DR. ENNIS: No.

MEMBER PALESTRO: No, it's free. Okay. There's a contract then, it’s a contract.

DR. ENNIS: Right. You agree to the liability.

MEMBER PALESTRO: Okay.

VICE CHAIRMAN GUIBERTEAU: Ms. Elee.

MS. ELEE: I was going to comment, and I'm digging way back in my brain, but when we first at CRCPD started our venture, which we'll go into in just a minute, on the diagnostic side because we are the only ones that really kind of tried to tackle that animal.

And it did come up about patients who have multiple exams, and then had an effect, but it doesn't really fit into what we're looking at, because all of those exams individually are fine and warranted. That's the risk versus benefit, but then in the end you may have an effect. And there's -- how do you capture that, you know. It's not an event, it's not a -- you know what I mean? It just didn't fit into what we were looking at the time.

MEMBER SULEIMAN: And it's no different than the cancer patient --

DR. ENNIS: And that would include -- yes.

MEMBER SULEIMAN: It's no different than a cancer patient who undergoes multiple therapies. They know they're getting higher risk from --

DR. ENNIS: Right. And the second thing, it's hard to track. I mean, it's really -- if they're having them all done at one facility, then you are probably aware that they're having all of those procedures done. But today they may be having them at multiple sites which makes it even more difficult to correlate.

VICE CHAIRMAN GUIBERTEAU: I think there's a very interesting discussion, just to put a brief perspective on it, because I know this is a side issue,

is that with the advent of electronic medical records and PACS systems, the Arsinay Consortium of Radiological Organizations is putting together programs by which institutions may share patient information. Because you are correct, I mean, in our city, Houston, we have patients going to multiple institutions, and we find out -- last year we had a patient over two years had 16 cardiac studies of various types because she had various doctors. And if the patients share their -- give you permission, then in the future we hope, just like they have in the French system, you can go online and find out not where they've had -- not what they've had but where they've had it, and be able to make some kind of rational decision on that. That is down the line, but that's a very important consideration. And, in fact, the ABR has submitted some PQRS measures to CMS, and they're very interested in following the issue when the technology becomes available.

But now I'll focus on Jennifer Elee from CRCPD who's going to speak to us on CRCPD's medical radiation database.

MS. ELEE: I'm Jennifer Elee, for most of you all I've met several of you over the years. For those of you don't know, I've been an inspector with the State

of Louisiana for over 20 years, and an active CRCPD member. I was a board member and the chair of several committees, so I've been involved with that organization for a long time. And I'm currently chairing the H-38 Committee on Medical Events.

Just a little bit of background. In 2010, we formed a committee. That was, as you all know, an active year in terms of events and publicity, and at that time we surveyed all the States, and we found that 23 had some type of reporting requirements for diagnostic or therapy machines, one or the other; we didn't specify.

We currently are conducting an updated survey, and as of August we've just sent the survey out, we have 26 responses, and 20 at that time of the 26 have requirements, six do not, of the States that responded so far. I don't think three have dropped their requirements, they just probably have not responded to us at this time.

In 2011, we conducted a pilot and all of our State program directors were sent reporting forms, definitions, and instructions on how to report events to CRCPD. Now, we -- in the time span from 2010 to 2011 spent a lot of time developing a definition, and the reporting forms, and all of this information, and we

collected all events for the first time. And I'm going to go into what our definition is.

We can accept events from any State or local agency that has reporting requirements in place, so if the State already has requirements for you to report to the State, the State would then send the information to us. It's no burden on the facility to further send the information; it comes from the State agency. And in 2013, we did enter into a Memorandum of Understanding with AAPM to further analyze some of our data that we felt would be better analyzed on their end.

Our committee provides an annual summary of our data to the Board of Directors, and we present this summary at the conference every year that we hold in May. Our current definitions include events resulting from the use of therapeutic radiation machines and from diagnostic radiation machines. When we developed these definitions they were not intended to be regulatory. Our H-38 Committee is not a regulatory committee.

I will preface that and say now both the diagnostic and the therapeutic definitions have been incorporated into our suggested State regulations, so if they choose to incorporate those into regulations for reporting requirements, they can, and they are. Well, for diagnostic they're in the current version that's

being worked up right now. We're updating our diagnostic x-ray regulation so it will be in there.

Our therapeutic definition we involve wrong patient, wrong site, wrong modality, weekly administered dose differs by more than 30 percent, total dose by more than 50 percent, or single fraction -- total dose by more than 20 percent, or single fraction by 50 percent. And any equipment failure, error, accident, anything that might be of interest that could cause an unusual harm to a patient, or significant harm.

Our diagnostic definition which we really ran around with a lot because we started from scratch here, and it's been a work in progress, but it is anything that results in an unintended dose to the skin greater than 2 gray or 200 rads for the same area, procedure, or series. An unintended dose greater than five times the facility's protocol, and exceeds 50 rads to an organ, or 5 rads total dose.

Wrong patient or wrong site for the entire exam and exceeds 50 rads in organ or 5 rads total dose. In this instance, we were trying -- for diagnostic we run into so many exams, and we were trying not to collect every time somebody even in a dental office x-rayed the wrong tooth. So, that's why we went with the -- we were

trying to collect only the significant events, every time a wrong hand or that sort of thing. Involves any equipment failure, or other accident or mishap, or unusual occurrence which exceeds the 5 rads total effective dose.

In 2011, this was our pilot year. We actually had 29 events reported, 48 in 2012. We had 10 States that were in our pilot study, and in 2012 we collected events from 26 States. In 2013, we had 30 events, 26 therapy, and four diagnostic. 2013 was the first time we actually did see some diagnostic events come in. And we received information from 19 of the 50 States.

And when I say that, about half that have reporting requirements at all, so we know that. So we've received from 19 of the about 23 to 25 States that we know have reporting requirements.

And this just kind of gives you some of the information we collect. This is from our 2013 data that tells you who the event was discovered by. It's very similar to what you've already seen. How it was discovered.

The other category is very interesting in that it stays fairly high. And this is something that we plan to work on and get AAPM's input on, as to is there

a category we need to add to the drop-down menu, or are these just isolated other events? It's hard to say really when you look at them. And some of them actually may fit into one of the other categories that were reported as other.

Causes and contributing factors. That can indicate more than one cause or contributing factor per event, so those numbers can go up.

In our 2013 summary, we had 15 minor consequences, 10 events with no consequence, and one with moderate. This is pretty consistent from year to year. On our diagnostic we had four events, three were CT, and one fluoroscopy, one was an equipment failure where the disk drive failed and they could not reconstruct -- although they already scanned the patient, the image could not be reconstructed so the patient had to be redone. Two wrong patients that were identified by the technologist, one wrong patient that was ordered by the referring nurse practitioner. When she received the report back she said that wasn't what she ordered. She accidentally ordered the wrong thing. It was interesting that we even got this one reported, because by definition, by our -- at least my State and most States there was an order when the exam was performed, therefore, it's not a medical event. Even

though it was the wrong exam, it was ordered.

This is how you can get our reporting forms. They're on the website, and to the facility you don't have to -- you shouldn't need to access these. Like the states actually complete these and submit them to Bruce at our agency, and he puts them into our system. And if you have any questions, that is my contact number as committee chair. Okay.

VICE CHAIRMAN GUIBERTEAU: Thank you very much. Any questions?

MEMBER ZANZONICO: I just have a question. I was a little confused on the data flow. So, events are reported per the standard regulations on a State by State basis.

MS. ELEE: Right.

MEMBER ZANZONICO: And then the State agencies forward that information. In what form is that done?

MS. ELEE: It's very similar to your reporting --

MEMBER ZANZONICO: It's another web-based tool that someone at the agency --

MS. ELEE: Yes, it's a web-based tool with drop-down boxes.

MEMBER ZANZONICO: -- will extract data

from the licensee's report, or the user's report.

MS. ELEE: Right.

MEMBER ZANZONICO: And enter it into --

MS. ELEE: Right. Right. Now, we don't collect facility information that is available to -- I mean, the address and all of that.

MEMBER PALESTRO: In your event definitions, it says diagnostic radiation machines. I assume, though it's not clear to me, that that excludes nuclear medicine studies, or not? And I didn't see any radionuclides --

MS. ELEE: We did not -- when we started all of this, and still, we have a representative from the NRC that serves on our Committee, and if it intended to only be -- was not nuclear medicine at the time, we intended for it to be separate because of the difficulty with merging the systems. But we didn't want to exclude that in the future.

MEMBER PALESTRO: So, at the present time you did not exclude it --

MS. ELEE: At the present time --

MEMBER PALESTRO: Not include it.

MS. ELEE: Not included, but that doesn't mean --

MEMBER PALESTRO: You won't.

MS. ELEE: Right.

VICE CHAIRMAN GUIBERTEAU: I have a question in terms of your overall system. I read through these last night and one thing struck me, and that was the sense that perhaps there's being the creation of multiple silos of collecting information. And I know the CRCPD is a large organization, and I wondered what your thoughts are in terms of sharing this information, and also preventing the collecting of the same information, such as happens in meta analyses every time, is that the radiation oncologist reports to ASTRO, and the RSO reports to you, et cetera, et cetera. So, I mean, have you gotten that far? I guess that's a question for any of the presenters; that's a concern.

MS. ELEE: I think our system was probably up and going early on, and in setting up our system we did not want to be a burden, an additional burden to the facility. There are a couple of other reasons, too, FOIA requests and that kind of thing, but we can take the information from the states themselves. So, our information is only events that have been reported to the states, and it's reported to us by the State agency, not the facility.

So, I guess no longer that way. The way we're collecting the information, if a facility is

reporting it to another agency, we're not making them report it twice to us, because we're collecting it from the state agency. And they would have had to have reported it to the state, anyway, if it was a reportable event.

VICE CHAIRMAN GUIBERTEAU: And you're insuring that the reporting requirements from the State match your reporting requirements.

MS. ELEE: Those are different. We only ask them to report the events that meet our requirements. And, in fact, in my State, we collect -- any and all patient that's imaged is reported. We get a lot of, you know, they got the wrong chest, portable chest, you know, the wrong patient had a portable chest. Well, that is not reportable in this system because it doesn't meet the dose requirement. It's an event, but it's not -- it doesn't go into the CRCPD database, so we ask the States to kind of --

VICE CHAIRMAN GUIBERTEAU: Dr. Thomadsen.

CHAIRMAN THOMADSEN: You have -- yes?

MS. TOMLINSON: Cindy Tomlinson from ASTRO. I think one of the other differences that I think you're getting at is that the RO-IL system is completely voluntary, so it's not -- there are State requirements that you still need to report to your State, or NRC, or

FDA. You still need to do that even if you are reporting to the RO-IL system, so it is a voluntary system. So, I think that that's kind of where the difference lies that CRCPD is collecting data that's already being reported to the States because it has to be. Whereas, our system is collecting other things that -- and it's voluntary. So, I think that that's where the difference -- does that answer your question?

VICE CHAIRMAN GUIBERTEAU: Well, it highlights a difference, and so the motivations are maybe different in terms of reporting.

MS. TOMLINSON: Right.

VICE CHAIRMAN GUIBERTEAU: Although, self-reporting in a sense is somewhat voluntary depending on the understanding of the reporting requirements. But I do appreciate that, and I think that somewhere in terms of overall safety culture we're getting, and that is being able to report things --

MS. TOMLINSON: Right.

VICE CHAIRMAN GUIBERTEAU: - without you know, in terms of understanding and correcting rather than have your hand slapped.

MS. TOMLINSON: Absolutely. And that's the whole purpose of the RO-IL system.

VICE CHAIRMAN GUIBERTEAU: I appreciate

that. Thank you.

MS. ELEE: And I think States have been very proactive in letting people know that if it's a reportable event in your State, putting it in the RO-IL system does not preclude reporting it.

MS. TOMLINSON: You've still got to report it. We make that very clear in all of our educational materials you still have to report to the State. You still have to report to FDA, you still have to report to NRC. But thanks for reporting to us, too.

VICE CHAIRMAN GUIBERTEAU: Sue.

MEMBER LANGHORST: I'm sorry if I missed this, but has this data been available to everyone or just to CRCPD?

MS. ELEE: No, our summary is -- I actually don't know. I will have to look at the website to see if they actually post the summary to the website. I know it's available through the annual meeting documents, the ones included in there because we present every year with our annual.

MEMBER LANGHORST: So, it might be if you're a member of CRCPD you can access it, or --

MS. ELEE: I think you can access the proceedings online.

MEMBER LANGHORST: Okay.

MS. ELEE: Yes.

MEMBER LANGHORST: Thank you.

MS. ELEE: And if not, let me know and I'll be happy to send it to you.

MEMBER LANGHORST: Okay.

MEMBER COSTELLO: In your diagnostic definition, it says results in unintended dose greater than 5 times the facility's established protocol. Is the expectation that the facility will have established protocol in terms of dose for diagnostic x-ray?

MS. ELEE: At the time that we wrote this, that we listed that definition there was a lot about protocols and facilities looking at establishing protocols for exams and all of that. I don't know that that has come to fruition as much as we would have liked to have seen it. But, yes, to answer your question --

(Simultaneous speaking)

MS. ELEE: -- but most do.

MEMBER COSTELLO: I don't think Pennsylvania would require that.

VICE CHAIRMAN GUIBERTEAU: Any other questions? Thank you very much. Our next speaker is Bruce Thomadsen, who we all know on the Committee as our Chair, but wearing a different hat this time for the Center for Assessment of Radiological Sciences.

CHAIRMAN THOMADSEN: And as a disclaimer, I am the President of the Center and the Director of its reporting system.

Just a bit about CARS. We developed this system in 2012. CARS is a patient safety organization listed with the Agency for Health Care Research and Quality. We went live for reporting September of 2013. This is the same reporting software that's used by the Veterans Administration. I don't think that we've been having the problems that the Veterans Administration has been having.

Our philosophy is to help improve radiotherapy quality and safety. We do this by working with the clients doing the reporting and the analysis events. And I'll talk about that in just a moment. We also work with clients to develop corrective actions that will work in their setting, and prospective quality management tools.

Our methodology of reporting is a little bit different from the RO-ILS, when a facility has an event or a near event, or just wants to report a hazardous condition, they go on line and fill out a very brief form just like their initial form. We put the questions on the form, sort of two things. One is just to let the people feel that they're doing something,

that they're answering some questions, and they're questions that are very easy for them to answer. And the second thing is once they submit it, we get an email saying that an event has been reported, and we call back. And we'll call back either the person who filed the report, or a contact person at the facility depending on how the facility wants to handle that. And we'll work that out with the facility beforehand.

And once we're talking with that person we'll go through, get a description of the event, and we complete the rest of the questionnaire. The AAPM data set is actually quite long, and asking the facility to fill in the questions leads a lot of times to the problem that you have with any facility questionnaire of an event, a lot of data is not entered just because either they don't know the answer, they don't understand the question, or they get tired along the way. So, we fill it in to assure that we capture all the data that's in the data set, and that helps avoid omissions of data. But it also gives us a better idea of what happened in the event, so that we understand the event better.

And after talking with them about the event we will then go off line, do a root cause analysis, try and figure out what happened and what we might recommend for rectification of problems, not just to prevent that

event from happening again. That's not too likely, anyway, but to try to address some of the latent conditions in the institution that led to the events in the first place.

And then we will complete the form, we'll send it back along with our analysis and recommendations, and talk again with our contact in the facility about our recommendations and our analysis. And we'll see how they feel that our recommendations could be enacted in their setting. A lot of times what we might recommend may not be practical at a given facility, in which case we'll work with them and come up with solutions that could be workable for them.

The advantages to this approach is all the incidents go into the database as opposed to waiting for the facility to decide to upload the event into the database. All incidents go in automatically. All the fields are completed, at least if they're applicable, so we aren't plagued by data missing in the analyses. The root cause analysis is done by professionals who understand the analysis and radiotherapy. And working with root cause analyses with different facilities, one thing we found back in the '90s when we started working with radiotherapy root cause analyses was that most people do them wrong if they don't have a lot of

experience doing them. So, rather than leaving the facility to do it themselves, we would help -- either we would do it for them and bring our results back to see if they think we've got it right, or we would be very happy to work with their root cause analysis team to try to help guide them through the process. We like to think that our clients are supportive in this way.

We also have an equipment reporting -- equipment problem reporting section of our reporting system. If somebody has a problem with equipment they can report it. When we get that report, or if the incident involved equipment we'll fill that in ourselves. We will take any of these reports to the manufacturer and try to work with them to see if there's solutions to the problems people have had with the equipment, and bring this back to the community. People can use the equipment section to look up if other people have had problems with equipment that they're interested in, see if there are any solutions posted for those.

CARS is run by radiotherapy physicists who are experienced in system engineering, and system engineers who are experienced in analyzing radiotherapy problems; that is, we are definitely a radiotherapy centric company that does this database.

We also have a panel of experts, other physicians, other physicists, other engineers that we would bring in to help in any type of an analysis.

Just like with RO-ILS, this system can serve as the local database for any facility because they always can look up their own data, and all that data is there. Somebody outside their facility is looking at their data, it's all anonymized. We do accept anonymous reports. If the reporter will give us contact information, we will follow-up with the reporter. We will not disclose who the reporter is to the facility, if we know who the facility is, if they give us that. We will let the facility know that there is a problem, and what the problem may be. We try to follow-up on the problem, and take care of whatever is being reported while keeping the reporter anonymous.

Our vision is we would like data sharing amongst all radiotherapy databases. As a PSO, our data is automatically periodically sent to AHRQ. They have a super database of all events in health care. Unfortunately, radiotherapy events don't get captured very well in their super database. They do periodically update their database for different specialties, and I talked to them about trying to update their database including the radiotherapy data set that AAPM

generated. They were very interested, except they said, and how many facilities do you have nationally? And we said it was 2,000 some, and they sort of laughed at it and said we'll do this, but the priority is going to be very, very low, so it's going to be a long time before we will have a super database that all of us can upload radiotherapy information to.

We do want to try to work with the regulatory databases, and I have talked with Ms. Elee, and with NMED, with the permission of the client, if there is an event, uploading data from our database into their database. We like to think that this would help complete the data that might be missing -- which we find a lot of data is missing in NMED, when we go through the annual medical event reporting system.

The information that we have would be disseminated to the community either in alerts, which would be immediate announcements we feel should go out to the community if there's some hazard that we've noted. Bulletins, which are important notices, periodic reports of our findings, and these would all be sent, emails to our clients, message to listservs, letters to the professional newsletters. And we have two slides with acronyms, since there are too many to fit on one slide.

VICE CHAIRMAN GUIBERTEAU: Well, thank you, Dr. Thomadsen. That was very interesting. Any questions? Yes?

MEMBER ZANZONICO: I have several questions. One is -- I mean, I've heard the acronym CARS, and roughly aware of what it does, but it's an entity within what, within AAPM?

CHAIRMAN THOMADSEN: No. It's a standalone, patient safety organization.

MEMBER ZANZONICO: And how is it supported?

CHAIRMAN THOMADSEN: We are not free. We're a not-for-profit, so we charge fees. And I can tell you the costing structure is: the first accelerator is $1,000 a year, the second is, I think, $850, the third is like $600. We don't charge for brachytherapy, simulators, anything like that, and it's just meant to cover the cost. That's how we fund it. You can also make donations. We will -- we know we're not-for-profit, but we're not a nonprofit.

(Simultaneous speaking)

MEMBER ZANZONICO: -- especially with all of these -- non-regulatory databases like RO-ILS and so forth, what's their, for lack of a better word, standing, or policy with respect to mitigation? I mean, these are data that potentially -- for events that could

potentially be litigated by a patient, and how is that handled?

CHAIRMAN THOMADSEN: By the Patient Safety Act of 2005, patient safety organizations that are listed with the Agency for Health Care Research and Quality can interact with their clients, those who have a contract, and that's why the contract is so important, so that data that is given to us, data that we give back, analyses we give back to our clients is protected from discovery. It cannot be -- we can't be subpoenaed. They can't get that data.

The client is responsible for keeping that data separate in their own -- and it has a fancy name, according to the Act. They have to keep that data separate so that it doesn't -- it can't be subpoenaed from their side, either. That does not mean that anything in the patient's chart is not discoverable. It is, it's completely discoverable, but anything -- any discussion we have with the patient, with the client is excluded.

MEMBER ZANZONICO: And that's true of RO-ILS, as well?

CHAIRMAN THOMADSEN: Yes. That is the carrot that Congress gave to try to get people to contribute data to a Patient Safety Organization.

VICE CHAIRMAN GUIBERTEAU: Dr. Suh, do you have a question?

MEMBER SUH: Yes. So, actually, the first question is the cost of it, but how many centers have you signed up for this system right now?

CHAIRMAN THOMADSEN: We have several contracts out that we're negotiating right now. We don't have any active. The VA has been using our system for a while, so at the moment that's where the data is coming in [from].

MEMBER SUH: In terms of root cause analysis, like what is your timeline, for instance, for turning data over, like if a client were to submit something, we had an incident on a machine, how do you envision it in the turnover --

CHAIRMAN THOMADSEN: We would get back to you to complete the data gathering as soon as we got the email and could make contact with whoever we're supposed to make contact with. The root cause analysis we would start right away, but we'd probably have to be talking with some of the people who were involved, and how long it takes depends on how accessible those people would be to discuss. The root cause analysis probably doesn't take very long once you get the interviews with all the people, so it's hard to say. It's hard to give a

deadline, but we try to do that very quickly once we get to talk with people.

VICE CHAIRMAN GUIBERTEAU: Dr. Palestro.

MEMBER PALESTRO: Yes, I have a question about this. This has been a session on event reporting mechanisms, and so far we've heard three different approaches to the event reporting mechanisms. And, presumably, as you acquire accrued data, we'll get to look at reports with the ultimate goal being able to improve patient care.

But given that you're three separate organizations, and there's no mandatory requirement for participating in any one of them, it seems to be that potentially, not saying it's going to happen, but potentially each of the organizations could wind up with different conclusions. So, for myself as a practicing clinician, if you will, radiation oncologist, who's right? Who do I follow?

CHAIRMAN THOMADSEN: I think the answer to that would simply be if they find that there's some hazards that you have to look out for, those are hazards you should look out for. If we find there's different sets of hazards that you should look out for, you should probably look out for those hazards, too. I don't think that there's a right or wrong. We're just all trying to

highlight things that you should be aware of, and watch out for in your own practice. We're trying to uncover the traps that you might fall into.

VICE CHAIRMAN GUIBERTEAU: Dr. Langhorst.

MEMBER LANGHORST: I think it's very important, as Dr. Thomadsen had said, to learn from others mistakes or problems, and so wherever you can gather that kind of data, I think it's very helpful. It would be nice to have one place to go to and you know, boy, they're really on top of it, but I think you have a lot of different sources to --

CHAIRMAN THOMADSEN: And our database is open to any researcher that wants access; they just have to register and they can look at all the anonymized data.

VICE CHAIRMAN GUIBERTEAU: Dr. Suleiman.

MEMBER SULEIMAN: I think it's a noble effort. I think we're moving in the right direction. I don't know how many years it's going to take, but I think part of it has to do with the whole error concept where people have to learn that reporting errors is not -- shouldn't be taken personally. And I think we realize that, if you collect data on a large scale you may see things that you're not going to pick up anecdotally, individually and say -- and I would want to know, if I made a mistake, did others make the same mistake because

of some underlying circumstance?

And, yes, I think this database sharing, even at FDA we have -- our experience, at least how I've seen how we handled things, because consumers can report through a pretty comprehensive way of reporting mistakes, but the companies are supposed to -- mandatory, they're legally required to report to us. And, of course, companies say this was a user mistake, or the consumer made a mistake, and vice versa, so you're never going to get that issue completely resolved. But when there's a problem you have to have all these databases, and surprisingly when you investigate something specific, they do coincide. We start to see trends, so they can be helpful. It would be nice; we all want a uniform one-size-fits-all. We're just never going to get it.

MS. ELEE: On our end, that was one of our main goals, was to look at if something is happening in one State, is it happening in another State. Does that State know it's happening? And the brain perfusion is a prime example where it happened in California and then it popped up in Alabama. Now, would Alabama and California have ever correlated the two had it not been so publicized and we'd known about it? Maybe, maybe not. It wasn't a large number of patients, but it was an event

in both States.

In ours, we don't give recommendations back to individual facilities on our end. We're looking at trends, we're looking at is something happening more than once? And, you know, is there -- if there's something that comes in and it's an immediate risk to health which we haven't, since the brain perfusion, we haven't had any of those. But if we did, what we would do is immediately siphon it off to our committees, our committee on CT, or mammography, whatever committee would deal with it, and have them issue a guidance.

VICE CHAIRMAN GUIBERTEAU: Dr. Palestro.

MEMBER PALESTRO: Yes. I understand what you're saying, and perhaps I used the wrong phrase when I asked who's right, but I think let me go back and rephrase it and say that with multiple different organizations, I think the potential exists for conflicting conclusions, if you will. Even if you're not making a recommendation, I may be reviewing the data and forming my own conclusion, saying Conclusion A based on your data, looking at your data maybe Conclusion B. I'm not saying that that's going to happen. I'm merely pointing out that when you have X number of organizations, and the more organizations you have approaching this, the more likely you are to wind up with

conflicting results.

VICE CHAIRMAN GUIBERTEAU: Yes, Dr. Ennis?

DR. ENNIS: I think since we're pretty early in this kind of self-reporting space, it would be natural for people to go to different solutions, and each one is going to have their strengths and weaknesses. And generally that's a good thing because over time you end up seeing what's working, what's not working, what are the strengths and weaknesses, and go down the road towards a time where we kind of converge on one solution. But I think it would be, probably, less than ideal if at the start we only had one way of doing things.

VICE CHAIRMAN GUIBERTEAU: Dr. Alderson.

MEMBER ALDERSON: I just want a clarification. Bruce, one of your slides says that CARS would like to provide information to NMED. And I heard you now said something different. Are you providing information to NMED?

CHAIRMAN THOMADSEN: Not yet, not yet. I had discussions with them about that, and it's something that we're looking forward to, if we can work things out.

MEMBER ALDERSON: Okay.

MS. ELEE: We discussed that early on, too, and I guess technically there's just some data talking

back and forth issues.

(Simultaneous speaking.)

VICE CHAIRMAN GUIBERTEAU: Mr. Costello.

MEMBER COSTELLO: Dr. Thomadsen, I was intrigued by what you had to say about root cause, that you probe a little deeper in your root cause, because having investigated a whole bunch of incidents and having root cause training, operator error is rarely the root cause, almost never. Yet, I think when things are reported, these are -- this is often the first and easiest thing to say, the therapists made a mistake, or what have you.

And if you're filling out the data and you're going to enter something like that, it'll look like that. But if you pursue that, okay, I think the real model comes from -- and what does anybody learn from operator error, you know, that means you're fallible. But if you pursue the real root cause, I think you may get information that may be far more valuable for other organizations. It came from ergonomics, the relationship between person and equipment; it can come from training; it even comes from safety culture. And I've certainly seen, and not just in the medical arena, where safety culture has played a critical role in events, and I can talk to people about that off line.

I mean, of all the ones I've heard, I think that is very, very important to do, is not just to stop at operator error and say well, what is the root cause of this event, because it almost certainly isn't.

MS. ELEE: And I'd say that most of ours that come in, even those a lot of them list the technologists as one of the causes, they always have more than one cause. In most all of our events there's multiple causes.

MEMBER COSTELLO: Sure.

MS. ELEE: Because like you said, that may be the initial cause, but it's not always the --

MEMBER COSTELLO: It's rarely the true root cause.

VICE CHAIRMAN GUIBERTEAU: I would like to go back to this issue of data sharing, because that has become extremely important in the safety culture, particularly in radiological procedures. And just in my own experience, as well as that as a number of organizations, the word anonymize means different things. Certainly, at a minimum the patient information is anonymized as per the HIPAA law. But, for instance, if we were going through an analysis of a certain type of safety infraction, taking each of your databases, is there going to be any information?

I think Ms. Elee talked about the regions, so you know if it came from a particular State, and perhaps city, but is there any information that would be helpful to the other persons- to a researcher, for instance, in wanting to put this data together?

MS. ELEE: I guess, I -- if you wanted to individually look at where an event occurred, we would require you to go to the State. We will tell you, you know, you have to go to them because it's the State's information. And they have all of that information, and if you requested it through the right channels, you would get that information I'm assuming from the State --

VICE CHAIRMAN GUIBERTEAU: -- It's very difficult to obtain this information.

MS. ELEE: It's difficult, but we don't want to be the easy way out to release the information so that you don't have to go through the State. That would be counteractive to what our whole purpose is, and what the organization is, since we're a collection of States speaking as one. But it could because -- I've had concerns, too, if we were to combine databases in some way, how to tell you're not double counting the same event, because ours are coming from the State, yours are coming from facilities. You would think that some of

those are going to be the same, so how do you make sure that you're not counting it twice?

CHAIRMAN THOMADSEN: Yes, anonymized data is just removing the name or anything that would identify the patient or the facility. Basically, anything else is up online, with the exception that if there's something about the procedure that would identify the facility, for example, were it a ViewRay™ event, seeing these only two facilities, we probably wouldn't put that up, because it would be hard not to be able to identify the facility from the description, given the few number of practitioners. So, we would look at the data and see if there was something identifiable, but otherwise it would all go on the database. And you have, I think, ASTRO's [inaudible]- but I want to hear from them.

VICE CHAIRMAN GUIBERTEAU: Well, I'll hear from you, too.

MS. TOMLINSON: Cindy Tomlinson, ASTRO. So, in terms of our making it anonymous, we ask for no patient information. There is a form; there is a section, or a slot on the website that does ask for a patient identifier. That is really for the facility when they go back and do their analysis, because if you're a big facility and you've got hundreds or even thousands

of patients, and you've got to go back and look at a patient record, if you're not intimately familiar with that case, with what had happened, you need some way of going back and figuring it out. So, we do ask for that, but it is not required. That is the only patient identifier that is in our data set.

In terms of facility information, as Dr. Thomadsen said, there are cases where it would be very easy to figure out which facility this was coming from based on equipment, or there are some proprietary software that some folks use; we strip all of that. We know because when our contractor, which is Clarity PSO, goes in and talks to facilities- when they're signing the contract they ask for specific information, such as do you have proprietary software, or is there something that you use that nobody else uses? So, we strip all that out, as well, so it is -- we try to keep it as anonymous as possible.

And I think as we all start collecting more and more data, because remember the PSO program is very young. The regulations only went into effect in 2009, so this is a very young program in general, for general medicine, not just for radiation oncology or anybody else. As we get more and more data it'll be easier to make it more anonymous, because we'll have more and more

data, and more and more people participating.

VICE CHAIRMAN GUIBERTEAU: Thank you. I think we'd like to proceed, if that's okay. Do you have a short question?

MEMBER SULEIMAN: No, that's fine.

VICE CHAIRMAN GUIBERTEAU: All right. I think Debbie has been very patient. I hope you're still on the line. Debbie Gilley.

MS. GILLEY: Good morning.

VICE CHAIRMAN GUIBERTEAU: Good morning, welcome. Debbie is a former member of this Committee, and it's always a delight to hear from you. Today she's representing the IAEA going to tell us about the SAFRON reporting system from IAEA, and at this time is yours, Debbie.

MS. GILLEY: Great. Could I have the first slide, Sophie?

MS. HOLIDAY: It's up, Debbie.

MS. GILLEY: Okay, it's not up on the webcast.

VICE CHAIRMAN GUIBERTEAU: Is there any slide up on the webcast?

MS. GILLEY: Yes. Okay, we're ready to go. Well, thank you first for letting me have the opportunity to talk to you today about the incident

learning system that's been developed by the International Atomic Energy Agency. It is the SAFRON system, and it is a user-based system that's identified. Our purpose: it's to improve safety and quality of care in radiation therapy, and its goal is to share knowledge that we collect from near misses and from incidences that are reported around the world. Next slide, please. Next slide.

MS. HOLIDAY: It's there.

MS. GILLEY: Oh, there's a delay between the webcast and the telephone. Please bear with me in the technology challenges we have in giving this presentation.

SAFRON is designed to be a clearinghouse of multiple reporting systems, and it contains information that's gathered by IAEA reported events, the ROSIS system out of Ireland that many of you are familiar with and the French Nuclear Regulatory Authority also participates and provides any medical events that happen in France directly into the SAFRON system.

In addition to that, there are about 35 individual clinics throughout the world that have no other options for an incident learning system that are using SAFRON as a base to do individual learning in their facilities. There's about 1,200 incidents in the

database system. It covers both actual events and near misses. It's designed to be non-punitive. It is anonymous not only by patient, facility, but also by country, and it is voluntary. You have to register to participate in the SAFRON system.

It tries to provide the most comprehensive source of information on radiation safety. It not only includes actual near misses and events, but we've also tried to include information and links to published scientific journals, so if somebody was looking at a particular event or near miss that happened at their institution, there would be a wide variety of resources that might be available to you to go in and look at maybe a failure mode effect analysis that's been performed by some other institution and they published that information. Next slide, please.

This is a really busy slide, but this is kind of to demonstrate the complexity of radiotherapy, or radiation oncology as we say here in the United States. And in external beam radiation therapy, IAEA has identified 92 different process steps from the time the patient is identified as needing radiation therapy until they complete their course of radiation therapy.

This is just for external beam. It could also look at the process steps for brachytherapy and

radiopharmaceutical therapy, and at every process step along the way there is an opportunity for error to happen. In treatment planning it may be that they pull up the wrong CT plan when doing the treatment planning and it's not caught, so the basis for SAFRON is to identify errors that occur at each individual process step along the way. Next slide, please.

This is the web page for the SAFRON system. As you can see, you can look at all 92 process steps along the way. You can actually do your own search for errors in the process. There's a place for you to look at any kind of reports, or scientific journals, or instant reports that might be out there. I hope your screen is not nearly as blurry as my screen is.

Every couple of weeks the website- or every couple of months they change the featured cases, and in this particular screen, when I took this screen shot, we were looking at calibration. And we also try to provide some documents and links to assist the participant in identifying some learning material that might be available. And in this case, we were referencing some of the task group reports that are published by the American Association of Physicists in Medicine. Next screen, please.

In this particular one, we're looking at

how to do a search. And you can see we can search on different process steps, we can look at how individuals who discovered the event, we can also look at how the event was discovered, and we can also use a free text search where we'd be looking at things like some of the newer modalities to identify any type of near misses or events that were reported.

I want to give you a little bit of -- next slide, please -- information on what we can do with this data. And I think it's important that we look at what the learning component is of collecting this information. In this particular case, we're looking at near misses and incidences that occur with setting up a patient with ISOCENTER set ups. And that seems to be an area where we could do some improvement in our processes and procedures, so that we don't have ISOCENTER near misses or incidences that happen that have impact to the patient.

There are many areas where the ISOCENTER issue is identified as a problem. It can be in the pre-treatment phase when we're doing the treatment planning, or even in the simulation, or it can actually occur in the treatment phase.

We also can look at who is identifying those particular incidences along the way. And as you would

expect, therapists at the treatment unit are actually the ones that are most likely to identify an incident that's associated with wrong ISOCENTER, or wrong shift from ISOCENTER in some instances. Next slide, please.

The way SAFRON is set up, we have the ability to look at what kind of safety barriers could be put in place at each process step along the way, in order to try to prevent those errors from ever reaching the patient. And in this particular case, we're looking at portal imaging as a safety barrier. We are also looking at chart checks as a safety barrier.

And one of the features of the SAFRON system -- next slide, please -- is the identification of the appropriate safety barrier within the safety system of radiation oncology. So, we try to capture that information from individuals reporting in, as to whether or not the safety barrier that they used that identified the error or the near miss was adequate, was not available, or if there was a better safety barrier that should have been used for that.

And this is one of the unique characteristics about the SAFRON system, and safety barriers are good, but if they're not appropriate for that particular area, we would like to be able to identify that so that we could put the appropriate

safety barrier in. There are situations where checklists work very well as a safety barrier. There are other instances where checklists are not the best choice in safety barriers for the safety systems. Next slide, please.

This is just a little bit further breakdown of looking at ISOCENTER, and whether the types of events that happen in the pre-treatment phase. As you can see, the common issues are treatment planning, is where the near misses incidents happen, and also with simulation.

In the SAFRON system in the questions that were asked of the participant bringing the information in is causality of those type of events. And I agree very much with the rest of you that human error is probably not an appropriate assessment in all cases, so we give them a list of options, a menu of potential items that might be causes for this particular near miss or event. And from the data that we've collected, we've seen that communication issues are problems, particularly with handoff and verbal instructions.

We have an issue where there are a lack of procedures that have been developed for a particular type activity. We see that there is a lack of positive safety culture, and that individuals aren't following the procedures that are in place. And we see that

sometimes with the newer technology, employees are not appropriately trained in how to do those procedures. Next slide, please. This set comes from the "Safety Is No Accident" document; and this is kind of where we are on the hierarchy of effectiveness. At IAEA... oh, excuse me. Sorry, wrong slide. This slide.

We talked about the sharing of information. We talked about sharing the information domestically. Well, at IAEA we feel that there is value in sharing this information internationally, and this is one of the cases that was reported. Sophie, would you hit the button for the popup box to show up, please?

There have been similar accidents between the other developing countries and the United States, and this, in particular, is one where commissioning of a stereotactic unit was done using the wrong size detector. This event happened in France in 2007. It happened in the United States in 2009. And as a result of using the wrong size detector for measuring the field, over 200 patients were adversely affected by that. So, there is value in an international global system and sharing information with others. Next slide, please.

SAFRON's goal and objective in setting up this program and gathering information of incidences

and near misses, are to start working on trying to improve the effectiveness of the activities that we do. And we start that with the training and education policies and procedures, developing checklist reminders, double checks, deciding what safety barriers work within the safety system.

Ultimately, as much as we can standardize about radiation oncology will reduce errors along the way and simplify. Realizing that we work with patients, and standardization is difficult sometimes in radiation oncology, when we are going off protocol or off standardized procedures, effective communication becomes very important. And, ultimately, we'd like to work with manufacturers out there to come up with ways to automate as much of this activity as we can, knowing that we will never ever, ever reduce the human element that's involved in radiation oncology.

There may be some other equipment or support that we can get through engineering capabilities with our equipment that can reduce some of the errors. Next slide, please. So, just to kind of go back over a little bit of about SAFRON. It is menu-driven. We use a lot of drop-down menus. There are some text boxes that are involved in adding information there. We have mapped systems to the SAFRON system from

other countries, so that we would be able to share that data and capabilities of doing that.

If you would like to look at the SAFRON system, it is open access to review any of the data. You would just be required to go to the RPOP website, access the SAFRON logo at the bottom. You do have to register with the gateway with IAEA, but then you can have access to review any of the data that is there, so it is publicly available.

Individual facilities can actually use SAFRON as their own internal local reporting system. There is a capability of doing that within the system. They can also compare data coming out of their system to whatever else is available in the SAFRON system.

One of the unique features is trying to identify the appropriate safety barrier for the type of event or near miss that occurs at different process steps along the way. And there's issues in continuously enhancing and upgrading the current system. Right now SAFRON is set up to do external beam. In 2015, they'll be adding brachytherapy, and hopefully radiopharmaceutical therapy to their system.

Their method of communicating issues that are going on with radiation oncology and results doing the queries are through RPOP website, and I'll give you

that address at the end. So, any communication on best practices, changes, identification of errors would be carried out, communicated through that website, which also happens to be the most popular website at IAEA.

IAEA has historically supported the safe use of radiation benefitting mankind, and draws on a lot of experience they have with other applications for improving safety in medical applications of radiation. If you're not aware, more accidents have happened in medical use of radiation than any other beneficial use of radiation in society, and this also includes any accidents that have occurred at nuclear facilities, including Chernobyl.

We also realized that having this information available and not sharing it is of little value, so it is geared toward sharing that information with the public. Next slide, please.

So, some of the things that we're doing to improve patient safety is education and training programs, capabilities, both providing that training to institutions as well as updating training curriculum on our website, supporting the development of policies and procedures as they become available and apparent that these are active; evaluating safety barriers and how well they work within a safety system, and if they are

appropriate to respond to the type of events that happen; promoting standardization as much as we can on treatment practices; working with manufacturers who we believe can help identify technology solutions to reduce errors. Next slide.

And with that, I would thank you and entertain any questions. And I have provided you the RPOP website at the bottom of the slide. Thank you.

VICE CHAIRMAN GUIBERTEAU: Thank you, Ms. Gilley, very much. Are there any questions specifically for Debbie Gilley from members of the Committee? I have a question in terms of your -- on one of your first slides when you're giving a definition here about SAFRON collecting information from various clearinghouses, and including individual clinics. Do you anticipate information collection from any of the organizations speaking today, or any other organizations in the United States?

MS. GILLEY: Well, I think we've talked both with Bruce and with Cindy Tomlinson about an opportunity to share information along the way to an international reporting system, so the conversation has been carried on. There are a few clinics within the United States that actually participate in SAFRON.

VICE CHAIRMAN GUIBERTEAU: Any other

questions? Dr. Langhorst.

MEMBER LANGHORST: I just want to commend all of the organizations for this attempt because it's not easy, and I'll be very interested. I know it's not easy to figure out what the questions should be, how you categorize things, and then how you grow a database like this, because it's a lot of care and feeding kind of issues that you have to do in order to build this bank of data.

So, I'll also be very interested to see how Dr. Thomadsen's group with -- how you approach it, and have someone who knows how to do these analyses ask the questions so that you can glean the most information with the person who knows how to look at these things, knows how to investigate, I guess. So, I just really appreciate what you're doing, and I appreciate that you shared it with us today.

VICE CHAIRMAN GUIBERTEAU: Thank you for your comment. Dr. Alderson.

MEMBER ALDERSON: Well, I'll just make a generic comment. I also compliment all of you on what you're doing. This, to me, resonates with what I see in so many other places. This is the big data problem, and in other agencies and in the private sector people are struggling about how to handle this problem. And I think

the answer they're coming up with is that the old method was let's form a new committee, and several committees, and that's the wrong way to handle this.

The way you have to handle big data is with computers, and some other agencies. The NIH, where I serve on a committee now also, they are now starting to create a group that's going to deal with all sorts of computerized data. And you need big computers to analyze big data, to put it into parts that are understandable. And then you've got to solve these privacy problems, and other things you're dealing with to ever get anything back out that can have any impact at all, or else we'll all just be spinning our wheels. And the private sector is going after this. There are companies out there in the private sector right now who are developing this technology- this is their business to take big data and reduce it relatively quickly to data that can be understandable, and then make an impact in the real world. So, I just hope that government agencies don't wind up getting left behind by that because it, unfortunately, costs a lot of money to do that. That's my comment.

VICE CHAIRMAN GUIBERTEAU: Ms. Weil.

MEMBER WEIL: I'd like to echo Sue's comment about the importance of this work for patient safety.

I think, though, that greater synchronicity in the kinds of data that is being collected would facilitate the aggregation of that data, and it would sense for these organizations to be collaborative in the way that the queries are formed, and the responses gathered.

CHAIRMAN THOMADSEN: Well, as I said, between -- we use the same data set which is the official AAPM-generated taxonomy.

MS. GILLEY: Ours is very similar.

CHAIRMAN THOMADSEN: Yes. Right.

VICE CHAIRMAN GUIBERTEAU: Mr. Fuller.

MR. FULLER: Thank you. Mike Fuller with the NRC. As I was listening to these presentations, I had a thought that kept coming to mind, and I don't have an answer... obviously, don't have an answer, more questions than answers, but as the regulator, you know, we have, Jennifer, I guess, could echo this ... traditionally had our role in wanting to have events, things reported to us that met certain thresholds.

And this is an entirely different set of circumstances, so my question, the thing that's kind of rolling in my head is we've had these four presentations to this particular body, to the ACMUI. It would be interesting to see as time goes on, and as we learn more

and more about this, what sort of recommendations or ideas that might come from the ACMUI on how the regulator could utilize this data for trending and so forth, because that's a big reason why we have this requirement- you know, if you look at the Statements of Considerations, a big reason that it is an underlying requirement -- or a big reason underlying our requirements for having to report these not only to, you know, look at it from our traditional role as the regulator, but also to aggregate data and so forth, and understand where trends are. It's always been a part of that, and we know it's an imperfect system.

So, it would be interesting to see what the ACMUI thinks that we, as the regulator, or the regulators, there's a lot of us, out to think about and maybe, perhaps, how we might utilize some of the things that are learned from these various systems, recognizing that that's not the main purpose.

MS. ELEE: I was going to say, I know just in the short period of time we've been doing this and just in talks with other States and other inspectors, I think we're seeing more questions asked at inspections regarding events. And I don't mean are you reporting your events, but what would you do if you had one, or do you know what to do, or what do you call an event on

the inspector side, just through education in this field who may not have... a lot of the inspectors probably did not know how to phrase the questions before.

MR. FULLER: Yes. I hope they'd be more along the lines of, you know, we're an agency that's committed to risk-informing our regulations. So as we learn more, and more, and more about where some of the higher risk incidents, or risks based upon higher incidents of occurrence, those sorts of things, maybe we could then, you know, focus our attention, as well. So, I just see this as something that has the potential to help us actually be better, as well. So, again, I'd like to just request that folks kind of think in those terms of what -- how the regulator might best utilize some of this in the appropriate ways.

But I have a question for all four, because one of the things that I also thought about as I was listening to all the presentations is that I think, especially when you're starting off, there has to be some difficulty, some learning curve on the part of the folks who are participating in these various systems for understanding how to recognize something that ought to be reported.

Because, again, if you have imperfect knowledge-- but not imperfect, but if there was a lack

of knowledge, a lack of understanding of exactly what could be identified, and collected, and reported, that goes a long towards validating the data, ultimately. So, anybody take a go, whoever wants to go first, help me understand a little bit about what sort of training goes in to use, how much training goes into the up front for folks, say it's the therapist, or the physicist, or the physician, or the administrator?

DR. ENNIS: I mean, ASTRO ran a whole bunch of seminars at its annual meeting, which was a couple of weeks ago about these concepts to help start educating the membership. But you're right, I mean, it's just the beginning of that process, and as people sign up and see what is happening, they will continue to learn. There may be some specific training when you actually sign a contract --

MS. TOMLINSON: Yes. So, there's a couple of things that ASTRO has been doing. One is we do have a lot of educational materials that are available to anybody on our website, so if you want to go to astro.org/ro-ils, you all can download them. They're -- the elements are public. It's not completely open- you do have to sign a form- you do need to register- you don't need to be an ASTRO member to download our guide, but you do have to actually sign in because we are

tracking who's downloading our guide for marketing and other purposes.

But in there are the data elements, there is a sample contract that has to be signed with Clarity PSO, and that contract, as I think we mentioned before, is what gives you the protections that are afforded to you under the Patient Safety Act. And I can certainly, off line, go into more detail than anybody probably needs to know about that. But once you do sign that contract with Clarity, they do training on how to use the system, but we also have a guide that walks you through each of the data elements, explains sort of the purpose of the data elements.

We're toying with the idea of maybe doing sort of a good/bad, like what's good data, what's bad data, but we're not quite there yet because we need to see what people are entering in. It is sort of our experience in talking to -- especially our beta testers, a lot of them are already collecting this type of information within their clinics. And one of the big impetuses for this program was because yes, each individual institution is collecting their own data, but they're not talking to each other. So, something might happen in one institution, and it might also be happening across the country, and the only way you're

going to know about it, and know what each other did to solve that problem is if you happen to be colleagues and talking about it. So, this is one of the things that we're trying- that we want to try to do, is to bring everything sort of nationally so that people know that you're not alone, that this is happening in other places, and here's a suggestion on how to avoid it in the future. So, there is a lot of education that goes on with that.

We will continue to do education at our annual meetings. And I know AAPM is also doing a program in February on incident learning, not just RO-ILS, but on this idea of reporting and tracking these kinds of things.

VICE CHAIRMAN GUIBERTEAU: Thank you.

MS. ELEE: I would just say on the therapy side, I think we're a lot more educated in terms of events, and the therapists, and the medical physicists, and the physicians knowing when something occurs.

On the diagnostic side, I think we have a very steep learning curve because it's just -- it's not been done before, a method – we're just seeing events start to trickle in. And I think a lot of that is facilities say, well, I didn't know that was an event, or I didn't realize I had to report that. And we're

getting the education out there but it's a slow, slow process on the diagnostic side at least.

MR. FULLER: And I have one last question for everyone. And as we talked yesterday, we were talking about the medical groups reporting to us. It's very helpful, and it's only been in the last few years that we've been able to actually collect data about the denominator. It's always been, I think, a little misleading to talk about the number of incidents, or the number of medical events, or whatever the case may be. And once we were able to get our hands on some reliable data about the denominators, how many of these actual procedures are done each year, it became very helpful for us, and also for the Commission to understand as we report these things, to understand that we're talking about extremely low numbers. Again, we're only talking about medical events, those things that rise to some level of concern, but I'm wondering if any of these systems that we've heard about today as a matter of routine, or as a matter of when someone reports an incident or a near miss, and so forth, that they also have an opportunity to say how many of those procedures they did that month, or how many procedures did they do annually and so forth.

CHAIRMAN THOMADSEN: That is data that we

collect if we have an incident, the questions is how many of these procedures are you doing per unit of time? How many patients are you seeing a month, a year? So, we do try to capture some of that data, but it's not giving you a denominator, it's only giving you the denominator for that facility.

MR. FULLER: Right.

MS. GILLEY: Hello.

VICE CHAIRMAN GUIBERTEAU: Yes, Debbie.

MR. FULLER: Hi, Debbie.

MS. GILLEY: With SAFRON systems they do fill out a registration that identifies the number of patients that they treat, approximate number of patients they treat per year, as well as some of the demographics of the type of procedures they're performing, and the equipment that they have on hand. And that's updated when they choose to update it, or annually when a notice to update that particular information goes out to them.

MEMBER ALDERSON: I'd like to echo what I said just a few minutes ago but in a different way. This detection and prioritization of low frequency events is the heart of informatics. So, what you all need is an informaticist. You ought to be talking to informaticists; you ought to be setting up programs so

that the computer analyzes these complex data for you, in addition to people, and then you'll start, I think, making some progress.

VICE CHAIRMAN GUIBERTEAU: Mr. Costello.

MEMBER COSTELLO: I would like to comment on something that you said in your opening statement there, Mike. You said regulator, and then you thought, you said regulators. I'd like to bring it back to regulator again. Okay? Because really, I don't think you expect individual States to do a whole lot with this data. I mean, at least not the State that I live in, anyway. However, I think you could expect the National Materials Program, that's why I think it's singular again -- this National Materials Program, the NRC and the States working collectively, that that's probably where it's best to be done. Not the NRC by itself, the National Materials Program reviewing events and getting information out of it.

MR. FULLER: And that's why I said it that way because I was sensitive to the fact that we all do work together, or we're working very, very hard to work together, and I didn't want anybody to think that I was just speaking only for NRC.

MEMBER COSTELLO: Ideally we're the National Materials Program- ideally. We're not there

yet, but we're moving in that direction, I think.

MR. FULLER: I agree.

MEMBER COSTELLO: Having a program with infrastructure and sharing data in which you'll have a much bigger denominator of people looking at this data.

VICE CHAIRMAN GUIBERTEAU: Dr. Langhorst.

MEMBER LANGHORST: And I would say that one of the things that hopefully, at least in my mind this allows NRC to do and NRC staff is to look at the bigger picture, not just radioactive materials, because there's a lot to learn from all of the medical applications of radiation. And I'll tell you, I get so frustrated when I talk to some NRC folks that say, oh I'm only allowed to look at the materials, and I can't consider anything else. I hope this allows NRC to be a player in the bigger picture as far as considering what is safety culture, what are lessons learned, how the risk compares across these modalities. My little cheer lead here, sorry.

VICE CHAIRMAN GUIBERTEAU: Dr. Suleiman.

MEMBER SULEIMAN: I'll take that and I'll raise you, because I [inaudible].

(Laughter)

MEMBER SULEIMAN: We have to look at it from an even larger perspective, because a chemotherapy

patient is ... may not have been exposed to radiation, and so medical errors transcend just radiation. I've got to remind you, this entire field has been based on safety. We've all been trained on how to deal with radiation. It's a level of concern that I don't think you see in other specialties. In a lot of the other medical procedures they learn how to treat the patient, and then they find out afterward there may be side effects with some of the things. Here we all learned about the hazards, or the risks of radiation, and then proceeded, so I think it's inherent -- it's intuitively obvious that we probably should have a lower rate of incidents, but just like doing a project, I think you've got to do a literature review. I think there's probably a whole lot of other organizations out there that are doing this on a broader, maybe better scale, and before everybody reinvents the wheel. Now, we've got to do it uniquely for regulation, but I think you have to sort of jump onto the bigger bandwagon. I think this whole medical records initiative [inaudible] I mean, I get shocked by the whole privacy issue. Private folks know so much about us, yet we get obsessed and [inaudible]

(Laughter)

MEMBER SULEIMAN: You know, it's like throwing the proverbial monkey wrench into the engine,

but there are easy ways to link things up by date, by height and weight. I mean, there are easy ways to link the data because these things don't happen hundreds and hundreds every single day at every institution that you could easily duplicate -- identify duplicates, you know.

So, I think a lot of these issues are all soluble, they're all solvable. But yes, rather than reinvent, I think the effort is to find and integrate it all. I think it's -- what you guys have done has been a step in that direction.

MS. ELEE: I agree with you, and I'll say that one of our CRCPD member's call this the radiation medical events database because when we started this we were looking at the big picture. And, in fact, talked to NRC at the time at the possibility of maybe taking the nuclear medicine events that are in NMED and putting them somehow, data dumping, if you will into the CRCPD database or vice versa. It became so large that we decided, hey, we've got to start somewhere. So we started with the machine side, because at the time there wasn't anything on the machine side. It may be that we're getting to the point now maybe it's time to bring that back around and see where we are, and if that's doable, or what is doable. I don't know.

VICE CHAIRMAN GUIBERTEAU: Mr. Costello.

MEMBER COSTELLO: Since I'm wearing two badges today, I'll talk on both perspectives separately. For my NRC badge, and I expect Mike will agree with me, you can't expect NRC inspectors to look at the machine-produced radiation. It's not going to happen. Okay? It's [inaudible] and generally the greatest risk, I mean almost always the greatest risk is from machine-produced radiation. Certainly have LINACs and proton machines and, you know, CTs and so forth. However, the regulations are the way they are and the people wearing this badge are not going to be looking into your notch.

If I could continue, wearing this badge, okay, I have inspected accelerators, you know. That's the advantage of the Agreement State Program, is that we can regulate all- we don't look at chemotherapy but we can regulate all uses of radiation. Okay? So, your friends from Region III, I think you're probably in, when they come wearing this badge, they're not going to look at your LINAC, they're not going to look at your CTs. Okay? They're not.

They may look at safety culture which spreads over, but they have got to tread very lightly. But the people with these badges can look at everything

in depth.

MEMBER LANGHORST: I just wanted to clarify, I wasn't saying NRC needs to inspect on linear accelerators. What the question is, I can't even talk to them about that perspective, so I hope that is something that- I hope we can get into that discussion of what it means on a bigger picture, even as Orhan says in the more medical, wider field of cancer therapy. So, that's my only thing. I wasn't saying NRC should do it.

MEMBER COSTELLO: As an inspector, okay, I'll talk to whatever it is, about whatever people want to talk about. Okay? And someone actually had a concern about the chemotherapy program. It is after all, we are State Department of Health. Okay? I'd like to get the phone number and give them a call. I'll talk to anybody about anything that appears to be a real safety issue. I won't step over dead bodies, as they say. But you really have to be aware that I play within the lines, you know, and not to do anything if I'm an NRC inspector, if you have a problem with your LINAC. But I've listened to you, and maybe passed on to the State of Missouri, or wherever.

VICE CHAIRMAN GUIBERTEAU: I want to thank the Committee for your comments and questions. I'm getting off-stage direction here. And I certainly want

to thank the speakers, Dr. Ennis, Dr. Thomadsen, Jennifer Elee, and Debbie Gilley for this very interesting bit of information on what's happening in our communities because it's something, and I think Mr. Fuller hit it correctly, I think the NRC needs to track this very carefully and decide how we can take advantage of it particularly, as you pointed out, disparate databases, and how to make some sense of that. But I think since this is rather fledgling as we move on maybe things will somewhat sort themselves out, but thank you very much.

Ms. Angela McIntosh is going to speak to us now as soon Dr. Thomadsen takes his seat. Here she is.

MS. McINTOSH: Good morning, everyone. I know we're running a little bit behind schedule. I'll try to make this brief, and yet informative for you. I'm here this morning to discuss -- we probably should call that the announcement for a public nuclear materials events database rather than proposal because I believe it's a foregone conclusion that it will happen, but I wanted to introduce this to you and let you know what we're planning on doing with respect to this effort. So, let's go on ahead and begin.

I have three more discussion points I'd like to cover, and they are the top three Agreement

States comments, NRC's response to those comments, and the proposed path forward. So, beginning with the top three comments.

One of those comments is that the State's law and/or policy prevents the release of the identity of licensees or the State believes the release of this information is inappropriate for the public version of the NMED.

Another one is that the State's law and/or policy prevents the release of the isotope's identity for those isotopes that are Category 1 through 3 IAEA sources, or the State believes that the release of any activity level is in conflict with Part 37 in the National Security Posture.

And then the other, or the third of the top three comments, is that the States will need to review the event narratives in order to ensure that inappropriate information errors are not inadvertently released on the public NMED, which would create an unacceptable burden on the States. So, let's go on ahead and review FSME's response to those comments.

To the first one that the State law and/or policy prevents the release of the identity of licensees. Basically, our comment to that is that the States can elect to not release this information, but

there is an asterisk to that statement. And the statement is that the non-inclusion of basic information such as this may lead to a lot of questions from members of the public who are looking at the information in the public NMED. And the NRC believes that any questions should be answered, or any questions along these lines should be answered by the State in question if the State is withholding that information.

With respect to the comment that the State's law and/or policy prevents the release of the identity of Category 1 through 3 sources, again States may elect not to release this information. And I should probably take just a moment to explain our internal guidance with respect to the release of this information.

We have internal guidance on the protection of what we call sensitive unclassified non-safeguards. We abbreviate that to SUNSI, the SUNSI information. Our internal guidance does prohibit the release of the activity of Category 1 through 3 sources in event reports. It does not prohibit the release of the isotope identity or activity of below Category 3 sources. So, we will release that information for below Category 3 sources, and we don't believe that that is in conflict with Part 37 or the National Security Posture.

Nevertheless, States that aren't comfortable with releasing that information can elect to not release this information in the public NMED.

Once again, it may generate questions. If some States choose to release it and other States choose not to release it, it may generate some questions from the members of the public why certain States are not releasing that information. And, again, we believe that the State in question is in the best position for answering that question to a member of the public.

With respect to the State's comment that they'll need to review the event narratives in order to ensure that NRC does not inappropriately release information on the public NMED and thereby wind up creating an unacceptable burden on the States. Our response to that is that we plan to have a 90-day hold on these events. So, to give you a for instance, an event occurred on October 1 would not be eligible for release to the public NMED until January 1. And we believe that the States should also supply the event narrative.

Now, what is the advantage that we see in this approach? We see basically four advantages. First of all, no historical information will be included, will need to be processed for release to the public NMED. So we're not going back retroactively and asking States to

supply events back from a year ago, or back from 10 years ago, but we will go forward in this effort.

And then the 90-day hold we believe will provide ample time for States to do their event follow-up, and they won't be rushed to do it. They'll be able to get the information that they need to make an informative public NMED record.

Also, we believe that if the State supplied the event narrative, that obviously will mean that NRC doesn't -- won't be providing the event narrative and, therefore, the State won't have to review what NRC has supplied to make sure that we have not inappropriately included information in the event narrative.

And along those lines, the likelihood of inadvertent release of inappropriate information means that the -- in most cases the States won't have to -- to do any sort of corrective action, because they are the ones who supplied the event narrative, and we didn't. So, that's what we believe is the best, for those four basic reasons, we believe that this approach for including events in the public NMED is the best approach.

And there were some other significant Agreement State comments that we received that are probably worth mentioning. And I'll go on ahead and read

-- there's three of them. One of them is that the reason for this is not clear. People are thinking why do we care if we do this now? What's the point?

Some States wanted there to be a disclaimer on the public NMED stating that State participation in this effort is voluntary. And some States were concerned that patients may wind up being identifiable in the public NMED.

And so, to address the first point that's listed there, the reason. Well, the reason for the public NMED, it's basically stakeholder-driven. And we did communicate this in a communication plan that was shared with the Agreement States in a letter that FSME sent out to the Agreement States on June the 9th. And so, we're trying to satisfy the stakeholders' desire for direct access to information contained within the NMED while remaining responsive to the Agreement States' concerns, and that's the general reason for this.

With respect to the disclaimer, the Agreement State can elect to not participate in the public NMED if they choose not to. Once again, this will probably generate questions, and maybe a lot of questions if as a member of the public approaches public NMED and they see that State A, B, and C, you know, or 20 States- you know, most States are participating but

three or four are not, they'll probably wonder why they can get event information from some States or most states and not from others. So, that's something to remain sensitive to.

And with respect to patients being identified- perhaps being identifiable, once again the State- if the State supplies the event narrative, we think the State supplying the event narrative is a root answer to a lot of concerns here.

The States can provide- they have the flexibility of supplying information in a way that would minimize the ability for the patients to be identified. And as we'll explore a little bit later in a slide coming up very soon, a release of the city where the event occurred will be optional. So, that would make it more difficult to identify a specific patient, which we do understand that in a small town where there's just no one clinic or something of that nature. It would be pretty easy to piece together information to figure out if you're from that area well, that's my neighbor that that happened to. So, we understand that, but we believe that for those reasons that the release of the city being optional is appropriate to help to protect the patient's identity.

And then another comment that we received

that we thought was significant is that if we release a publicly available version of the NMED, it could damage trust between the Agreement State and its licensee. And, basically, the sentiment being expressed there is that the States have the relationship, they've developed trust with their licensee, and have assured their licensee that they're not going to release information that is sensitive, and so they don't want to ruin, the States don't want to damage that trust, and we understand that. And yet, again, we would argue that this is one more reason that it's best for the States to supply the event narrative.

Each State understands their own licensee. They have that relationship with the licensee, understands the licensee's concerns, and therefore can determine... the State is most sensitive to how to frame the event so that sensitive information is not inadvertently released.

So, now we're at the point where we're discussing the path forward. We had a meeting with the Organization of Agreement States Board on July 24th of this year to discuss issues and a proposed path forward. And this is what was discussed at that time, ideas that were proposed.

It was proposed that in the public NMED that

there not be an event narrative included. And, also, to withhold the licensee's name, street address and city, but release the identity of the State. So, basically, if this option were adopted, as you go to the public NMED all you would see, and I'll just pick on Maryland since that's where we are. You go to Maryland and we adopted this option, all that you would see for Maryland is that a medical event happened on such and such a date in Maryland. That's all you would see.

The other option is to include the event narrative, but still withhold the licensee's name, street address and city, and release the identity of the State. And we are more comfortable with this option. We believe that it will best serve the public's interest. It'll be maybe a little hard to defend and/or explain why we would have a database that didn't even characterize with any detail at all what happened, just said it happened. We don't think that that would be very useful to most people, so we are again... we believe that the second option to include the narrative, which again the Agreement State and/or NRC for all our licensees we would supply, but release the State so that people know the State that it happened, but they wouldn't know the city, and they wouldn't be able to- it wouldn't be easy to piece together information to figure

out sensitive information about the event.

I think it skipped. It skipped on me. Okay. So, yes, there we go. Thank you. It was discussed at that July 24th meeting that the Agreement State should provide the event narratives, so the Agreement States were on board with that idea.

It was also discussed that the Agreement State should respond to any public inquiries. We recognize that we are not in the best position to respond to an inquiry about a state that's not our jurisdiction, so everyone agreed that the state in question should reply to inquiries about events that happened in that state.

The State will assist OAS to distribute a survey to the Agreement States. That has actually happened, and we're having a follow-up meeting on October 14th with OAS to discuss the results of that survey, to see if they've come to any consensus about the issues that were raised. And there's also going to be an October 22nd meeting, a public meeting here at NRC Headquarters in the Commissioner's Hearing Room from 1 to 2:30 to introduce the public NMED to the members of the public. So, I'll be glad to take any questions anyone might have.

CHAIRMAN THOMADSEN: Thank you very much.

Mr. Costello.

MEMBER COSTELLO: Angela, the Agreement States were concerned- had a lot of questions when we were at the OAS meeting. And you've characterized them very accurately up there. And I'll be interested to see the results of the survey. But my question is- I have a different kind of question.

When the States report events like this, they initially report them to the HOO, right? And in it they include all this information that we want to withhold, you know. They report the name of the licensee, and the patient information, the location, and an event description, et cetera.

MS. McINTOSH: Per SA-300.

MEMBER COSTELLO: Yes. And we follow that faithfully, sometimes. However, all this information is posted very quickly on the NRC's website, right? I mean, you know, very frequently I'll check on the website to see what other States are reporting, and any member of the public, if they want to know what events are being reported by the States, can go on there. It's searchable, you can search it, and get the narrative, and where it happened, and so forth, and so on. And it's there, and it works fine, you know. I'm a regular customer. That being the case, what does the public NMED

add in addition to that that we already have?

MS. McINTOSH: The current NMED is not publicly available. In AASB though, the stakeholder request was that we make the NMED available to the members of the public so that anyone can go to the NMED and look up events.

As we proposed that idea to the States, and the States came back and said well, there's certain information that we prefer not be released in the public NMED, and we recognize that the information that they said that they don't want to release, we recognize that if that information was available in the event notifications that are on our public website, so it is difficult to argue just from a logic point of view to not include that information in the public NMED.

MEMBER COSTELLO: My question is a little different. It's that any member of the public can mine the NRC's website now...

MS. McINTOSH: Yes.

MEMBER COSTELLO: ... to get all the events that have been reported by let's say Pennsylvania, or pick whatever. And it works very well, I think. And I review the NRC's posting events almost every day because there's fascinating stuff there. I'd encourage you all to read it. I just don't know that NMED is going to

provide the public a whole lot more information than it already has. In fact, it will probably provide less information than it already has.

MS. McINTOSH: NMED provides, it will provide information that is right. You know, the event notifications, it's preliminary information, so that's probably the biggest improvement over...

CHAIRMAN THOMADSEN: Ms. Weil.

MEMBER WEIL: The purpose of public NMED is to provide greater access for information to members of the public. The fact that the information is already available on the NRC's website may or may not indicate how easy it is to navigate, how do you find that stuff? I haven't tried, so I can't comment on Mr. Costello's comment that it's there already. It's simple to find. Why reproduce it?

It doesn't make sense to me that NRC would provide this, you know, watered down source of information without making it -- without providing a direct link to where you could get more information, or providing -- making it easy to access the additional information. I don't see a point. I know you're trying to meet the needs of the Agreement States, which is reasonable, but if that information is publicly available, what obligation does NRC have to make it more

difficult for the public to find this stuff?

MS. McINTOSH: I preface the answer to that by saying now you see another reason why we want the States to answer the public's questions, because it is difficult to explain.

CHAIRMAN THOMADSEN: Dr. Langhorst.

MEMBER LANGHORST: For those of us who don't know the system as well as you two do, would you explain the process of States putting in event notification information?

MS. McINTOSH: Sure. What happens is if an event is required to be reported within 24 hours. It's not necessarily what happens with events required for 30-day reports, but if the event is required to be reported immediately, which is within four hours or 24 hours according to our regulations, then the event has to be called into the headquarters operations center. The event initially -- in an Agreement State the event is to be reported to the State regulator, and then the State regulator makes the commensurate report or a report within a commensurate time frame to NRC. So, our staff at the headquarters operations center makes a report that we refer to as an Event Notification and it includes the licensee's name, the date, the city and the State, and of course an event narrative explaining what

happened. And that gets put on our website- after a 5-day hold, I should say, after a 5-day hold on the event that gets put on the NRC's public website.

MEMBER LANGHORST: Okay. So, the Agreement States do not have a choice whether they report an event or not to NRC. They have to- that's a requirement by the Agreement State.

MS. McINTOSH: Correct. It's a requirement per our regulations and we communicate the requirement in the document called SA-300.

MEMBER LANGHORST: Okay. So, in my opinion, one of the wonderful benefits of being on this Committee is to be able to see the database. And I know in looking at the event notifications that has been a way for me as a licensee to look at what are lessons learned, and it's not easy to find additional information on how it all turned out, even if it's an NRC licensee. But it is impossible to learn anything more if it's an Agreement State. I've never learned how to mine that information.

Having looked at NMED data, it's not always satisfying either, because my understanding is NMED is voluntary for the Agreement States to participate.

MS. McINTOSH: But it's not.

MEMBER LANGHORST: It's not. Okay. It seems

like there's a dearth of events in the NMED from certain Agreement States, like they never have a problem, so that's why I was curious whether it was voluntary or not. So, then NMED you're saying is Agreement States are supposed to be putting their information in there.

MS. McINTOSH: Yes, if they have a reportable event, if it's a non-reportable incident it's not required.

MEMBER LANGHORST: And then on this public part, that's where they have the choice to participate or not participate.

MS. McINTOSH: Correct.

MEMBER LANGHORST: Okay.

MS. McINTOSH: And we're thinking also of making that -- for those who do participate, the data would be limited in quantity.

MEMBER LANGHORST: Right. Thank you.

CHAIRMAN THOMADSEN: Ms. Weil.

MEMBER WEIL: So, this request that the disclaimer for the voluntary participation be public, if that disclaimer is not on the public NMED website, then that leads the public to believe that this is comprehensive information when, in fact, it isn't. So, what does NRC- what do you plan to do with that request from the States? The States want it to be there, I think,

for a different reason than I as a member of the public would want it to be there.

MS. McINTOSH: I'm not sure I understand the question.

MEMBER WEIL: Well, if you add the disclaimer that participation in the public NMED site is voluntary for States --

MS. McINTOSH: And we do plan to have that.

MEMBER WEIL: You do plan to have that.

MS. McINTOSH: We do.

MEMBER WEIL: Okay.

CHAIRMAN THOMADSEN: Mr. Costello.

MEMBER COSTELLO: Going back to Sue's comment that some States report more than other States, and often times- and there are reasons for that. You know, the reports don't originate in States, the reports originate with the licensees. And oftentimes if there's a well-known event, let's say the prostate cases for a number of years ago. The States who were associated with that from their inspections might put event reporting high on the list of the things they may look at inspecting. So, those cases that were so famous that occurred in Pennsylvania, and were associated with one of our licensee's, and we put a lot of emphasis when we did the inspections, and not surprisingly we have a fair

number of reports. Other States such as Wisconsin did the same thing. Wisconsin put a big emphasis on that, and they have a great number of reports, which I think was mentioned in somebody's presentation.

Sometimes I talk about events, you know, at meetings which you've been to, I think, of CRCPD, and OAS and such, and I will note because that some States do not have as many reports as you might expect considering their size. Why that's happening, I don't know. I mean, it may be just the amount of emphasis on-- maybe the inspectors don't emphasize event reporting, perhaps they're emphasizing other parts of the safety program. I think the States themselves, though, are pretty good about passing on the NRC reports they hear about.

CHAIRMAN THOMADSEN: Dr. Zanzonico.

MEMBER ZANZONICO: Is it possible, this issue of the disclaimer, is it possible to share some draft wording of the disclaimer that you're proposing- that will be on NMED, public NMED?

MS. McINTOSH: We haven't discussed the language of the disclaimer with the States yet, so what I can do- to offer you some draft language, it would just be my rendering of some language. It wouldn't be the actual- have been anything that had been discussed and

vetted. But it would say something along the lines of certain States have elected to not participate, or State X, name of the State, has elected to not participate in the public NMED. Please contact, and we'd probably have the Radiation Control Program Director's information there, some information, something along those lines.

CHAIRMAN THOMADSEN: Dr. Langhorst.

MEMBER LANGHORST: I want for our newer members to make one clarification, that always confused me, because NMED sounds very medical, doesn't it? But it's not just medical, it's Nuclear Material Event Database.

MS. McINTOSH: Yes.

MEMBER LANGHORST: So, it's not just medical, so I just wanted to pass that along.

CHAIRMAN THOMADSEN: The acronym is NMED, nuclear materials events database.

MEMBER LANGHORST: Yes, so that confused me for a long time. I just thought that might be helpful to others.

CHAIRMAN THOMADSEN: Any other comments or questions? In that case, thank you very much.

MS. McINTOSH: Thank you.

CHAIRMAN THOMADSEN: And with that we have a break. It's just a 15-minute break. We are running a

little behind schedule, so try to be back by 10:30. Thank you.

(Whereupon, the above-entitled matter went off the record at 10:15 a.m. and resumed at 10:28 a.m.)

CHAIRMAN THOMADSEN: Welcome back again, and our order of business this afternoon will be a little bit special. And to start this off, we have Mr. Holian to make a special presentation.

MR. LORSON: Well, thank you. Just a clarification. I'm actually not Mr. Holian. I'm filling in for Mr. Holian.

(Laughter)

And I'm sure that the resemblance gives you --

(Laughter)

I'm actually a few years younger than him, maybe like 20. So I understand the mistake.

I'm Ray Lorson. I'm the Acting Deputy Office Director for the Office of Federal and State Materials and Environmental Management Programs, and I'm pleased to be here this morning to recognize three individual members of the Committee for their strong commitment to public safety and to help further the NRC mission.

And having said that, I would like to ask Dr. Welsh to please join me. Dr. Welsh has been a member of the ACMUI since February of 2007. He was nominated for a second term in February of 2011. He has briefed the Commission on multiple occasions, has been a member of several of the subcommittees, including the very important subcommittee related to permanent implant brachytherapy, which, as we all know, has been a very strong policy issue that we have wrestled with over the last several years.

So we do have a couple of gifts for Dr. Welsh, first being a flag that was flown over the U.S. Capitol at the request of Chris Van Hollen, a representative from the State of Maryland. This is one gifts that we'll provide you.

MEMBER WELSH: Thank you.

MR. LORSON: Secondly, we have a certificate of appreciation from our Chairman Macfarlane in recognition of eight years of service and leadership on the Advisory Committee on the Medical Uses of Isotopes, which resulted in significant contributions to the work of the U.S. Nuclear Regulatory Commission. Congratulations.

MEMBER WELSH: Thank you.

(Applause)

MR. LORSON: We have more. We have more. And, last, we have a gold pin commemorating Dr. Welsh's service.

MEMBER WELSH: Thank you so much.

(Applause)

MR. LORSON: Okay. I would like to thank Dr. Welsh for having the easiest name to pronounce, and the difficulty is starting to increase here.

But I would like to request that Dr. Suleiman please join me. How was that? Was that close?

MEMBER SULEIMAN: Enough.

MR. LORSON: Dr. Suleiman has been the second-longest serving member of the ACMUI. He began his service here in 2004, has also been a representative of the Commission -- or has made several presentations to the Commission, has been involved with many subcommittees, and including the very contentious issue of substantive patient release. So he has provided his valuable insights to help us in that policy endeavor. Thank you, Dr. Suleiman.

We also have some gifts for you. First off, with respect to the flag, the flag has been ordered, but it has not yet arrived. So in lieu of that we gave you a certificate for a flag.

(Laughter)

MEMBER SULEIMAN: Anything over $35, I can't accept gifts, you know.

MR. LORSON: Well, rest assured, the flag will arrive here, and then we will send it to you via an appropriate transportation method and you will receive it.

We also have a certificate of appreciation honoring Dr. Suleiman, in recognition of 10 years of service and leadership to the Advisory Committee on the Medical Uses of Isotopes, which resulted in significant contributions to the work of the U.S. Nuclear Regulatory Commission.

(Applause)

And we also have a gold pin.

MEMBER SULEIMAN: Thank you.

MR. LORSON: Thank you very much.

(Applause)

And the difficult names continue with Dr. Guiberteau.

(Applause)

Dr. Guiberteau is actually unique in the sense that he is the first diagnostic radiologist to this Committee. And I think what's striking is that he recognized the need to have a diagnostic radiologist

to this Committee and began as a volunteer. Later, I think, we recognized the need to have someone with that skillset and made him a term member of the Committee. So thank you very much.

We also, because of the late notice, and in lieu of a flag, have a paper that has a flag picture on it.

(Laughter)

That will be soon replaced by a real flag.

VICE CHAIRMAN GUIBERTEAU: I will fly this over my home.

(Laughter)

MR. LORSON: We also have a certificate of appreciation for Dr. Guiberteau, in recognition of six years of service and leadership to the Advisory Committee on the Medical Uses of Isotopes, which resulted in significant contributions to the work of the U.S. Nuclear Regulatory Commission. Thank you.

(Applause)

And can anybody guess what comes next? Congratulations.

VICE CHAIRMAN GUIBERTEAU: Thank you.

(Applause)

MR. LORSON: With that, I will turn the meeting back over to Dr. Thomadsen. If you liked what

you heard, then my name is Lorson. If you didn't like what you heard, my name is Holian.

(Laughter)

CHAIRMAN THOMADSEN: Dr. Welsh, would you care to grace us with some words?

MEMBER WELSH: Should I sit over there or right from here?

CHAIRMAN THOMADSEN: Sure. Come on up.

MEMBER WELSH: Thank you, Dr. Thomadsen, for reminding me last night that this was going to happen, because it's kind of a surprise to me, and I apologize to those who assume that I read each and every word of all the documents that are sent to me months in advance. But it wasn't until last night that I learned that on that second page that had allegations and ethics training, that I quickly closed it, that there was more than just that this morning. So this is a surprise.

The second surprise is I'm very pleased to see Dr. Ron Ennis returned after his first experience yesterday.

(Laughter)

But I have to admit that my departure today, the expiration of my term, comes with some bittersweet emotions. And seven years ago I don't

think I would have said that. This was hard work back then, and it certainly felt like hard work. It still is hard work, but it's very different today.

The somewhat adversarial interactions and the antagonism have undoubtedly, unequivocally, and palpably yielded to a sense of cooperation and constructive collegial interaction. So it's still a lot of work, but it's actually a lot of fun. And I mean that.

In the past year or two, I have grown to look forward to the emails from Frank.

(Laughter)

There is something of interest there. I don't agree with that. I'm going to change it, type this in, and I'm going to send out the email and -- oh, Bruce doesn't agree with this. Oh, but I'm going to hold my ground, you know, type another email. And now what have I done? Maybe I should assign you more homework because --

(Laughter)

But it has been very beneficial, and it has been constructive, and I have enjoyed it. I have had the pleasure of participating in numerous subcommittees, including the short list I see here of Medical Event Subcommittee, the Patient Release

Subcommittee, the Radium-223 Chloride Subcommittee, numerous Y-90 Microspheres Subcommittees over the years, and most -- most intensively, Permanent Implant Brachytherapy Subcommittee, which has been going on for I guess seven years, maybe many years before that.

And these subcommittee interactions have recently been very enjoyable. I will look forward to comments from Dr. Zanzonico and Steve and Sue, and then I'll respond to these emails. And then I'll start putting together my presentation or summary, and then I'll look back and say, "Why didn't I concur with Orhan to begin with? I should have concurred. If I had only concurred, I wouldn't have to do this whole thing over again."

But I have learned an awful lot by being on this committee, and I have enjoyed it a lot. I have had the pleasure of introducing some things to the staff and this Committee, including the SHINE technology of hybrid fusion fission methodology for producing medical isotopes, which was something new and interesting to me.

I also recall giving a presentation on variations in half-lives of radionuclides as a function of solar activity, which, after giving the presentation, I found Dr. Zanzonico commenting that

this has elevated us to an all-time high in terms of nerdiness of the Committee.

(Laughter)

I think that he is quite right, that being on the ACMUI has certainly changed me. Preparing for being on the ACMUI was quite a change for me in the first place. I remember asking one of my ASTRO colleagues how to prepare myself for this, and I heeded his advice. I proceeded to buy and read cover to cover three textbooks of nuclear and particle physics only to learn afterwards that it was a joke. I didn't get it. I wasn't laughing.

(Laughter)

But I was quite nervous. I was anxious and actually filled with trepidation as I was joining this Committee, and I did prepare myself quite thoroughly well in advance. But I do recall people asking me, how did they pick you? What happened? So in addition to reading my textbooks, I started reading about the history of this.

And I learned that this was once called the Advisory Subcommittee on Human Applications of the Interim Advisory Committee on the Isotope Distribution Policy of the Manhattan Project. It's quite a mouthful. When the Atomic Energy Commission took

over, it became the Advisory Commission with the Subcommittee on Human Applications of the Committee on Isotope Distributions within the Atomic Energy Commission. Still quite a mouthful.

So I learned that it was shortened to the Sub-Human. And when I explained this to my colleagues, they all said, "Yeah, now it makes sense. We do have the right person."

(Laughter)

It has been a lot of fun. And being on the ACMUI has had a lot of beneficial effects for me personally and professionally. I've gotten to work with Cindy and many others from ASTRO over the past four to eight years, and these positions have been of increasing importance and relevance.

I am going to become the President of ACRO next year. I have had the opportunity to lead the clinical neutron program, fast neutron program and BNCT program at Fermi National Accelerator Laboratory. I have worked with the American Nuclear Society and the International Conference on Isotopes. These are things that I doubt would have happened in my career had I not had the privilege of being on the ACMUI, and certainly the NRC.

Additionally, I am on the Board of the

Society of Brain Mapping and Therapeutics, SBMT. And this also stems from my tenure here, because before Dr. Suh joined us I realized and I was told that there was a void in our experience and expertise on gamma knife. So I would go to -- every week I would go to another hospital, a rival hospital, to observe and learn about gamma knife.

And they were gracious enough to allow me to do that, because they wanted me to be capable, if called upon, to provide useful, meaningful, intelligent advice to the Nuclear Regulatory Commission on gamma knife. I took that to an extreme, whatever Dr. Suh -- read his review articles and a whole lot more, and actually sat for the Neuro-Oncology Boards and became one of the few people who is dual certified in radiation and neuro-oncology. But it was because of my compulsion to be capable of serving the Nuclear Regulatory Commission to the best of my ability.

Another very clear example of how being on the ACMUI has affected me, stems from one of the meetings that we had here where we were talking about the medical isotope crisis. And I don't remember exactly what my comments were -- I was probably running my mouth as usual -- but Dr. Malmud said, "So, Dr. Welsh,

what it sounds like you're calling on is perhaps a large scale, perhaps a Manhattan Project scale governmental effort to solve this isotope problem."

I wasn't truly expecting that. I wasn't holding my breath. But it gave me an opportunity to put those nuclear physics and engineering books to good use, and so I helped establish Coqui Radioisotopes and Radiopharmaceuticals. And if we get the funding, I would look forward to continuing to work with Nuclear Regulatory Commission colleagues down the road.

So, clearly, the ACMUI has benefited me personally and professionally, but I certainly hope that my participation here has benefited the radioisotope community at large, the medical user more specifically, and ASTRO and radiation oncology in particular.

I, most importantly, hope that my contributions here have benefited the Nuclear Regulatory Commission during some trying times where there were rough times with a lot of tough questions, particularly in 2009, 2010, with the permanent implant brachytherapy challenges, the prostate implant situation.

And I recall my maybe weekly telephone calls with Mike, with Ashley, and certainly with Dr.

Ron Zelac in particular during those times. And I don't want to get into that, because it feels too much like hard work again.

I will just conclude by saying that this has indeed been a bittersweet moment for me to depart from the ACMUI. I truly enjoyed my tenure here, and I have made a lot of excellent professional contacts and colleagues and a lot of good friends. And I think that those friendships and contacts and collaborations will endure.

Thank you very much for the opportunity to have served on the ACMUI. Thank you, everybody.

(Applause)

CHAIRMAN THOMADSEN: Thank you very much, Dr. Welsh. And on behalf of the Committee, I would like to thank you for all of your contributions. You always kept bringing us back to science, a lot of it arcane. You always kept in mind the calculations that authorized users should have and tried to keep us to task to make sure we recognized that.

You brought a lot of your experience -- it has been varied -- and practicality to what we do. I'm sure from what you just said you were the best prepared ACMUI member to come on board, and probably the only one who owns a tortoise.

MEMBER WELSH: I thought that was a prerequisite.

(Laughter)

CHAIRMAN THOMADSEN: But thank you again. We will miss you, and we hope that you will enjoy what you do next.

MEMBER WELSH: Thank you.

(Applause)

CHAIRMAN THOMADSEN: And while Jim should have had some warning about this, Orhan, you weren't listed on here, but would you care to give us some parting words?

MEMBER SULEIMAN: Yes. I have appreciated working with all of you, including your predecessors. I am getting off the Committee because I am basically retiring from federal service, so I'll have put in 39 years in another month, and I'll be retiring Halloween. So I will be on call for another, you know, 30 days.

This was another one of those other duties as assigned. "Orhan, we'd like you to represent the agency," you know. And I've been following, you know, I mean, my -- my career started with a local health department where I established, in the State of Florida, and interacted with the NRC way back then.

And so I sort of followed, you know, NRC rulemaking over the years, and I knew they were revising [Part] 35. And I'd hear about it and I said, "Boy, am I just glad I'm away from that kind of stuff." And this is like a decade or so ago.

So a few years later when I moved from the Center for Radiological Center for Devices and Radiological Health, where most of my FDA career early on was with X-ray, mammography, CT, and so on, when I did my master's thesis in graduate school with nuclear medicine, it was sort of like riding a bicycle, sort of getting back up to speed.

And I haven't answered the one question I remember was, are they more bureaucratic than the FDA, you know. And even to this day, it's sort of like one week I -- I get pretty depressed when I interact with you guys, and I'm never sure which group is more bureaucratic. Okay?

But I learned from -- collectively, but looking at a bigger picture, I think we have come a long way historically in terms of radiation safety. I think back, again, relating to my personal experience, we were advocating quality control test procedures in the '70s, because Ford and Benning and all of these people that -- it hadn't been done in this field. And here

we are several decades later and some of those concepts are still, you know, gaining traction or coming back as a new, improved, you know, version.

I beg to differ with Frank, but that's not difficult. I think human error is almost always at the root cause, because humans design the equipment, humans program the equipment, and, if you want to blame technology, you'll probably find out that something was done wrong with the technology. And that has been one of my biggest beefs.

And this is something that a technologist told me 40 years ago. She said, "We are getting these photon timers, so the X-ray equipment will automatically terminate exposure. The skill of measuring the patient and selecting the right energy and MAS is going to go away. They are going to start relying more and more on the technology, and I'm afraid people are going to lose their skills."

And I'll fast-forward it. When the medical events were -- with the radiation therapy devices were proliferating, some therapy physicist told me, "Orhan, I can't calculate the dose like I used to. It's all done by the computer." And that's good news because it has allowed us to do more sophisticated things. It is bad news because we have become

inherently more reliant on the technology.

And to me, when the rubidium incident occurred, I was furious because we have qualified people onsite, we have supposedly knowledgeable people at the company, and what really was a breakdown in my opinion is, if you've got automation taking care of a lot of your issues, but you don't know how it works, then you ought to be replaced by somebody off the street, because some of the people, some of the so-called qualified personnel onsite abrogated their responsibility and didn't understand what the technology was doing.

So just because it gets automated, and just because it gets easier to perform the tasks, I think it's going to be tough in the future. But for us to -- the humans are going to have to make sure that the technology is doing what it is supposed to be doing, which means they have to understand what it's doing.

And we see this in -- so I don't know how we address that, but it doesn't mean we rely more and more on technology and at the same time cut back on our responsibility. So good luck. I think that's an area that we will have to somehow address.

That's it. I don't want to really say much more. It has been fun. There is -- I think the

committees that I've been on have been much more civil than some of our predecessors. I mean, there was a time historically -- and some of these people are still alive, but --

(Laughter)

I mean, that this Committee had some very, very ugly, you know, chemistry. And I have learned this with my own experience at FDA with some of our advisory committees. I think one of the most important characteristics to serve on a committee is to be able to communicate and respect other people's opinions.

And I think sometimes we just get too defensive, you know, in terms of we think we've got to protect our profession when in fact it's a collective problem that we sort of -- you know, you've got a wonderful group here with some real understanding of the subject matter. And so you need to tap into each other's experiences.

Otherwise, thanks so very much.

(Applause)

CHAIRMAN THOMADSEN: And, Dr. Suleiman, on behalf of the Committee, I want to thank you for your years of service, which predated mine. It's amazing, your longevity here, that you've been able to put up with it that long. Maybe coming from the FDA,

sometimes this might be a breath of fresh air. It's hard to tell.

But we have really appreciated your views on things, the deep experience that you have brought from various corners of your history, your idealistic caring for what's right, the passion with which you try to see that done, the standard for quality and for the patients has always been something that we respect and need, and the vision that you have helped to bring to this Committee for all of that.

Thank you very much.

(Applause)

Now you shouldn't be surprised.

(Laughter)

Would you care to give us some wisdom as your --

VICE CHAIRMAN GUIBERTEAU: I would like to make some comments.

CHAIRMAN THOMADSEN: Please do so.

VICE CHAIRMAN GUIBERTEAU: Well --

CHAIRMAN THOMADSEN: Do you want to do it from there or --

VICE CHAIRMAN GUIBERTEAU: I'll do it from here. You know, I have been very honored to be the first diagnostic radiologist to actually be a member

of the Committee. A number of years ago when I was President of the American College of Radiology, it was my goal, also as Chair of the Commission on Nuclear Radiology, Nuclear Medicine, it was my goal to have the diagnostic portion of radiology recognized by the NRC for the depth and breadth of its involvement in radiation-producing devices, but also in terms of radiopharmaceuticals and radioisotopes, understanding that in terms of diagnostic isotopes, diagnostic radiologists perform the largest number of procedures in the country, non-cardiac procedures.

The point of this, really, is just that the training and the acceptance of the NRC of that training has been -- has always been with us. But I think as we have evolved it has become even more necessary, particularly PET being a primary example, which started as a research tool many years ago. It really didn't go anywhere until FDG came along and fluorine-18, and it has mushroomed. I mean, it is virtually everywhere.

And I think to the NRC's credit they have recognized the importance of expanding the purview of this Committee with the expansion of the -- of the use of radioisotopes in diagnostic radiology.

In terms of my own interests, I have always been fascinated by negotiations and consensus, and I

think, as Orhan said, I have been at this Committee as a guest many, many -- many times in the past, I mean, before your times, and it wasn't always like this. But this has been really a sheer pleasure, and just chairing the committee/subcommittee I just did, it was amazing how the more we talked -- we didn't start out altogether, but the more we talked and the more we took the various perspectives together, the easier it was for us to come up with what surprisingly was a unanimous recommendation.

And so I think -- I think everyone who has spoken has said this, but I think it is really true that the advice you are getting from this Committee now is -- should be very useful to you in making decisions on how we think regulations should evolve, particularly, in my case, in terms of the new procedures that have come in diagnostic and interventional radiology.

In terms of the current Committee, I want to thank you all, because I have enjoyed working with each and every one of you. And in terms of the staff, I think the staff has been more responsive to this group as a committee than I have ever seen. I think -- I haven't worked with Laura Dudes much yet, but I hear very good things about you.

Mike Fuller has been tremendous.

Donna-Beth Howe is a treasure. She keeps us from getting in trouble when we want to go down the wrong path.

(Laughter)

But she has already been down many times, and that has been a real -- of course, Sophie, and Ashley before her, have been excellent in providing us the support that we need in terms of being members.

So I want to thank everyone here, and I want to -- I really appreciate having been here for my last six years. Thank you.

(Applause)

CHAIRMAN THOMADSEN: And, Mickey, you too I want to thank on behalf of this Committee. And personally, as to the Vice Chair, thank you for your support and back up all the time. You are --

(Laughter)

-- very secure about that, particularly noticing things around, such as people who want to speak. And you noticed things about the issues, and you always bring us back to the issues at hand as we start straying into strange territories. You understand reality, and you bring that perspective to the discussions when we start thinking too globally possibly.

You distilled the discussions often into their essence, and we really appreciate that. You see things very clearly, even when you don't have your right glasses with you.

(Laughter)

And for all of that, I think everybody here has appreciated your contributions, and we thank you very much.

(Applause)

Before we get to the administrative closing, we have a couple of issues to take care of. And the first is taking care of the Water and Energy Bill, which I hope somebody is going to pay.

The Committee has seen a copy of the proposed legislation. ASTRO has been addressing this, and I'd like to ask Cindy Tomlinson from ASTRO to tell us what ASTRO has done so far.

MS. TOMLINSON: Hi. Cindy Tomlinson. It has been a long time since I've gotten to speak with you all.

So we obviously are very concerned about this Bill. We have talked with Hill staff, and our biggest concern was that it likely could really impact patient access to treatments, not just therapy but likely diagnostics as well. And they told us that the

intent was not that, not to impede patient access, but, rather, to curb our reliance on materials made from highly enriched uranium. And we were a little shocked by that.

So we are right now working to revise this language to send back to the Hill in the hopes that they will accept it. We think that our revisions hopefully capture what their intentions were. It -- also, we are striking -- just to give a little taste, we are going to strike the language specific to gamma knife and teletherapy and well water.

So, but we are still in the process of revising that language. We are working with our leadership, with our committees, to revise that language, and we I think are certainly happy to share it with you when we get to that point.

CHAIRMAN THOMADSEN: Thank you. Thank you very much. And what I think might be an effective use of this Committee is to have the -- well, maybe our incoming therapy physician and the current mid-career physician on our committee work with ASTRO to keep in touch with what sort of comments they are making in this Bill, which I have seen it and maybe we should send to the rest of the Committee.

And I think the recommended language that

they are coming up with would address our concerns about this also, and have the members who are working with ASTRO keep this Committee apprised of where things stand with that proposal, in which case we may want to endorse their comments, or, if we want to say something else, we might make recommendations for changes in that.

But at the moment, I would ask Dr. Suh and -- Sophie, can I ask Dr. Ennis to look at that unofficially or something at the moment? When does he come on board?

MS. HOLIDAY: He actually does not officially come on board until Dr. Welsh's term ends in February. However, if you are just asking for Dr. Ennis in the capacity to work with ASTRO, he could kind of serve like how Dr. Guiberteau did in the past, as a consultant before an official member. So he can certainly do that.

CHAIRMAN THOMADSEN: I would like to ask him to do that. And if Dr. Welsh is still here until February, why let him get off so easily?

(Laughter)

You've got to give the flag back.

(Laughter)

Is the Committee comfortable with that

action on that? Mr. Costello?

MR. COSTELLO: I'm comfortable, but I want to make a comment. I have also read the Bill and it has many, many problems. But it doesn't just affect isotopes used in therapy in medical institutions. It affects blood irradiators and it affects research irradiators. In fact, in terms of numbers, there probably are way more of those than there aren't.

So when you think of the scope of what our comments would be, ASTRO may not address those. I suspect ASTRO would not be addressing blood irradiators or research irradiators.

But the Bill is as bad there as it is for gamma knife. So this can certainly -- I would expect this -- these do affect medical institutions. I would expand the scope to include other areas.

CHAIRMAN THOMADSEN: I think that's an excellent point. I think that most of the changes that they are making would probably catch that in the net. And, if not, we have to make sure that we do in what we do. Thank you for keeping that in our sights.

If everybody is comfortable with that, I think we will just proceed at the moment with those actions.

The other item of business is that the NRC

has questions out dealing with proposed changes in Part 20. Some of these issues we have dealt with in the past, such as maximum permissible doses based on international standards. But I would like to name a subcommittee to take a look at the questions that are out and make a proposal of what the ACMUI response to these questions should be. And I would ask Dr. Langhorst to chair that committee, and Dr. Zanzonico and Mr. Mattmuller and Mr. Costello to also sit on that subcommittee and come back to this body at our next meeting with what we -- what you propose our response to this should be.

Everybody agrees with that?

MEMBER LANGHORST: Yes.

CHAIRMAN THOMADSEN: Very fine.

MS. HOLIDAY: Dr. Thomadsen?

CHAIRMAN THOMADSEN: Yes, please.

MS. HOLIDAY: I'd just like to add that the ANPR that Dr. Thomadsen is referring to was published in the Federal Register I think July 18th or somewhere around there, right around the time that the Part 35 proposed rulemaking was published.

Now, it is officially out there for comment until November 24th. However, I did speak with staff internally, and they are -- they will gladly welcome

ACMUI's comments and feedback at any time. But just to kind of explain our regulatory rulemaking process, the ANPR is kind of put out there for comments to kind of get a feel for things. And then from that, staff drafts a regulatory basis. And then the regulatory basis has to be sent up to the Commission, and then the Commission makes a decision whether or not to pursue rulemaking.

So this is the very preliminary stages. So similar to the Part 35, when we do actually go into the rulemaking phases, ACMUI will get that official 60-day minimum comment period to provide their officials remarks.

CHAIRMAN THOMADSEN: Should we up the deadline? And, I mean, it's not that hard of -- the questions aren't that hard.

MS. HOLIDAY: I would request that.

CHAIRMAN THOMADSEN: What's that?

MS. HOLIDAY: I said I would request that.

CHAIRMAN THOMADSEN: Yes. What is the deadline for --

MS. HOLIDAY: It's actually November 24th, but I can take it, you know, maybe by the end of the calendar year.

CHAIRMAN THOMADSEN: Do you think by

Thanksgiving you could get the response in?

MEMBER LANGHORST: This is Sue Langhorst. Yes. You would expect an ACMUI teleconference for this.

CHAIRMAN THOMADSEN: I would think that we would need to do that.

MEMBER LANGHORST: Yes.

CHAIRMAN THOMADSEN: In which case, Sophie, can you set a time and --

MS. HOLIDAY: Sure.

CHAIRMAN THOMADSEN: -- a conference line.

MS. HOLIDAY: I'll set it up similar to how we did for our planning.

CHAIRMAN THOMADSEN: Yes.

MS. HOLIDAY: I'll do a meeting wizard and we can try to figure out which day works, and then we'll announce it in the Federal Register Notice.

CHAIRMAN THOMADSEN: Great. Good. Thank you very much.

MS. DUDES: Excuse me.

CHAIRMAN THOMADSEN: Yes.

MS. DUDES: I just wanted to comment. I really appreciate you moving that up -- the date, and the work that you are going to do. This Committee is

so important to be advising NRC on their rulemakings. And although it is a long process in drafting the regulatory basis -- and we talked about this I think at the meeting in the spring -- the -- to the extent that we can engage the Committee as early as possible in the development of the thinking, is where we will reap maximum benefit in making sure that the regulations, as they are drafted, are reflective of the views of this community. So I do appreciate very much you moving up your deadline and working that.

CHAIRMAN THOMADSEN: My pleasure.

And with that, I think we are ready to adjourn for lunch. Oh, no, the administrative closing.

MS. HOLIDAY: You're just rushing because you know what's upstairs.

CHAIRMAN THOMADSEN: I know.

(Laughter)

And it's all your fault for showing me the pictures.

MS. HOLIDAY: I know. I tempted Dr. Thomadsen this morning by showing him the picture.

CHAIRMAN THOMADSEN: Of a brownie, but that's --

(Laughter)

Are we still live?

MS. HOLIDAY: A picture of brownies.

CHAIRMAN THOMADSEN: Please, Ms. Holiday?

MS. HOLIDAY: Okay. So during the May meeting, we discussed moving the spring meeting to the March/April timeframe, so that there is actually six months in between the spring and the fall meeting. So we looked at the March and April calendars. And so similar to all of our other meeting plannings, I sent out a meeting wizard, and so everyone indicated their availability.

And when I sent this out, I was also informed that if the ACMUI wishes -- and I'm sure the ACMUI does wish to have a meeting with the Commission, so that we can get back on the annual Commission briefing, the days that they are available is March 24th or March 26th.

So with that in mind, on the 23rd and the 24th, it appears that only one person had a conflict and that was Ms. Weil. And we did speak about that, so I think we have solved that issue.

And then, of course, for the alternative Commission meeting date of the 26th, that would mean the ACMUI meeting would be the 26th and the 27th. There are three members who have conflicts, or actually two

since Dr. Guiberteau will not be joining us. So that is another possibility.

And then, when you look at other dates, say we say that our first choice is the 23rd and 24th, because that appears to have no conflicts with anybody, then you would just need a tentative backup date. If that's the case, then there are a few days where there is just one person or two people that have conflicts.

Dr. Ennis?

DR. ENNIS: I have a conflict with the 23rd and 24th.

MS. HOLIDAY: Oh, no. Okay. Well, then my question, Dr. Ennis, is do you have a conflict -- well, do you have a conflict with the 26th and 27th?

DR. ENNIS: I don't. I think those dates would be okay.

MS. HOLIDAY: Okay. So then my --

MEMBER MATTMULLER: Excuse me. Sophie, I actually have a conflict on the 27th.

MS. HOLIDAY: On the 27th. So it's looking like, if we want to meet with the Commission, if we do it on the 23rd and the 24th, our newest member will not be able to join us. If we plan it for the 26th and 27th, we will have three members who will not be able to join us. Or if we pick a different date where

all of the Committee members can be here, or one or two are not here, then we will not be able to have the Commission meeting on the 24th or the 26th.

CHAIRMAN THOMADSEN: Do we have a date that all the members could attend?

MS. HOLIDAY: I think Dr. Langhorst has a --

MEMBER LANGHORST: On the 13th and 14th of April, that is not ideal for me, but I can make it --

MS. HOLIDAY: Okay.

MEMBER LANGHORST: -- here, if that works for everybody.

MEMBER SUH: Also, Sophie, the 19th and the 20th I am not sure why I am shown out. I am actually available those days.

MS. HOLIDAY: Okay. So then the days -- well, then, the days that everyone was available is March 19th and 20th. Does that work for you, Dr. Ennis?

DR. ENNIS: March?

MS. HOLIDAY: March 19th and 20th.

DR. ENNIS: Yes.

MS. HOLIDAY: Yes. Okay.

CHAIRMAN THOMADSEN: What about Dr. Suh?

MEMBER SUH: I'm checking my Outlook. It's okay, actually.

MS. HOLIDAY: Okay. And then -- so then it appears that the next set of dates where everyone is available, although not ideal for Dr. Langhorst, is April 13th and 14th. Is that correct?

So, then, would we want our first choice for a meeting to be March 19th and 20th, with the backup date of April 13th and 14th? And we can work with the Commissioner's staff to see if we could possibly move dates.

CHAIRMAN THOMADSEN: Yes. But it sounds agreeable. Yes.

DR. ENNIS: Could you give the dates again?

MS. HOLIDAY: Sure. The second set of dates, Dr. Ennis, is April 13th and 14th.

DR. ENNIS: April 13th and 14th?

MS. HOLIDAY: Not good?

DR. ENNIS: Not good.

MS. HOLIDAY: Okay.

DR. ENNIS: I apologize.

MS. HOLIDAY: That's okay. Well, what we can do is we can either pick our backup date to be either March 23rd and 24th or April 13th and 14th. And what I can do is I can ask the Commissioners' staff to see, first, if we can do a Commission meeting either on March

19th or 20th. And if they say no, we can see if they can do it the 13th or the 14th.

We already know that there is going to be a conflict for the 13th and 14th of April and the 23rd and 24th of March for Dr. Ennis. But as backup, because that will be our backup date. Our primary date will be March 19th and 20th, with the backup dates of either March 23rd and 24th or April 13th and 14th. Does that sound like a plan?

CHAIRMAN THOMADSEN: Sounds like as good as we can do at the moment.

MS. HOLIDAY: Right.

CHAIRMAN THOMADSEN: When do you think you will have this --

MS. HOLIDAY: I will reach out to staff maybe this week or next week. Hopefully, I can have a response to you guys, because they do Commission agenda planning at a specific date and time. So I have to work around their schedules. I think you have a comment.

CHAIRMAN THOMADSEN: Oh, I'm sorry.

MS. FAIROBENT: Yes. Lynne Fairobent. Just to point out, the NCRP meeting is the 16th and 17th. I don't know if it would be more beneficial for members to be able to meet on the 18th and 19th and not -- for

those who would be attending the NCRP meeting, which is on radiation regulation this year.

CHAIRMAN THOMADSEN: Dr. Langhorst?

MEMBER LANGHORST: I have a commitment already on the 18th for a subcommittee then, so, no, it wouldn't for me, but --

MS. HOLIDAY: Okay. So I will proceed with March 19th and 20th as our first date. Our backup dates are March 23rd and 24th or April 13th and 14th.

Okay? So now that brings us to our updated recommendations and actions chart for 2014. So I'll start off by saying for Item 4, which is the Subcommittee on the Y-90 Microspheres Medical Event Reporting Criteria, I can officially close this subcommittee and remove it off of our list as we have committed to do in removing all subcommittees off of our list because that subcommittee has already presented their report.

And then if you move down to Item 10 -- just a little bit up, Gretchen. Right there. Item 10 -- Items 10, 11, 12, and 13 have to do with the recommendations that came out of the Y-90 Microspheres Medical Event Reporting Criteria Subcommittee.

The ACMUI endorsed all three of the recommendations, and then endorsed the overall

subcommittee report, which means that the report will be published on the NRC reports website as the Committee's report, final report.

Item 14 refers to the ACMUI bylaws. The ACMUI endorsed all of the changes to the bylaws, including the proposed changes or proposed language in Section 1.3.5 and 3.1 and also the changes that Ms. Dudes recommended, being the main change for the office and the division.

Item 15 is where the Committee requested that staff provide them with a contact list for the NRC Commissioners. I am compiling all of the information of all of the staff contacts that I think you should have, including Commissioners, the new NMSS management, and the medical team members. So I will send that out to you all either this afternoon or tomorrow.

Item 16 refers to the memorandum that I sent to the Commission regarding to the international practices of patient release. I did commit to provide that to the Committee, and I sent that out last night. So I hope everyone received that. Not sure if you would have read it, but I sent that out last night. So I consider that item closed.

Item 17, Dr. Thomadsen tasked Dr. Langhorst and Mr. Costello with creating a proposal to present to

the Committee and staff regarding the costs and logistics for an additional face-to-face meeting and/or a medical regulatory information conference.

Dr. Langhorst?

MEMBER LANGHORST: Can we clarify yet that that -- we will have a staff member to work with?

MS. HOLIDAY: You will. We just --

MEMBER LANGHORST: I mean, it's --

MS. HOLIDAY: As soon as management has identified who the staff person will be, I will update this chart and inform the both of you.

MEMBER LANGHORST: Just because I don't know that Frank and I can do this on our own.

MS. DUDES: We will provide that, and I think, you know, part of the discussion -- so I'm glad, Frank, that you're doing that, is to see if -- you know, to take a step by trying to see what we can add on a day at OAS and how we would fund that. So I will get you a contact person shortly and see what topics the committee would like to include.

I think Boston is a good location. We get a lot of -- should get some places to --

MR. COSTELLO: That's a great location.

MS. DUDES: Yes. I just --

MS. HOLIDAY: Okay? Item 18 is where we

have tentatively scheduled the meeting. I won't repeat the dates again, because we just said it.

And then another item that I did not add, the last two items that I did not add because we just discussed them, was that Dr. Thomadsen has tasked the existing radiation oncologists on the ACMUI -- and he requested the assistance of Dr. Ennis -- to work with ASTRO for their proposed language changes to the FY15 water and energy bill.

These individuals will then present this information to the Committee for their endorsement. Are there any issues with that recommendation or action? Okay.

And then, the very last action that I have is that Dr. Thomadsen created a subcommittee to review the ANPR for the Part 20 that was published in the Federal Register. They will have their recommendations around the Thanksgiving timeframe, and we will tentatively set a teleconference sometime after that report comes out.

The members on that subcommittee are Dr. Langhorst as the Chair, Dr. Pat Zanzonico, Mr. Frank Costello, and Mr. Steve Mattmuller.

Are there any questions or comments on any of these recommendations or actions?

CHAIRMAN THOMADSEN: Mr. Mattmuller?

MEMBER MATTMULLER: Yes. I'm pleased to see the subcommittee for gallium-68 made it to this list. But, also, should not the subcommittee on addressing Part 35 rulemaking make it to this list, or it's okay that it's on an older list?

MS. HOLIDAY: It's on an older list, because that subcommittee did all of their work on 2013.

MEMBER MATTMULLER: Okay.

MS. HOLIDAY: So until further actions come from the rulemaking subcommittee, they don't make it back onto the chart, so we don't, like, carry over. It is just whenever the next action comes up, then you are added on the list.

MEMBER MATTMULLER: Just didn't want it to be forgotten.

MS. HOLIDAY: So I'm sure that there will be a flurry of activity in 2015. I'm sure there will be quite a lot of activity from that subcommittee. So have no fear.

CHAIRMAN THOMADSEN: Thank you. Mr. Costello?

MR. COSTELLO: Yes. I'd like to comment on -- thank you -- something that initially came out during Dr. Welsh's presentation on medical events that

I would like us to at least consider having the subcommittee look into, and that is the interpretation of patient intervention.

And during our discussions about Y-90 microspheres, at least it was clear to me I think that the interpretation of patient intervention by the medical -- most members, not all of the members of the -- of our subcommittee, was different than what I understand the interpretation of patient intervention to be from my time at the NRC and my time in Pennsylvania.

I believe that -- and the NRC can correct me or not -- that the traditional interpretation basically is intentional or unintentional action by the patient that changes the course of the treatment. So if a patient gets off the -- up off the table from external beam, or the patient pulls tubes out during HDR, or something like that, it could be while they are sleeping or it's unintentional or they become uncomfortable and they stand up, or what have you.

But I think what came out during discussion is, well, one what I would call passive patient intervention, where the physiology of the patient -- remember you talked about the pubic arch when you were talking about the prostate. And it came up when we were discussing the Y-90.

Now, the physiology of the patient is such that despite the physician doing everything properly, and the medical staff doing everything properly, the outcome of the treatment is that an unintended organ gets a dose beyond what the limits would be, or the intended organ gets a dose under what it would be.

I think there is a big difference in understanding what patient intervention means. Patient intervention can include what I would call this passive intervention. And so I think it might be worthwhile for some members of the Committee to get together.

And now the rule -- I don't think this requires a rulemaking, really. The rule I think is what it is; it's a matter of interpreting what is meant by "patient intervention. Should that include passive interventions, physiology of the patient, the pubic arch, or is it only limited to things the patient actually does?

So I think it might be worthwhile for us to talk back to -- give the NRC some recommendations.

CHAIRMAN THOMADSEN: I agree fully. And the -- I had planned on having a discussion of that at our next meeting.

MR. COSTELLO: Okay.

CHAIRMAN THOMADSEN: And naming a subcommittee to come up with a proposed interpretation at that time. If waiting until the next meeting is acceptable--

MR. COSTELLO: I think that's fine.

CHAIRMAN THOMADSEN: It's fine.

MR. COSTELLO: Excellent.

CHAIRMAN THOMADSEN: So -- I see Sophie is writing down already, so I think we have – you've got it on the agenda.

Any other comments from the Committee on where we are or what we need to do? And hearing none, thank you very much, Ms. Holiday.

At this point, I'll ask, is there anything else that you would like to bring up before we break for lunch?

MS. DUDES: No. I know everybody wants to go to lunch. I will talk to you during lunch. But I just wanted to thank you again. I appreciate all of the participation. I thought the discussions yesterday were fascinating and very rich, both topically and the sharing of information. So I look forward to comments on Part 20, ANPR, and our next meeting.

Thank you.

CHAIRMAN THOMADSEN: Thank you. So we

stand adjourned for lunch.

(Whereupon, the above-entitled matter went off the record at 11:30 a.m. and resumed at 12:41 p.m. in Closed Session.)