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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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MEETING

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MONDAY,

SEPTEMBER 29, 2014

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The meeting was convened in room T-2B3 of Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, at 8:30 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
ASHLEY COCKERHAM, FSME/MSSA
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

MEMBERS OF THE PUBLIC PRESENT:

DEBRA BENSEN, Elekta

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

LYNNE FAIROBENT, American Association for Physicists in Medicine

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

C O N T E N T S

P R O C E E D I N G S

8:32 a.m.

CHAIRMAN THOMADSEN: Good morning. And welcome to the Fall 2014 ACMUI meeting. And to start us will be Mr. Fuller.

MR. FULLER: Thank you Dr. Thomadsen. As the Designated Federal Officer for this meeting, I'm pleased to welcome you to this public meeting of the ACMUI. My name is Michael Fuller, and I am the Medical Radiation Safety Team Leader. And I have been designated as the Federal Officer for this Advisory Committee in accordance with Title 10, Code of Federal Regulations, Part 7.11.

Present today as the Alternate Designated Federal Officer is Sophie Holiday. This is an announced meeting of the Committee. It is being held in accordance with the rules and regulations of the Federal Advisory Committee Act and the Nuclear Regulatory Commission. The meeting was announced in the July 15, 2014 edition of the Federal Register.

The function of the Committee is to advise the staff on issues and questions that arise on the medical use of byproduct material. The Committee provides counsel to the staff, but does not determine nor direct the actual decisions of the staff or the

Commission. The NRC solicits the views of the Committee and values their opinions.

I request that whenever possible, we try to reach a consensus on the issues that will be discussed today and tomorrow. But I also recognize that there may be minority or dissenting opinions. If you have such opinions, please allow them to be read into the record.

At this point I would like to perform a roll call of the ACMUI members participating today. Dr. Bruce Thomadsen?

CHAIRMAN THOMADSEN: Here.

MR. FULLER: Dr. Mickey Guiberteau?

VICE CHAIRMAN GUIBERTEAU: Present.

MR. FULLER: Dr. Philip Alderson?

MEMBER ALDERSON: Here.

MR. FULLER: Mr. Frank Costello?

MEMBER COSTELLO: Here.

MR. FULLER: Dr. Vasken Dilsizian?

MEMBER DILSIZIAN: Here.

MR. FULLER: Dr. Sue Langhorst?

MEMBER LANGHORST: Here.

MR. FULLER: Mr. Steve Mattmuller?

MEMBER MATTMULLER: Here.

MR. FULLER: Dr. Christopher Palestro?

MEMBER PALESTRO: Present.

MR. FULLER: Dr. John Suh?

MEMBER SUH: Here.

MR. FULLER: Dr. Orhan Suleiman?

MEMBER SULEIMAN: Here.

MR. FULLER: Ms. Laura Weil?

MEMBER WEIL: Here.

MR. FULLER: Dr. James Welsh?

MEMBER WELSH: Here.

MR. FULLER: And Dr. Pat Zanzonico?

MEMBER ZANZONICO: Here.

MR. FULLER: Okay, I would like to note for the record that we do -- we have established a quorum for this meeting. I would also like to add that this meeting is being webcast so other individuals may be watching online.

We have a bridge line available, and that phone number is (888) 370-8140. And the pass code to access the conference call bridge line is 91489#.

Following a discussion of each agenda item, the ACMUI Chairman, Dr. Bruce Thomadsen at his option, may entertain comments or questions from members of the public who are participating with us today. We ask that one person speak at a time as this meeting is also being closed captioned.

At this point I would like to turn the

meeting over to Dr. Laura -- I'm sorry, to --

MS. DUDES: Oh, thank you very much. I like that.

MR. FULLER: Turn the meeting over to Ms. Laura Dudes. She is the Director for the Division of Material, Safety and State Agreements, for her opening comments. Laura?

MS. DUDES: Good morning everyone. I'm happy to be here. I want to welcome you all back. It seems like six months has gone by very fast. And I appreciate all the efforts that have gone on in the last six months with discussions and other things for the very important work we have to do.

People first. So I really want to take a moment to recognize people. First of all, Dr. Suleiman will retire from the FDA and also from this Committee this year. And I can't express enough gratitude, thanks and appreciation for all that you've done both for the Committee and for the Nation in your service, so I thank you.

(Applause)

MS. DUDES: It's going to be a big pair of shoes that we'll have to fill. So I appreciate all of that.

Dr. Guiberteau, his term will end in January

2015 and we will be soliciting for that. But I want to thank you as well. I've only been as you know, with this Committee and with this job for about a year now. And I've come to really appreciate the individuals and their perspectives that they share. And I see them through emails and other.

I also go back in history to look at papers and positions from the Committee. And so thank you, you've been an incredible contributor to the ACMUI.

(Applause)

MS. DUDES: And Dr. Welsh, your term will end in February 2015. So again, the same expression of gratitude and appreciation for your opinions and your willingness to dialog on the issues. In the last meeting I thought you were a very active participant. And we appreciate that. We need that.

As you know, during our Commission meeting there was some discussion about how we get our medical advice. So active participants in this Committee help us shape regulations that keep people safe. But also support you know, the medical community in this country. So thank you.

(Applause)

MS. DUDES: Okay, and I'd like to extend a special welcome to Dr. Ennis who will be joining the

Committee. And I am glad you could attend this meeting. Hopefully it will be a good dialog and we'll make some progress and set some future goals for our meeting in March -- March? Sometime in the spring.

So I just wanted to talk briefly. So Mike introduced me as the Director of Material, Safety and State Agreements. As of next week the Office of Federal and State Materials and Environmental Programs, known as FSME, which I finally learned how to say, will merge into the Office of Nuclear Materials Safety and Safeguards - which is where we came from.

Many of you who have been working with the medical community and the NRC and the medical branch know that this was a branch in this office. Cathy Haney will be the Office Director. Scott Moore is the Deputy Office Director.

We're very lucky, I'm very lucky too, because my two new bosses have extensive experience in this area. And in particular Cathy worked on the Part 35 Rule. She worked on Patient Release ten years ago. So she's very familiar with what we do. And she's a big supporter of the Committee and the work that we do.

So -- and I know they would like to be here, and they will probably drop in at some point during the meeting. I don't feel like that this will impact the

Committee at all. But if you see any impacts, please don't hesitate to call me if services or interactions change. We don't want the merge to impact the work that we're doing.

You also may have heard Commissioner Magwood went to Paris to head the Nuclear Energy Agency over there under the Organization for Economic Cooperation and Development. And Commissioner Apostolakis has left the Commission.

We have two new Commissioners. Jeff Baran will be joining us I believe mid- to end of October, planned. And also Mr. Steve Burns, who used to be the General Counsel for the NRC. And he should be here in November. So we look forward to having you know, the full compliment. Five is always better. We get more opinions and more thoughtful dialog amongst the Commission when it's full.

So those are a couple of the announcements I wanted to make. I also wanted to thank Ashley Cockerham who has been our technical assistant for the past five or six months. But she's not here, so I'll wait to do it so we can publically thank her later.

I know there's a lot of technical issues to be discussed. I know we have patient release and then Y-90 microspheres on the agenda. I did want to talk,

I know we did send to all of you the draft Senate Appropriations language regarding Source Security. It's an active topic on the Hill right now.

Myself, Michael Weber and Mark Satorius went down to speak with the staffers in the Senate Appropriations Committee as well as the House Appropriations Committee; and then we had a meeting with some folks on the Authorizing Committee.

And so we're just having discussions about what's in that legislation and what it may mean for the future of Source Security. I don't really have anything more definitive then that. This -- the Congress is now in recess until after the election. So we'll keep you informed as things go on.

So with that, anybody have any questions? Comments? Okay. Well I look forward to the meeting. And hopefully we can all have an active and engaged dialog on these topics. Thank you.

CHAIRMAN THOMADSEN: Thank you. Thank you very much. And Sophie, are you ready? Yes. We're going to go over our old business and see where we stand on the issues that we dealt with. This looks like a handout that should be in front of you. Ms. Holiday.

MS. HOLIDAY: Good morning everyone. So I think this is our most favorite topic of every meeting,

to go over our old past recommendations and see what the status of those recommendations and actions are. And see if there's anything open.

So as I've said probably for the past few meetings, everything here on 2007 -- bear with me, I got a new clicker, check out this brand new and fancy clicker -- maybe we're having some glitches with it.

Everything on 2007 is included in our current Part 35 Rulemaking. So there's no update on that. As you all know, the proposed Rule was published in the Federal Register in July and is open for public comment until November 18. So we thank the Committee for all their extensive work on that.

And we go over to 2008, this is the same. Everything is included in the Part 35 Rulemaking with the exceptions of Items 5, 19 and 22. Similar to the May meeting, these are delays, meaning they are not included in this current proposed Rulemaking.

And you go over to 2009. These two items here are again in the current Part 35 Rulemaking. 2010, of course, all those items were closed, so that chart is not included.

In the 2011 chart, the same thing goes. Everything is in the current Part 35 Rulemaking, with the exception of number one, which is with the release

criteria. That's delayed. And then of course Item 5 is the annual reporting structure review.

And then you move to Item 2-- or chart 2012. That again is the annual Committee's review saying that they have to continue reviewing the Committee reporting structure.

We move to 2013. This was the year that we had the two teleconferences on the Rulemaking. So all these are considered in the Part 35 Rulemaking except for Item 21 which has to deal with -- I'm sorry, I'm moving a little too fast.

Item 21 has to do with Mr. Mattmuller's request for regulatory relief for the decommissioning funding plan for germanium/gallium-68 generators. This again is touched upon in 2014.

A subcommittee was formed and that subcommittee was supposed to present to the full Committee at this meeting. But it was delayed until the next spring meeting.

Item 27 talks about the bylaws subcommittee. I have closed, per the Committee's request at the May meeting I've removed all the subcommittees from these recommendation action charts except for the subcommittees who have not closed out their actions yet.

So for Item 27 this has to do with the subcommittee that was formed to revise the ACMUI bylaws. Hopefully by this afternoon we can revise those for good.

Then we move over to 2014. The first Item on the report has to do with Dr. Guiberteau's subcommittee to revise the medical reporting criteria of the yttrium-90 microspheres 35.1000 licensing guidance. We look forward to hearing from that subcommittee later on this morning.

Item 6 has to deal with that decommissioning funding plan germanium gallium-68 subcommittee which I've already mentioned. Item 7, I have this in red because I've closed this Item. I committed to providing that germanium/gallium-68 subcommittee with guidelines for developing a regulatory basis. This was distributed to that subcommittee on June 6.

Item 8 is where the ACMUI committed to holding this meeting on September 29 and 30. And it looks like everyone is here. So we can close that Item.

And for the last Item, this came from the August 20 teleconference meeting where the ACMUI met to discuss revisions to the ACMUI bylaws. But it was decided that we would defer that vote and further discussion until this meeting today.

Are there any questions?

CHAIRMAN THOMADSEN: I see no questions. Thank you very much for the rundown.

MS. HOLIDAY: Thank you.

CHAIRMAN THOMADSEN: Next is the discussion of the Physical Presence -- Physical Presence Requirements for Perfexion™. And this conversation will be led by Dr. Suh and Dr. Howe. Dr. Suh, yes?

MEMBER SUH: Good morning. I'm going to discuss Physical Presence Requirements for the Gamma Knife Perfexion™. And the objectives are to provide a brief overview about the Gamma Knife for those of you who are not familiar with the Gamma Knife.

It provides some fundamental differences between the Perfexion™ Model B, C and 4C units. And discuss the current requirements for physical presence for the Gamma Knife.

In terms of the Gamma Knife, the Gamma Knife is a device that allows us to deliver a very high dose of radiation to a precise located target. The accuracy is within 0.5 millimeters. It's one of the major forms of stereotactic radiosurgery used to treat vascular malformations, benign brain tumors, malignant brain tumors and functional disorders.

In the United States since 1987, over 221,000 cases have been performed with the Gamma Knife,

if you look at the past 26 years. In terms of the various units, the older units, the Model B, C and 4C units, these units have 201 cobalt-60 sources which are stationary. There's an external helmet which has different sizes, 4, 8, 14 and 18 millimeter apertures which are directed towards the target.

And the Model B uses manual trunnions where the physician or therapist or medical physicist actually manually sets the X, Y and Z coordinates. Whereas with the automatic ignition system, which is shown here, in the Model C and 4C, this is done by the onboard system.

The Perfexion™ is different than the Model B, C and 4C units in that it has, rather than 201 cobalt-60 sources, this has 192 cobalt-60 sources which are -- which move within eight permanently installed independent movable sectors. And these sectors are the 4, 8, and 16 millimeter beams.

So there's one common air body with different diameters of the beams which correspond to the different positions where these beams come into place. And this is -- the machine itself uses a robotic cable which positions the patient's head position so that the beam is precisely delivered to the intended target.

So in the current regulations, the Model B, C and 4C are regulated by 10 CFR 35 Subpart H, whereas

the Gamma Knife Perfexion™ is 10 CFR 35 Subpart K as shown.

So here's the background of the current regulations. All Leksell Gamma Knife procedures are regulated by 10 CFR 35.615. And requirements are via the 10 CFR 35.615(f)(3). It states that an Authorized User, AU, and an Authorized Medical Physicist, AMP, are physically present throughout all treatment involving the unit. The NRC defines physical presence as a distance "such that each can communicate with the other within hearing distance of normal voice."

In terms of Leksell Gamma Knife, there's a lot of training which is involved with this -- with these units. The training involves the device operation, the safety procedures which are involved, and the clinical uses which are involved with the Gamma Knife as well as the requirements of the Authorized User and Medical Physicist.

In terms of the operator, proper training is very important to ensure safety to the patient. And some of the requirements of proper training include how to release the patient from the couch. How I can move the couch out of the machine when there's a malfunction in the machine. How to release the frame from the frame attachment. And also how to shield the doors manually.

So these are all the forms of proper training for Gamma Knife uses.

In terms of rationale behind removing physical presence requirements for the Perfexion™, we know that the events requiring Authorized User or Authorized Medical Physicist are very rare. Patients -- they also, one of the thoughts is that patient safety would not be compromised by not having the Authorized User and Authorized Medical Physicist physically present throughout the entire treatment. But any person who is properly trained would be able to perform this task.

Now, if you take the ViewRay™ System, which also uses cobalt-60, it actually has a large source of cobalt compared to the Gamma Knife. This uses three cobalt-60 sources on a rotating gantry assembly that's integrated with an MR unit. So it's a very unique radiation delivery system.

This is regulated by 10 CFR 35 Subpart K. In lieu of 35.615(f)(3), this requires an Authorized User or Authorized Medical Physicist will be physically present in the department during the patient treatment and immediately available to come to the treatment room in an emergency. So this is a difference compared to the Gamma Knife Perfexion™'s regulations at this point.

So how often does a person actually enter the Gamma Knife unit to mainly undock a patient and close the shielding doors, which would be one of the concerns that one would have. So no one really knows the actual incidence according to the manufacturer of the Gamma Knife which is Elekta. This occurs very, very infrequently. And what they estimate is that this occurs about one in five thousand and one in ten thousand cases.

The time to physically undock a patient who is physically stuck to the unit and the amount of exposure that occurs, so the time to just undock the patient would take about 30 to 60 seconds. So it does not take very long. Again, this is provided that the person who is undocking the patient is properly trained. The exposure is less than 10 milligray, which has really negligible effect on the patient.

In terms of reasons for continuing Authorized User presence, there are a number of potential reasons why we would continue to have the AU physically present throughout the entire treatment. It would verify the integrity of the setup at the treatment machine.

We know that on occasions when we look at some of the reports of some of the deviation that occurs

to Gamma Knife, it occurs with wrong site being treated. So actually having the Authorized User there from the very beginning would help really minimize that from occurring.

Also verified cart position with the use of in-room cameras that are focused on the patient and machine. So one of the things that I do when we are physically treating a case, is actually watch which direction the patient is moving so we know that if we're treating a left sided region, the patient should move over to the right and vice versa.

Also manage any clinical issues and/or treatment related toxicities that may occur during the Gamma Knife procedure. Also to be physically present for any critical decision making processes such as aborting the procedure in case something occurs where the patient's unstable during the treatment. Particularly for those treatments that are very long.

Also disconnect the patient from the machine in case of a malfunction. Which, although quite rare, is something that does require that the patient is physically released from the machine in a quick and expeditious manner.

And also to provide greater confidence to the patient and family during treatment by being present

near the console areas. So in the rare event that an event should occur, the physician, or Authorized User is actually there to explain what has happened.

In terms of safety and Authorized User presence, it's important to recognize a problem when a situation does occur. So by actually physically being there to actually witness what actually occurred during the event, make a determination of the severity of the problem. And also to know the dose that was delivered to the incorrect treatment site if that were to occur as well.

I'll take any questions?

CHAIRMAN THOMADSEN: Before we take the questions and have discussion on this, one of our members will be recusing herself; Dr. Langhorst, would you like to explain?

MEMBER LANGHORST: Yes, thank you. I just wanted to let the Committee know that Washington University in St. Louis has a license and sent an amendment request into our Region Three office requesting a change in Authorized User presence for Gamma Knife therapies.

And we're asking is what we had in place prior to the change in Part 35 in 2002, where that physical presence of the AU and AMP was first required.

What we're requesting is to go back to the Authorized Medical Physicist will always be present, or an Authorized Medical Physicist. And then the Authorized User will be present at the beginning of the therapy.

And then either the Authorized User or the Neurosurgeon involved with this patient, who knows the patient well, who is trained in the exact same way that the Authorized User is trained by the Gamma Knife manufacturer -- Goes through that same treatment planning and all that training and emergency training and emergency medical response.

So I just wanted the Committee to know that I had this request into change our license. And so I was going to recuse myself from the discussion.

CHAIRMAN THOMADSEN: Thank you for the clarification. Now Dr. Suleiman.

MEMBER SULEIMAN: These may be pretty basic questions. But maybe somebody else doesn't understand them either. How many treatments per patient is it, by conventional therapy? I've got four questions, so let me run through them and maybe you'll be able to answer them all quickly.

How long does it take to do a single treatment? A minute? Five minutes? I have no feel for the system.

When you said ten milligray, is that to the target organ where you said turning the patient out would result in possibly an extra ten milligray. Is that to the target organ then is what I'd assume?

And when you said one in five thousand, do they know about -- are these predominantly equipment failures? Or you know, user problems?

And the last question was a -- a fifth actually. You said that there's been over 221,000 cases through 2013. What's the annual workload on these types of devices?

MEMBER SUH: They're not invalid, so. Well let's go through them one by one, so.

Typically for a Gamma radiosurgery it's a single fraction or single session of radiation, although there is a modification with the Gamma Knife which actually allows us to do fractionated treatments. But for all intents and purposes, it's a single fraction of radiation for the various conditions, the benign tumors, malignant brain tumors, vascular malformation function disorders.

In terms of the treatment time, it really varies on a number of factors: the number of lesions that we're treating, the dose that we're using, and the activity of the unit itself. So a very short treatment

would be 10 to 15 minutes. A very long treatment could be five hours.

MEMBER SULEIMAN: Okay.

MEMBER SUH: So it really varies from patient to patient. In terms of the dose, the organ is actually the target site itself. So one of the nice things about Perfexion™ is that the amount of radiation exposure to non-target organs is much less compared to Model B, C and 4C.

In terms of the actual incidence of one in five thousand, again that's what a -- that's what the manufacturer -- or one in ten thousand is what the manufacturer is estimating the risk to be. And that can typically be a malfunction.

One of the things that happened to us is that we had power outage, it actually kicked the patient out of the machine. But if things don't work, sometimes you have to manually retrieve the patient if that were to occur.

And then in terms of the 221,000 cases per year, that number continues to go up. Worldwide over seven hundred thousand patients have been treated with the Gamma Knife as of 2013. So each year the number goes up.

And in terms of each institution, there are

some institutions that don't do many cases. There may be less than a hundred per year, whereas very busy centers go over five hundred per year. So you have quite a range in terms of the number of cases being done.

CHAIRMAN THOMADSEN: Mr. Costello?

MEMBER COSTELLO: I have two questions, mainly to do with the NRC. You referenced the requirements for the ViewRay™, right? It got approved?

MEMBER SUH: Yes.

MEMBER COSTELLO: Okay. And you mentioned it's under 35.600. Why isn't the ViewRay regulated under 35.1000? I know it's going to be regulated under 35.600. So I think with that requirement, the ViewRay™ really is going to product for the ViewRay™. I think that the NRC or somebody is going to come up with requirements for the ViewRay™. Am I right there? Are they seeking that?

MR. FULLER: Yes, this is Mike Fuller. Yes you are correct Mr. Costello. And in fact I think that's what Dr. Suh said. The ViewRay is being regulated under 35Subpart K, which is what we refer to as 35.1000. And yes, so they'll --

MEMBER COSTELLO: I thought that 35.600 referenced up that for the ViewRay™. Maybe I'm figuring that --

MR. FULLER: Yes, so he said for the Gamma Knife, it was 35.600, Perfexion™ 35.1000. And for the ViewRay™, so that he had -- yes, 35.1000(k).

MEMBER COSTELLO: Okay, so the slide that's up there now says in lieu of 35.615, part (f), is that what the requirement is for the ViewRay™? Okay, thank you.

And the other question I have is, are the -- the position that you're taking, would that be any different than the other Gamma Knives that we've had? In other words if we were to relax the AU presence requirement for the Perfexion™, should we consider relaxing them for the other Gamma Knives?

MEMBER SUH: So Gamma Knife is one form of stereotactic radiosurgery that uses radioactive isotope cobalt-60. The other stereotactic radiosurgery systems actually use linear accelerators for that. But they're not regulated by ACM -- or by NRC.

MEMBER COSTELLO: But I meant to say, the other Gamma Knives that they've talked about, okay. If we relax the physical presence requirements for the ViewRay™, should we relax them for them as well?

MEMBER SUH: So apparently all the Gamma Knives, the B, C, 4C, Perfexion™, all are Authorized User presence for the entire treatment. And that's for

stereotactic radiosurgery. So in my mind stereotactic radiosurgery is where you're giving a very high does or an ablative dose of radiation in hopes of in the case of benign brain tumors to ensure the patient and to return the function where it's actually like a very small target.

Whereas with ViewRay™, I think in terms of clinical applications, they are -- they can use it where they're actually treating different body parts.

MEMBER COSTELLO: Understood, I'm not talking about the ViewRay™ anymore. Okay. I'm saying this presentation's about the Perfexion™ unit?

MEMBER SUH: Yes.

MEMBER COSTELLO: Well if we were to conclude that we want to recommend that the physical presence requirements for Perfexion™ be relaxed, should we relax them for the other Gamma Knife types?

CHAIRMAN THOMADSEN: Dr. Welsh?

MEMBER WELSH: If I could just quickly comment. My interpretation of Dr. Suh's presentation was that we were not planning on relaxing Authorized User presence for Perfexion™ or any of the other Gamma Knives.

MEMBER COSTELLO: Okay.

MEMBER WELSH: So please correct me Dr. Suh if I've misinterpreted this.

MEMBER SUH: No. So my position is that the Gammas have a very long and successful track record of safety. And Perfexion™ is a very -- is a great device in treating patients. And right now the current standards that we have in terms of having Authorized User, Authorized Medical Physicist present, I think has helped ensure that.

So I think any change from that, I think would require a lot of discussion and a lot of thinking about what implications that might have.

MEMBER COSTELLO: I understand. I knew there was a request, you know, or an incident request, to relax the request, as it were, before, to cause material… In fact when you talked about how infrequent these events occur, that we might want to support that be relaxed. But that's not your position.

MEMBER SUH: No. I'm just presenting both sides though.

MEMBER COSTELLO: Thank you very much.

MEMBER SUH: In fact we're not going for it and we're for having the current requirement to continue at the present.

CHAIRMAN THOMADSEN: Dr. Alderson?

MEMBER ALDERSON: Yes, two questions. The first one has to do with when you're talking about

wanting the Authorized User to still be present, if the Neurosurgeon's there and has been trained, do you consider an Authorized Medical Physicist plus the Neurosurgeon, is that adequate or does the Authorized User still have to be there?

MEMBER SUH: So right now, Neurosurgeons are not Authorized Users. They have participated in the case. They're very involved with frame placement, treatment planning, helping ensure that we have accorded care of a patient. They are not an Authorized User. So that would not differentiate.

MEMBER ALDERSON: That would not, okay that's the answer to that question. The second question has to do with the Energy Bill that Ms. Dudes mentioned in her introduction, the Source Security Bill.

Now I read through that, and it states in here in concern of Source Security and cobalt-60 is a source about which the Government is quite concerned. That within five years, that they'd like to see those sources replaced with some other kind of source.

And as I looked at that, and I have a little experience, not like you have with the Gamma Knife. I mean, I didn't know what that alternate source might be, or if that, you know, proposal threatened the very existence of the Gamma Knife.

So I just thought -- is this Bill actually approved, or is it still just being discussed?

MS. DUDES: Yes, the Bill right now, it came from the subcommittee of the Senate Appropriations Committee. So what would have to happen is they'd have to conference with the House Committee on Appropriations and then agree on some language.

And so, no. It's still in draft form. And there's still a lot of discussion on that. Although I would like to hear some discussion on that -- the issue you raised because that comes up in our discussions with the congressional staff, in terms of is there an equivalent. And what would the impact of phasing out this particular source? What type of impact would that have on the medical community?

And as far as I know, you know, right now, I'm not sure there are alternatives that are equivalent. So there's only --

MEMBER ALDERSON: I think that the two kinds of instruments, and I'm not trying to distract us from your issue, I'll make this brief. Blood irradiators and blood banks, that's a cesium source. And they -- there are people now that are manufacturing different types of blood irradiators that don't involve radionuclides.

MS. DUDES: Right.

MEMBER ALDERSON: So I think that would be relatively straightforward. But this one, I don't know what you would do to replace those powerful cobalt-60 sources.

MS. DUDES: I don't know either.

CHAIRMAN THOMADSEN: I do want to talk about that issue later in the meeting as a --

MS. DUDES: Okay.

CHAIRMAN THOMADSEN: As a topic. But right now I think we should stick with the Physical Presence issue with this. Ms. Weil?

MEMBER WEIL: So the requirement for the presence of the Authorized User and the Medical Physicist clearly has a benefit to the patient in terms of safety. But is there a countervailing barrier to using this treatment? Making the availability of the treatment because of the time commitment of the Authorized User?

Would clinicians perhaps recommend a different, maybe the linear accelerator based LINAC, do I have that word right?

MEMBER SUH: Um-hum.

MEMBER WEIL: Go in that direction where the requirement is less onerous? I guess my question

is simply, is there a -- does this create a barrier to access to treatment for patients?

MEMBER SUH: So in terms of access to barrier, I do not believe it impairs access to their treatments. It does from the workplace standpoint requiring an Authorized User to be physically present throughout the entire treatment, would impede his or her ability do other medical tasks.

So -- because the current guidelines recommend that -- or current guidelines state that the Authorized Medical User has to be within voice distance. So I can't be you know, a hundred yards away. I mean I would violate the rules in terms of what's required.

So from a patient standpoint, for practices where you would have a very busy Gamma Knife practice, that is something that you do need to juggle in terms of how you have an Authorized Medical User present during the entire treatment. And there are different ways of doing that in terms of ensuring that that occurs.

In part, it's just, you know, working with the schedules to make sure that it fits with this. There are some centers that actually have dedicated bays where the Authorized User actually is present for the entire treatment. So they know from start to finish that he or she will be present for that entire day.

Some of the centers will split up the schedules where there's an Authorized User for the first part and there's another person for the second part of the day. So there's different ways of doing it.

So in terms of access to care, as I mentioned, the use of Gamma Knife really varies depending on the center. There are some centers that are not very busy. They do maybe a couple of cases a week. Whereas other centers will do five to 10, 15 cases in a given week with no problems. So I think it's imperative to access for patient care.

MEMBER WEIL: So do you think that the use of this particular therapy is impeded, because clearly it's a more precise way of delivering radiation, correct? To use the target site.

Do you think that there's less use of this particular modality because of the required presence of the Authorized User? Or is it simply that of those cases that need to be done are getting done this way. And loosening up the requirement would not create more availability for patients to this particular modality?

MEMBER SUH: So there are different forms of stereotactic radiosurgery, there's high dose, high precision radiation. Gamma is one of multiple units that are out there. So depending on your medical center,

what you're familiar with, that's the device you would use.

So I do not believe that this requirement is going to decrease the use of Gamma. If anything the use of Gamma is actually increased. Particularly for patients with brain metastases, which is a very common condition.

Each year over 200,000 Americans develop brain metastases. And it's becoming the preferred treatment modality over the traditional whole brain radiation therapy that we've used for the past 60 years.

So again, I don't think that's a barrier in terms of treatment. But it does from a workplace standpoint, at least for some practices it can make the work a little trickier and that one needs to work around that.

CHAIRMAN THOMADSEN: Dr. Welsh?

MEMBER WELSH: I have a few comments and questions if I might. First, in regards to Dr. Suleiman's question earlier, another factor of course is that the duration of the treatment is inversely proportional to the age of the cobalt-60.

Regarding the estimated manufacturer's figures of one in five thousand or one in ten thousand, anecdotally, I think those are very, very conservative

figures out. I think that if you've had one instance Dr. Suh where you've taken a patient out, and I have and others who've used the Gamma Knife might report something from a few years back. It amounts to something higher than one in five thousand, one in ten thousand.

And that gets to an important point about the Neurosurgeons not being Authorized Users and not being fully equivalent to radiation oncologists in terms of their appropriateness as potential Authorized Users. Without any disrespect intended, they do not have the training in radiation physics, radiation biology and certainly not in radiation safety.

And the one week course that I took, that we all have to take for the vendor's specific training from Elekta or from an institution that uses the Gamma Knife. Certainly is not satisfactory for someone to become an Authorized User without the four year background in radiation oncology in my opinion.

So for radiation safety purposes, a radiation oncology Authorized User presence is still certainly justified. And as he pointed out, the track record of safety with this instrument perhaps justifies maintaining the status quo.

Additionally the fact that this is single fraction stereotactic radiosurgery as opposed to

fractionated radiation therapy differentiates this Gamma Knife from other means of external beam radiation therapy including the ViewRay. And therefore radiation therapists who may be appropriate for a ViewRay™ management and maybe Authorized User presence could be relaxed with a ViewRay™, that analogy does not hold for the Gamma Knife which is single fraction, stereotactic radiosurgery with often with a device bolted to the cranium.

And removing the patient from the machine might require different efforts from what would be expected from a LINAC or a ViewRay™ device. So radiation therapists might be capable of managing the situation with the ViewRay or LINAC, but I don't think a Neurosurgeon would be the appropriate person for any of the above.

For Dr. Alderson's question, I would like to point out that what -- an alternative device, the CyberKnife. In my personal experience, and I've got a fair amount of experience with both the Gamma Knife and the CyberKnife. The involvement of the Neurosurgeon was essentially zero because we do not bolt the device directly to the cranium in the CyberKnife.

Other institutions may have different policy and philosophy, but the Neurosurgeons may bring

up a case in tumor board and suggest radiosurgery and that would be the extent of their involvement. The treatment, stereotactic radiosurgery, whether it's done with a Gamma Knife, a CyberKnife or another appropriate technology is radiation oncology and the physician involved is the radiation oncologist. The Neurosurgeons role is likely as a referral physician.

That is not always the case with the Gamma Knife where the Neurosurgeons have traditionally been more actively involved. And they do have a hands-on role. And that's a slight distinction between Gamma Knife and the other approaches. But it's more of a philosophical rather than a mental or procedural difference.

And as far as Ms. Weil's comment, I think that in my personal experience, there really hasn't been any impedance to patient flow in the clinic from a physical presence requirement of the Gamma Knife. And it hasn't really been very different with CyberKnife versus Gamma Knife.

When there's a CyberKnife case going on, yes I could be doing other things perhaps. But first and foremost it's my obligation to be available for the activity going on in the CyberKnife vault.

So in essence, there really has been no

impedance to workflow or use of the Gamma Knife because of the requirements. And for those reasons, I still advocate as Dr. Suh has mentioned, keep maintenance of the status quo in keeping the Authorized User presence the way it is.

CHAIRMAN THOMADSEN: Point of clarification Dr. Suh. If there's an emergency with the Perfexion™ to remove the patient from the device, do you need to unbolt the patient from the frame?

MEMBER SUH: Yes. We have to release them from the machine itself.

CHAIRMAN THOMADSEN: You release the frame from the machine?

MEMBER SUH: From the machine.

CHAIRMAN THOMADSEN: You do not unbolt the frame from the patient?

MEMBER SUH: No, that's done later on. Yes. So you'd have to release the treatment couch, pull the patient and release them from the -- the tact -- the machine itself.

CHAIRMAN THOMADSEN: I'm sorry what?

MEMBER SUH: You'd have to release them from the machine itself. So the frame itself is not -- you don't remove the frame while the patient's inside the machine.

CHAIRMAN THOMADSEN: Okay. Can we go to your slide talking about -- I think it's the fourth from the end on the requirements for -- yes, that one right there. Of those reasons, which ones would be compromised by having the patient be -- the Authorized User present in the department but not necessarily in that room?

MEMBER SUH: Well the setup I think is very important for the Authorized User to be present at the very beginning. Because if that's set up incorrectly, the treatment's not going to go well. So I think that's imperative in my opinion.

I think correct positioning. We have seen cases through this Committee of wrong side being treated. And that's the last effort of saying am I treating the correct side and is the patient with the correct right. Typical function case, I think that's very important.

The -- and if there's any clinical issues or -- that occur, if I'm not -- if I'm -- again, this is where I think the definition becomes very difficult. There's what constitutes being present in the department. Because as you know, there's some departments that are buildings away.

So you know if I'm in a different building

and I consider that being present in the department and there's some issues that occur, I'm not going to be available for the patient. So I'd say point number three is also -- would be important.

Current decision-making is in my opinion the -- anytime you do a -- this is called radiosurgery. And although it's not surgery in the classic sense, it does require a very high dose of radiation where we are trying to emulate what a surgeon would do in the operating room, whether it be ablated doses to a tumor or to a vascular structure or to a nerve itself.

I think being present for the critical decision-making process whether or not to abort the case, there's some issues with the patient, I think again require Authorized User presence. Disconnecting a patient, that's something that again, I think if someone is properly trained that can be done, although I personally would want to be present if that were the case.

And I think the last bullet point is really more the, you know, from the patient and family standpoint you know, if something were to occur and I were not -- or if the Authorized User were not physically present during that event, and let's say it took me five to ten minutes to come over to actually see what

happened. I measure how that would be perceived by the patient and family.

So again, I think you could -- in my opinion, I think these are all reasons for having Authorized User presence. I think one could argue if one is more critical than the other. But I think it's very important, the set-up is very important. Making sure the correct position is very important in terms of treatment delivery.

And I think if there's any issues that occur during treatment, I think the Authorized User needs to be present to make that decision of -- if something should happen, to abort the case, stop the case. There's sometimes where the patient will, especially if it's a long treatment, they'll say, "I need to get up because my back is really hurting me." I've got to get up because I have to urinate. For various reasons, they have to reset the patient.

So, you know, for those reasons, I think having an Authorized User presence is important.

CHAIRMAN THOMADSEN: Yes, Dr. Zanzonico?

MEMBER ZANZONICO: Pat Zanzonico. I have no first-hand experience with these modalities, so I have a couple of basic questions. The first is what typically, or how do you typically recognize a problem?

It strikes me that that could be subtle and really would require insight on the operation of the entire system and so on, that no any individual might have.

So what typically, if there is a typical instance, how do you recognize that a problem is occurring?

MEMBER SUH: So again, I think you can divide it up into several. So one could be medical. And so we really watch the patients through a couple of cameras that are in treatment. There's also a microphone above the patient so he can say something. So if the patient says, "I'm not feeling well, I need to get out of the machine", we are able to press abort, for the patient to come out.

So I think there are medical reasons for that. I think sometimes you'll see something -- and again, it's very rare, but something in the machine just doesn't, something isn't moving right. And that's another case where you have to make that decision. Do we stop and have the patient come out? Again, it's very rare, but again I think being there and to make that decision as well.

And ultimately from the patient standpoint, my personal experience has been when we go through the risks and benefits of the Gamma Knife

procedure, go through what could happen, what may happen as a result of the treatment, during treatment, that patients have a seizure while they're undergoing treatment. That I have to be actually physically present, I think it's just a lot more comfort to the patient and families that are in this, that entire treatment process.

So I view this very much as being part of a surgical procedure. As making sure that I'm there for all the parts of the treatment.

MEMBER ZANZONICO: I had a second question. If a treatment needs to be aborted, can it be effectively resumed?

MEMBER SUH: Yes it can be.

MEMBER ZANZONICO: Or is it a one opportunity only and if it's not done correct --

MEMBER SUH: No, no, it can be done again. So there are times where -- so there are some patients who for physical reasons, they have a lot of back pain. They say I really need to take a break right now. So we just try to take it between the various shots of radiation so that can start with the next shot.

Sometimes patients will say, "You know, my bladder's getting full, I need to use the restroom." So again, patient comfort is also very important as well.

With the Perfexion™, one of the things that's happened is that in terms of throughput of patients, it's clearly better than in the older units. So the treatment itself are faster, and which is I think great from a patient care standpoint.

Also from an Authorized User standpoint, the physical amount of time that you're spending at the Gamma is going to be less than if you have an older unit like a Model B or Model 4C where you're physically swapping out the various helmets or actually making some changes with the trunnions if you have an older unit.

MEMBER ZANZONICO: Dr. Suh, you know I believe there's some radiobiological advantage to delivering this dose at a high dose rate in a single fraction. So I understand if a patient had a sort of a easing temporarily in single imaging session, stop as you say to urinate or whatever. But what if it was something where the patient had to be treated not later that day, that same day, but a day later or a week later. Could that be done and still be effective?

MEMBER SUH: Since this requires the patient to have a frame on the patient's head, we don't like to keep the frame on the patient's head for a very long time. There have been instances where we have actually kept the patient on -- the frame on the patient

that evening, and treated early the next morning for various reasons.

So again, we want to try to do the treatments in a specified period. So we would not keep the patient's frame on for a whole week for instance.

There is a product that Elekta has made which is called the Extend System, which is a bite-plate system that uses a mold in the back, which actually allows for fractionated treatment, one to five fractions of treatment.

CHAIRMAN THOMADSEN: We have a member of the public who would like to speak.

MS. FAIROBENT: Thank you Dr. Thomadsen. Lynne Fairobent with AAPM. Dr. Suh, of the Gamma Knives in the U.S., about how many of them are there today?

MEMBER SUH: So there are about 100 and -- I'd probably say 120 to 130. I don't have the exact numbers. But if it's a --

MS. FAIROBENT: That's fine. And of those, my understanding is most of them today are Perfexion™. That most of the older units have been replaced. Is that correct?

MEMBER SUH: I don't know if it's most. But I know many of them are being replaced. In fact Elekta has you know, are no longer going to be servicing the

older units. They are moving towards Perfexion™. I mean that's what they want to use as a treatment.

And it has a lot of carry back advantages over the older units, Model B, the C and the 4C units.

MS. FAIROBENT: Okay. And on the slide that Dr. Thomadsen asked you to address, which of those could the Authorized Medical Physicist who has to also be physically present during the entire treatment, if the AU was -- if their requirement was relaxed so that the AU could be in the department, but the AMP had to remain physically present, is there anything there that you would see after the initial setup with the AU present, him moving into the department to do other things?

And I agree, if the department's in another building, we might have to look at the definition distally or geographically what that might mean. But versus personally at the console.

MEMBER SUH: So, I would say that bullet point number five, disconnecting the patient from the machine in case of malfunction is something that a Medical Physicist could clearly do if they're properly trained. I think in terms of the set-up, the Physicist could also be involved as well.

Although again, in my personal opinion, I

think it is very important the physician is there for the set-up because that's where you catch potential errors from ever reaching the patient. I think verifying the position, I think ultimately the Phys -- the Authorized User, which is the radiation oncologist, has to make that decision as well.

And in terms of clinical treatment-related toxicities, that's not the role of the Medical Physicist. Clearly the decision making and they can have some part. But ultimately the Authorized Medical User has to be making that decision.

And in terms of patients and families, Medical Physicists are very important in terms of the overall treatment. For patients with gamma radiosurgery ultimately the physician that has to be the person there.

MS. FAIROBENT: Might this then be a case where the physical presence of the AMP could be relaxed, but the physical presence of the AU maintained?

MEMBER SUH: I think it's a team effort. And as Dr. Welsh mentioned, I think if you look at the safety record for Gamma Knife radiosurgery, I think it's really -- I think it epitomizes when proper training is done and when there's proper education and how safe directors can be quite high for radiosurgery.

And it is a treatment that is continuing to be used more and more often. So I think it is very important that we continue to maintain that high safety standard.

MS. FAIROBENT: Thank you.

CHAIRMAN THOMADSEN: And thank you. We have another member of the public. Please identify yourself.

DR. GOETSCH: Yes, I'm Steve Goetsch. I'm a Medical Physicist at the San Diego Gamma Knife Center. We're about to have our 20th anniversary. We've treated about four thousand patients there.

I'm appearing today as a consultant with Elekta. I've been helping them with the Gamma Knife Perfexion™ since the first one was installed in 2006 at Washington Hospital in Freemont.

I obtained a license before their physicist came onboard. I'm also the Chairman of the AAPM Task Group 178, which is a group I worked for five years on QA and dosimetry calibration procedures for the Gamma Knife.

I want to thank John for his excellent presentation and add one more thing. Two weeks ago in ASTRO, Elekta finally unveiled, although under very restricted circumstances, the newest evolution, the

Gamma Knife Perfexion™ Plus. Coming for some time, I believe it is now FDA approved. And it includes a cone beam CT.

The extended frame that John was talking about has not been very well accepted. There's like five or six in the United States. The new one has a face mask and head frame system. And the whole idea is to do fractionated treatments.

I think it's going to be very well accepted. I think it may end up changing clinical practice of the Gamma Knife. More and more Gamma Knives may go to four or five fractions.

To be blunt, in January of last year, the Fiscal Cliff Bill, language was inserted in that Bill strikingly reducing the amount of money for the Elekta Gamma Knife for single fraction. There's a huge financial incentive to do four or five fractions. People are looking at that.

So that may change things. One other comment I -- perhaps someone here could verify this. At the AAPM meeting in Texas this summer, a Medical Physicist from Texas tells me the State of Texas now places Neurosurgeons on their Gamma Knife license. I haven't verified this myself, but it's been talked about before.

It is an interesting idea. I am not sure I can recommend it, but it is an interesting idea.

CHAIRMAN THOMADSEN: Thank you Dr. Goetsch. Mr. Welsh -- or Dr. Welsh?

MEMBER WELSH: Just a few additional comments to a follow up. When Dr. Zanzonico asked about how we recognize patient problems and what are some of the justifications for physician presence or Authorized User presences. And as Dr. Suh pointed out, in my experience as well, sometimes these patients will have seizures. And appropriately swift intervention may be appropriate.

And there was one instance that I recall where a patient had a mouthpiece in and was unable to communicate through the microphone. But you could see the stomach going up and down. We recognized that this patient is about to vomit.

And had we not been there to recognize that -- and with all due respect to our therapists and Physicists who are there, they didn't pick this up as quickly as the physicians and the Authorized User. That could have been a disaster because of aspiration with the patient locked there in place and that was an example that I could call needing appropriate quick intervention.

As far as the use of fractionation in stereotactic radiosurgery, it's not infrequent and depends on the diseased entity. Maybe not so much for a brain metastasis, but for other conditions, such as acoustic neuroma, is a good example.

Fractionation stereotactic radiotherapy is often used in lieu of single fraction stereotactic radiosurgery. Such fractionation has traditionally been far more frequent with LINAC-based radiosurgery such as the CyberKnife, then it has been with the cobalt-60 based Gamma Knife.

However, I've just heard from Dr. Goetsch that maybe with the -- in the future with the Gamma Knife Perfexion™ Plus, fractionation would be more common with the Gamma Knife as well. But from my perspective, the biggest difference and perhaps the largest justification for Authorized User presence with the Gamma Knife continuing, is that one is cobalt-60 radionuclide source which cannot be shutoff if there is a malfunction.

Whereas with the LINAC-based radiosurgical techniques, they can always be electrically overridden and shut down. So that's one of the main reasons why Gamma Knife radiosurgery differs from say the CyberKnife.

Now this analogy does not hold with the ViewRay™ because it's more akin to conventional fractionated radiation therapy. I would say that if we're dealing with a true stereotactic procedure with the ViewRay™, the analogy may hold. And maybe we could have an argument in favor of Authorized User presence there too, based on the same logic.

But as it is right now, the stereotactic radiosurgery where the patient is immobilized intensively, Authorized User presence is justified with the cobalt more than it is with the electrically administered treatments.

CHAIRMAN THOMADSEN: Thank you very much Dr. Welsh. Yes, Dr. Palestro?

MEMBER PALESTRO: Yes, just a couple of quick comments. Radiation oncology is away from my field, it's nuclear medicine.

And in listening to your presentation at the beginning, in terms of having an alternative to the Authorized User or the Authorized Medical Physicist, I was thinking in terms of malfunction of the equipment of one sort or another that would require shutting it down and removing the patient and so forth.

But as I heard you and Dr. Welsh talk, it becomes apparent particularly since most or maybe all

of these therapies are devoted to the brain and central nervous system, that reasons for discontinuing the procedure may be far more than a mechanical malfunction. They can be serious complications, seizures, perhaps a cerebrovascular accident.

That in this slide where it says any person properly trained would be able to perform the task. I would think that that person would have to have a very sophisticated knowledge of medicine to recognize what all was going on and to be able to do more than just shut off the machine for example, or end the procedure.

MEMBER SUH: I agree. I agree. I think having a physician present, I think the -- and one of the things -- one of the things I also want to bring out as well is you know, when I think about stereotactic radiosurgery, it's very much a team effort between you know, there's radiation oncologists involved, the way the Gamma is done, there's much stronger a surgery presence, a strong Medical Physicist presence as well.

So it takes a team to ensure that treatment is delivered safely, it's delivered accurately. It's delivered precisely as well. So I think it is very much a team effort and as these slides are showing, the track record for Gamma Knife radiosurgery has been superb.

And I think if you compare it to some of the

other radiation device policy, and we have to, it is -- it is something very high. And I think part of it is there is very rigorous training involved. And the processes are -- it's somewhat very prescriptive as to how things are done.

So in terms of trying to, in terms of getting an error to occur, I think we want to try to minimize any of those errors from occurring. So whether the QA is on the machine, et cetera, it makes it very easy to deliver the radiosurgery very accurate, very precisely for patients.

There are plenty of patients who benefit from this technology.

CHAIRMAN THOMADSEN: Thank you for the question and for the clarification. Other comments from ACMUI? I'm hearing none. We don't seem to have any motion before us. So I will thank Dr. Suh.

And we have a break time scheduled at this moment. We'll be resuming at 10:00. Please be on time.

(Whereupon, the above-entitled matter went off the record at 9:38 a.m. and resumed at 10:02 a.m.)

CHAIRMAN THOMADSEN: Welcome back and our first presentation will be by Ms. Holiday to enlighten us on how the NRC decides on licensing their 10 CFR

35.1000.

MS. HOLIDAY: Thank you.

So, this talk may sound a little familiar to a few people in this room since I gave it last month as OAS, so I'll speak to this a little bit for this Committee.

So, I will speak to you this morning on how NRC licenses, emerging technologies and your 10 CFR 35.1000. We all know that this is a topic of particular interest to the Committee, especially since just last year, we issued guidance under 35.1000 for the ViewRay™ device and there are other technologies that are coming down the pipeline that we suspect will also go under 35.1000 in the very near future.

So, what is this all about? Again, 35.1000 or 10 CFR Part 35, Subpart K captures emerging technologies. This was in response from the medical community.

A final rule was published in April of 2002, which codified into regulations what NRC has been doing for quite some time. So, we created this new section called Subpart K, or better known as 35.1000.

And the real beauty of 35.1000 is that it helps us avoid extremely lengthy rulemaking. As I'm sure we all know how long it takes to push a rule out, by

putting emerging technologies that can't meet certain sections in the regulations into 35.1000, we're able to avoid that.

For example, the ViewRay™ guidance was published within nine months start to finish versus maybe ten years for the rulemaking.

So, today, what actually initiates the review? So, what happens here are different pathways that we are either notified or what prompts staff to start looking.

So, for the first bullet points, staff may hear by ear or by word of voice about the universe of technology that's coming down the line.

We may also hear via a formal request from an agreement state through the OAS Board or from just general conversations about new emerging technology that may be licensed in an Agreement State.

We may also hear from the FDA about a new emerging technology. Dr. Howe, in particular, gets information from the FDA from time to time about new devices and this may prompt her to reach out to the medical team about, hey, there's this new device, maybe we should look at it and see how this may affect our current NRC regulations.

In addition to this, new sources and devices

have to go through a Sealed Source and Device Registration Application. So from that, our Sealed Source and Device Registration team here in our Division of Material Safety and State Agreements, as it currently is named, may pass that information along to our senior health physicist, Dr. Howe, and she then shares that with staff.

We may also get information by a technical assistance request from our NRC regions and they will share information with us from time to time about new devices or emerging technologies that may come through their way versus headquarters.

And lastly, though very rarely, and to my knowledge this has never happened, but there's a possibility, a very minute possibility, but that a manufacturer could come forward to NRC and say here's our device, how do you think this should be licensed. Although we know typically when they come to NRC, they already have in mind how they want it to be licensed, but there is that one chance.

So, what is the process? So, we review, we evaluate and we develop. So, a project lead or a working group, which I'll touch on a little bit later, has to review all of the information that's available. This includes information from the Sealed Source and Device

Registration, manufacturer's supplied information such as owner manuals, 501(k), am I saying that -- 510(k), things such as that.

So, we review all that information and we take it into consideration. So, then you evaluate all this information for its resemblance to other categories in 10 CFR Part 35, whether that be in Subpart D through H and need to develop a recommendation.

So, do you believe that this should be like licensed under an existing category, D through H, or should it be licensed under 35.1000? Again, I'll expand on 35.1000 in just a second.

If the emerging technology will be licensed under one of the Subparts D through H, and it's a very thin line of, I don't know, can it be 35.1000 or could it be D through H? If it's not very clear, then it's possible that you could develop a safety basis, for example, with radium-223 dichloride which the Committee worked on pretty recently.

But if you do determine that it should go under 35.1000 or Subpart K, then licensing guidance must be developed. For example, the Perfexion™ device has 35.1000 licensing guidance.

So, what makes it 35.1000? There are a few basic rules or questions that we ask ourselves when we

consider or when you decide if an emerging technology should be licensed under 35.1000.

First of all, can it meet all of the requirements in an existing category? For example, if it's a teletherapy device, can it meet everything that's in 35.600 for teletherapy devices?

Next, does it have any unique components or features that would need additional radiation safety precautions? That means things that are not included in the existing regulations in 10 CFR Part 35.

And if not, does that mean you need an exemption or multiple exemptions? If that's the case, if any of these three things can be met, then more than likely, this device will need to go under 35.1000.

So, next comes a working group. I know I said a project lead or a working group. In the past, many, many years ago, it was just NRC that would develop the licensing guidance. But maybe within the past decade, there have been 35.1000 licensing guidances that have come out as the result of working group efforts.

A working group can be created using an Agreement State representative, multiple Agreement State representatives; it could include a consultant; it could include ACMUI members; it could include NRC staff from headquarters and/or the regions.

So, for example, with the ViewRay™ device, we had staff from headquarters, we had staff from Region III, we had three Agreement State representatives on the working group who either had the SS&D Registration or they had active licensing actions. And we also had Dr. Suh serve as a temporary consultant to the working group.

So, there are many avenues in which the medical community can provide feedback. There's a possibility for ACMUI members to be involved if we see that we need that we need your technical expertise.

So, then the next question is, now that you've developed this 35.1000 guidance, do you think that it's the time for change? So, for example, I know I keep referring to Dr. Suh, but he just gave a presentation about 35.1000 guidance for the Gamma Knife Perfexion™.

There is a question about whether or not you wanted to change the existing guidance and because it's 35.1000, staff has the ability to go in and change within the existing guidance as we've done in the past for the yttrium-90 microspheres as you will hear later on today from Dr. Guiberteau.

As it's stated on the NRC Medical Toolkit, where we house all of our 35.1000 guidance, licensing guidance will be updated when it's necessary to address

comments from stakeholders.

So, you're developing this guidance because it's a new emerging technology. As time goes on and more people are using the device, you may find that there are things in there that can be relaxed or there are things that are not covered in the guidance that should be addressed. So, we're able to address that by going in and changing our 35.1000 guidance and not the lengthy rulemaking.

So, here's the link to the Medical Took Kit which, I am sure everyone is familiar with. There will be a chance to come in the near future. For example, on our Toolkit, the whole Toolkit is going to have a makeover, but specifically for the 35.1000 guidance, this is all captured under a section called "Other Guidance".

Well, it's kind of ambiguous, you don't really know what is "Other Guidance". So, we plan to section it out so there's "Other Guidance," but then there's also a bullet that says 35.1000 Guidance. And in that section, it'll list all of the guidances, but it will also identify who is on the working group or what that current status is.

Do we think this emerging technology will go under 35.1000 or is it just pending?

So, are there any questions?

CHAIRMAN THOMADSEN: Yes, Dr. Langhorst?

MEMBER LANGHORST: Thank you. So, what [inaudible] before us?

CHAIRMAN THOMADSEN: That's what that was.

MEMBER LANGHORST: That's what that was.

Sophie, thank you very much for that talk. You say that NRC staff can ask that ACMUI member or as a consultant to help with review of guidance documents and so on.

MS. HOLIDAY: Yes.

MEMBER LANGHORST: Does the reverse hold true? Can ACMUI request that a member help with certain guidance workgroups?

MS. HOLIDAY: Absolutely.

MEMBER LANGHORST: Okay. That's good to know.

And then the process of how you change 35.1000 guidance, is there opportunity for the community to make comments before the change goes into place or is it just you have comments once the change is in place and then eventually, more change will happen? Or is there a process of changing the 35.1000 guidance?

MS. HOLIDAY: I think what generally happens in what -- Ashley's here because she has a lot

of familiarity with this topic being that the yttrium-90 microspheres guidance has changed multiple times. So, please correct me if I'm wrong, Ashley.

When we receive multiple comments from the medical community, this is before we put out the guidance, we take them into consideration before we go forward in making any changes.

And then, as always, we always put the guidance up on the website so then it becomes that if there are further comments, then we take it back and we review it again -- kind of similar to when I published the ViewRay™ guidance and you came back and you had suggestions about the page edits and things like that. We went back and we changed that, I think, rather quickly.

So, it's just a matter of will the medical community inform us and time resources, is all this really is. Did I capture that correctly, Ashley? Thank you.

DR. HOWE: I think it might be helpful to understand what that process is and how the medical community can participate in that and I think that would be great to have as a short little guidance document of how you propose changes to guidance documents.

MS. HOLIDAY: Sure.

CHAIRMAN THOMADSEN: Dr. Howe?

DR. HOWE: I think one of the things that is documented on the NRC -- I think one of the things that the Committee needs to keep in mind is, many times when we have a licensing action where a licensee wants to use a new product and because of that, we need to act fairly quickly to get the guidance out there.

So, we don't have the ability to come back and ask the ACMUI in its spring meeting what its comments are and then again in the August -- in the fall meeting.

So, the other thing to keep in mind is that the guidance is guidance and that it is to some extent, always kind of considered as a proposed. So, anyone can provide comments on it once we publish it at any time. So, it's never in concrete the way rulemaking is. It's always flexible and a living document.

And Ashley has gone through many, many changes with the yttrium-90 microspheres because it is a living document.

And so I think that's the part the ACMUI needs to keep in mind is that even though we put it up on the website, and sometimes we aren't able to go back to the ACMUI before we get it up because we have licensing actions and our people do need to get these things in use.

But you always have the ability to comment whether you're nationwide or a member of the public or licensee. Okay?

CHAIRMAN THOMADSEN: Thank you for that clarification.

Other questions or comments? Dr. Welsh?

MEMBER WELSH: This is James Welsh.

As Dr. Howe has just pointed out, there are some advantages to having things in Part 1000 such as the Y-90 microspheres which, as we all know, has been a living evolution of guidances over the past several years.

But there are other situations where maybe Part 1000 is viewed as sort of wasteland and there is a rumor that once something is relegated to Part 1000, it kind of stays there inordinately long.

And what I'm thinking of in particular is the Gamma Knife Perfexion™, which I think I argued many years back, but probably could have gone right into 600 from the start when we saw that the wording in the CFR didn't match it precisely enough and things would have to be changed.

Now, the Perfexion™ has been around for a good number of years and it's clearly a stereotactic radiosurgery cobalt-60 based device and it probably

should be in Part 600 by now.

And I'm wondering when that's going to happen? What the disadvantages of not having it in 600 might be? And is there a time line that we should be thinking about for something that clearly is destined for say 600 like Perfexion™ or maybe the ViewRay™, which is glorified teletherapy unit within its guidance.

When are they going to get to 600? Because Part 1000 is perhaps not where they belong long term.

CHAIRMAN THOMADSEN: Dr. Howe?

DR. HOWE: If I could respond to that? Our intentions are to move things out of 1000 when they stabilize and we -- the ACMUI, many of you members weren't here, but from 2002 when the last rule took effect to today, we've been bringing back things that were potential rulemaking.

And one of them was the Perfexion™ and we put it on our list for a request for the rulemaking people to look at and add it. And our intention was to put it in the current rulemaking, but the current rulemaking was so big that they believed they wouldn't get the rulemaking through if they added the 1000 to it also and there were a number of other issues that they dropped out.

So, we tried to get that into rulemaking as

quickly as possible. Perfexion™ may not get into the 2023 medical rule making, you know, but it does take a long while for rulemaking to happen.

And, in the meantime, I'm also hearing that the Perfexion™ is not the only product, it's Perfexion™ Plus and that allows for that in the Perfexion™ Plus.

So, we did try and get it in as quickly as we can, but we have no control.

CHAIRMAN THOMADSEN: Mr. Fuller?

MR. FULLER: Yes, just to add a little bit to what Donna-Beth said, 35.1000, and as those of you who have been around a long time understand, it was something that was done primarily to allow for us to be a little more nimble and we have a number of examples where, if it required rule making, it was just going to be a multi-year process and we really, in the Commission, made it very clear that we needed to be a little more nimble and this was the way to do that.

So, that's a good thing. The double-edged sword, though, is that when it comes to rulemaking, rulemaking takes a long time and you have to score. And what I mean by score is you have this thing called prioritization of rulemaking where the agency as a whole only can do so many things at one time and with everything that we do, there's multiple rulemakings going on at any

one time.

And there's a centralized group that looks at very, very specific criteria based upon health and safety or radiation safety and review the immediate needs of that and so forth.

And various rulemakings, there is topics already and it is focused on safety first and then things that are prioritized. Those ones go right into rule making that multi-year process, things that are too -- a little bit better but if the Commission directed, then they get ranked and so on.

So, the long and short about this is that because we have, and this is, I think why based upon some of the things that I've heard about the decision about this current rule making that we now have out as a proposed rule for public comment, is that when it came to the Perfexion™, it didn't score very high because it doesn't -- there wasn't an immediate health and safety reason for pursuing it.

It's really frustrating for all of us, I think, but just to give you a little bit of background on that. At some point in time, we had to kind of -- the agency had to sort of had to cut it off and so that's where it allowed.

But as Dr. Howe said, we never stop thinking

about ways that we can continue the process looking for the things that need to be addressed in rule making and we've put together those plans. We try not to do one before we finish the one.

So, we've got one right now that we're working, when this one's done, I'm certain there will be a list not only from our perspective as staff, but from this body's perspective as well the things that need to be addressed in the rule making space. And so, we'll all be working together on this.

CHAIRMAN THOMADSEN: Dr. Suleiman?

MEMBER SULEIMAN: 1000 has been sort of, I use the term carefully, a "temporary parking lot" but it's not really temporary because sometimes the series are too prescriptive and so you can't put something into one of the categories because you'd have to change the rules in 300 or 600 or whatever.

So, you take something that's 95 percent compatible but not quite and you leave it in the 1000.

I think the problem is that the subcategories are all too prescriptive. You know, I use an example, so bear with me, but I always felt in FDA sometimes we should say thou shalt have a dose display and leave the prescriptive nature of a better way.

Then you have this, and I'm sure you deal

with it, the NRC deals with it too, you have our letters and our enforcers and nobody says, well, you have to spell it out because if you don't spell it out, we can't enforce it. If we can't enforce it, it has no value.

And so, you start -- and then we have people who really love to go into detail like we all do in different folks that you work with. And so they start to get more and more prescriptive. After a while, you've pretty much narrowed it down, but along comes a new technology that may not have some of those and the safety feature may have been incorporated.

So, the art is to make the rules safe but not too prescriptive but allow some tolerance otherwise you're going to wind up parking a lot of stuff into the 1000 series.

And, to be honest, I've said this before, the technologies are evolving; they're interdisciplinary; you have hybrid products. I think you can't really categorize them into a simple series.

And so, there's a fundamental problem there. So, I think rather than, I think what you have to do is let them do the best you can with what you have and, yes, this prioritization comes out of here, but, you know, back at the NRC, you're talking about competing with other priority issues.

CHAIRMAN THOMADSEN: A question I would have for Mr. Fuller or Dr. Howe is what's the disadvantage of having something parked in Part 1000?

I guess we have a volunteer answer if you could start.

MEMBER COSTELLO: I'm sorry. I believe that the 1000's a sort of a compatibility Category C?

MS. DUDES: Yes, that's correct.

MEMBER COSTELLO: So, the things that are in 35.1000, the States have more flexibility on how they implement it. They may just take what's on the website as we in Pennsylvania do. But States don't necessarily have to do that.

You may remember a discussion about the radium-223. With some States who want to have it be in 35.1000 and some states at one time were, still naturally, they argued it should be 35.1000 and they've had some variety on how they licensed it -- its authorized users and so forth.

I think that the disadvantage of having 35.1000 is that you may not get the uniformity that you get when something's in 35.200, 300, so forth. You may have some variety and, you know, we discussed this -- you discussed this, the NRC discussed this, with regard to the current Part 35 rulemaking with regard to

reporting requirements or permanent brachytherapy.

And the States argued that they would like to see compatibility C and eventually right now, the current version of it is compatibility B. And the very reason why I think the ACMUI and the community wanted it to be B, was to have their uniformity with the rule itself.

If it keeps up in compatibility C for a very long time, you'll have, you know, perhaps greater variability among the States.

CHAIRMAN THOMADSEN: Thank you for that clarification, a very important point.

Dr. Welsh?

MEMBER WELSH: If I might expand on the answer that Mr. Costello just provided, I think that the point is critically important and although Dr. Suleiman referred to as Part 1000 euphemistically as a temporary parking lot, which I think is, perhaps, politically more correct than my terminology of a wasteland.

I mean that if something is in Part 1000, it opens up some doors that maybe we should be cautious of. And if something is the 1000 and stays in 1000 inordinately long, it provides opportunities for these doors to be wedged open very widely.

And, specifically, I'm thinking about the

Perfexion™ unit which I argue should have been put in 600 a long time ago and now the Gamma Knife Perfexion™ Plus which will be a modification within which guidance and capability of fractionation. And things like the ViewRay™ which have sophisticated image guidance, these are more appropriately placed in Part 600 because they are stereotactic gamma emitting units or gamma emitting teletherapy units.

And, if they're maintained in Part 1000 for too long, as Frank said, it opens up the possibility of variability from state to state and it also opens doors for other physicians to apply for use of these devices.

For example, I think we heard of neurosurgeons in one State petitioned to be authorized usage for the Gamma Knife. You can imagine the thoracic surgeons wanted to use the ViewRay™, et cetera, et cetera.

These might not be the best things for patient radiation safety. And, therefore, my recommendation for the NRC would be that if something obviously should be in Part 600, and I think Gamma Knife, whether it's a Perfexion™, Perfexion™ Plus or whether the modern teletherapy unit, the ViewRay™, if it belongs in 600, we should move it there as efficiently as possible.

And when we do move it there or make the modifications to 600, we should probably be careful and do what Dr. Zanzonico has recommended when we're talking about the radium-223, don't pigeonhole it for radium-223, open it for all alpha emitters that might come along in the future that fit this general category.

And, we're talking about alpha emitters, how different are they from beta emitters clinically and from a radiation safety perspective?

If they're not that different, modify the appropriate categories so that it can accommodate all technologies or radionuclides that belong in that category.

And so, I hope that it's not 2023 that we have to wait to until before 600 is appropriately modified, but when it does get modified, I would recommend that it be generalized enough so that these issues don't occur and things don't stay in 600 -- the 1000 temporary parking lot for too long.

CHAIRMAN THOMADSEN: Thank you very much.

Do we have a member of the public?

MS. FAIROBENT: Thank you, Dr. Thomadsen. Lynne Fairobent with AAPM.

You asked the question of what our potential negativisms with Part 1000. I think when we all

conceptualized Part 1000 a number of years ago, it sounded great. The operating history of it has probably has mixed -- if we did lessons learned on it.

And the mixed bag comes from the back, nothing's even been moved out of Part 1000, which was the intent; it was not to be a permanent licensing position, but a temporary place for us to be able to quickly license new and emerging technologies.

I see two major downsides. One is when something is licensed under Part 1000, the licensee community does not have the opportunity to provide official and formal comments on it because it's not done through the formula. So that's a negative.

And secondly, because it is licensed through guidance, I totally agree with agreement states. There is no compatibility. The Agreement States do not have to follow any NRC guidance document or adopt it, so we have, as a matter of fact, 37 different licensee schemes.

We don't think that that's what we end up with but we do end up with a variability. So, I do see those as two big negativisms.

CHAIRMAN THOMADSEN: Thank you very much for that comment.

Other comments from the ACMUI or from the

general public? Please introduce yourself.

DR. ENNIS: Hi, Ron Ennis, ACMUI member to be. This is greatly [inaudible].

So, from all this discussion, it seems clear from my involvement in the brachytherapy rule that one of the fundamental problems, and this is really for NRC to comment on, is that rule making takes just way, way too long in the modern world where things are changing too fast.

And it sounds like 1000 was a great idea to give some flexibility but there are clearly problems in it.

So, I think that goes to more core of that rules involved in rule making, that's the part that I'm really naive about, and if that's been addressed over the past and where that stands, but I think that at a core, this is really the problem.

CHAIRMAN THOMADSEN: Thank you very much.

Mr. Costello?

MEMBER COSTELLO: I didn't mean to suggest for a compatibility C is a better fix. I mean it didn't sit very well here. That's better than being a witness of that idea and let the record show that I didn't say that. I think it was somebody else for the next meeting.

I just want to point out that that is

something we have to consider when we leave something in 35.1000 for a long time, is that as time goes by, more and more flexibility could be exercised. And I think it was Texas that might be, you know, including neurosurgeon for a gamma and, well, they can do that, I think, and so could Pennsylvania and so could the other Agreement States.

And I don't believe that that is your intention. It is our intention that if it stayed there for a very long time.

I did want to really suggest compatibility C is a bad idea. I just love the letter C.

CHAIRMAN THOMADSEN: Mr. Fuller?

MR. FULLER: Well, just a follow-up a little bit on Dr. Ennis' question. Yes, I think everyone would agree that rulemaking takes a long time.

Now, this rule making that we're currently in the middle of, or I should I should say in our public comment period, does take a number of years and there's been a number of reasons why we won't go back and revisit all that history.

But there's always that risk of you start a rule making, you go through the public comment period, you think you're close and then you find out you're not. I mean this is -- probably medical rulemaking is one of

the toughest because of the very deliberative process in the public interaction.

We do continue to do other things throughout the entire process through interactions with the ACMUI and the more general medical community. Through this, we've learned a lot of things and that -- but it's just a necessary evil, it takes time.

And so, that is our challenge. We would all like to do it faster and more efficiently but we do have requirements and really good reasons for being very deliberative and very much engaged in the public process.

And so, again, the double-edged sword.

CHAIRMAN THOMADSEN: Thank you for that clarification.

Any other comments from the committee?

In that case, thank you very much, Ms. Holiday.

And now Dr. Guiberteau who will discuss the Yttrium-90 Microsphere Subcommittee report.

VICE CHAIRMAN GUIBERTEAU: Good morning.

I've two disclaimers before I begin. The first is that in moving these slides back and forth through the Internet, there are some formatting errors which I believe to not be distractions, but they appear

differently than what I had submitted. But they're not perfect, but I don't think they will distract you.

The other disclaimer has to with a personal distraction and that is on the flight here, I neglected to notice that my distance glasses were on my tray when taken away. The distance here really is defined by the back of my retina to the front of that screen.

So, I decline an offer, having worked for many years in low level waste disposal for the State of Texas, I'm somewhat of an expert there, but not an expert in ordinary trash, so I declined an offer to look through the trash to find them, so, I will be giving my presentation on a printed version, but I will try to keep the slides in sync with what I am reading and what you are seeing.

We are, of course, talking about Y-90 microsphere brachytherapy which is the poster child, I think, for Subpart K and actually, our Committee felt that this was not really a consternation, but probably an opportunity for us simply because Y-90 microsphere brachytherapy is different from anything that has ever come before this organization to regulate.

We call it brachytherapy, but it is very different in some ways from conventional brachytherapy and in some ways, it shares characteristics of unsourced

treatments in the sense that it is not transvascular but actually intravascular and we'll talk about that as we move along.

These are our subcommittee members and because this is a team therapy, just like Gamma Knife, all members of the medical team are represented in addition to the RSO member and a regulatory member from the States as well as our staff, Donna-Beth, who kept us on track so as not to get in pathways that had been previously tried and discarded. So, we're very grateful for her participation.

The one member that we didn't have actually that it would be involved in this because our Committee is recommending some changes, is the member representing the public. But we did have discussions of this because in terms of what this procedure offers, there is a lot of doctor-patient interaction which I will address in this.

So, originally, our charge was to determine whether and under what conditions the deposition of inter-arterial Y-90 microspheres in GI tract constitutes a reportable medical event. And specifically, regards the notation in the written directive and what actually is what actually happens, that is what is actually administered and the dose to

the GI tract, and to develop recommendations for some changes with respect to the GI tract.

However, I think with the wisdom of Laura Dudes, who subsequently made comments about expanding this charge from the GI tract and that turned out to be a very good thing for this Committee that at the discretion, our discretion, we could develop a way that where any other aspects of this question that needed to be answered.

And, in fact, in some ways, we reoriented this toward how what that constitutes a technically successful administration rather than the GI tract, per se, but we did limit this to non-target activities and to offer recommendations for changes to the guidance.

So, our process was to basically reduce this current treatment processes and state of the art protocols and relevant literature because the procedure has evolved significantly since its original appearance in approximately 2000, although it was before that.

And with the initial guidance and with the publication of commonly accepted protocols in the medical community, namely the one from ASTRO, SIR, the Society for Interventional Radiology, and the ACR. So, there had been changes and even that were not addressed in the revision of the guidance in 2012.

And review the scripts routinely performed to eliminate or minimize the non-target doses that we're talking about as well as to identify an appropriate measure that is a metric to determine the technical success as opposed to the clinical success of the dose activity delivery that aligned with current practice because we felt in many ways the current guidance does not align with what is actually being done.

And to determine what the criteria for that metric need be in order to pronounce this a technical success and to propose, obviously, changes to the Y-90 guidance.

In addition, and not on this slide, it was also a subtheme to align this with the medical use policy of the NRC. Namely that these procedure be performed in accordance with the physicians directive and you'll see that's a very important thing here in terms of what the current guidance requires in the written directives and to not to intrude on the medical judgment of those of the medical team in terms of effecting patients, which in this instance, it's also very important.

I want to put in perspective what this treatment is about. It is not a curative treatment. The patients receiving this treatment are very sick and essentially terminal for most of these patients.

So, if it is essentially for those with unresectable tumors of the liver, metastatic as well as primary tumors, primarily from the hepatocellular carcinomas, they are to -- this treatment is to relieve pain, that is they palliate patients, make them more comfortable, to improve their survival, it can do that. It is not curative.

It can improve the time of progression which is very important because some patients who have unresectable primary tumors can be cured by transplantation.

And finally, it can be used as a clean-up procedure in say cryotherapy in which the majority of the tumor is debulked but the remainder of the tumor needs to be addressed.

So, that's where this stands.

The rationale of the procedure is essentially in terms of being different from other therapies is that the Y-90 microspheres are injected through a catheter selectably positioned in the hepatic artery because most tumors do not -- the normal liver receives its blood supply from the portal vein from the venous system. But these tumors, by and large, are primarily supplied by the hepatic artery.

So, that is a real boon in order to deliver

a dose to the tumor with minimal effect on the adjacent liver.

These microspheres are too large to pass through the capillary bed so they become permanently trapped within the tumor tissue and thereby giving a therapeutic dose which is why these individual devices, each microsphere, is a device. It is a brachytherapy device and that is a very different concept.

So, this is an example just because we think it's important for those of you who are not on the committee who don't do this procedure or you're not a physician, and particularly since our reports -- subcommittee reports are intended for the staff, and I know some staff, like Donna-Beth, are very familiar with this, but others may not be, and all of that is addressed in our actual written report that you'd be familiar with essentially what is trying to be accomplished.

And here you can see the tip of the catheter marked there with an arrow and the little circles there are the microspheres and you can see them being administered through the catheter into the branch of the hepatic artery and into the tumor.

I want you also to keep an eye on those vessels that do not have dots in them and we'll address those in a minute because those are the vessels that go

to the GI tract in non-target tissues that may cause doses that need also to be addressed.

In terms of safety and effectiveness that each patient has to meet a strict selection criteria. I will go into those but they are strict. Some patients are not candidates for this.

This procedure must be meticulously individualized for each patient and I'll go into that in a little detail.

And the technical success, that is the proper administration of the proper dose to the right place rather than whether it actually helps the patient. The technical success is what we are interested in and that -- it depends on very detailed physician oriented interventions and preparation of these patients. It is very complex and very individualized.

And this ensures accurate delivery as much as possible to the tumors while minimizing doses to non-target tissues such as the lung and the GI tract. And that is what we're talking about; we will address that part, not delivery of the dose to the tumors but delivery to the non-target tissues in this presentation.

So, let's start with the lung. The mechanisms in which this material gets to the lungs, these microspheres as opposed to the GI tract are very

different.

In terms of the mechanism to the lung, it's arteriovenous shunt. Now, confusingly, both of these mechanisms are called shunting.

But in this instance, because these occur, these transmit occurring in normal tissue, normal liver, but the specifically in the tumor that rather than having a convenient place where the vessel narrow in the capillary bed to be tracked and give their dose, the vessels were abnormal and they go directly into the venous system.

And when they do that, they get to the lungs and as a consequence, the lungs can be treated and the radiation pneumonitis itself is uncomfortable, but it's the delayed effects of that, the scarring in the lungs particularly in the patients who have underlying pulmonary disease. This can be a problem.

So, here's just a quick clip for you that if you inject these here at the bottom there, you can see the catheter going into the hepatic artery. You can see the tumor in yellow. Those particles that aren't trapped go into the venous system and ultimately into the lung. And those are arteriovenous shunts.

The pretreatment of lung activity is estimated because, you know, the question is how do know

they're there? We give a non-loaded with Y-90 substitute, a surrogate for that, an imperfect surrogate, to be sure, but technetium showed MAA which is currently used every day for lung scans and those particles, if they appear in the lungs, represent arteriovenous shunting and that's what will happen when you give the dose.

And so, shunting within these tumors can't be corrected, so must be managed. And right now, the community has gotten together and decided that there is a limit to the amount that you may administer to the lungs and that is 30 gray for a single treatment and 50 gray for a multiple treatment.

However, even though those limits are in grays, doses to the lungs are not routinely calculated. Instead, the amount of shunting is and incorporated into the formulas that determine the dose that you're going to give.

The administered treatment activity is, therefore, titrated down if you have shunting and at some point, for instance, if it's greater than 20 percent in general, 20 percent of the dose you give, goes to the lungs, the treatment is not ordinarily performed and that is a contraindication.

If the lung limits would be exceeded again

by using the appropriate dose, and remember that at some point, you can reduce the dose too low then it doesn't really deliver a dose to the tumor. So, this is a balance here, at some point, if that's the case, then the treatment won't be effective and that, again, would limit your ability to give this.

Now, let's move on to the GI tract in a moment, and that's for the next -- because these are really the two most important of the non-target tissues.

The mechanism is also called shunting, but in this case, these pass from the catheter and instead of going just to the branches that go to the tumor, they go to other sites resulting in GI treatment and inflammation or ulceration of the stomach, the duodenum, the gallbladder and the pancreas. The most common of these are the stomach and especially the duodenum.

So, you can see that those two vessels that I showed you before that if, depending on the size of the catheter, the placement of the catheter, the resistance in the vessels, that in this case, the black arrow show the one below shows that it's going to go to the GI tract.

The upper arrow shows that if there is stasis and reflux of this or if it's injected to quickly, it may -- you would get back flow around the catheter

and into the upper vessel. So, it's there by way of in terms of administration if these vessels that you see are as positioned on that slide.

So, the activity in the GI tract can be estimated by using a non-treatment surrogate again, the MAA, but doses are not calculated and there are no established limits on the GI tract. There are no dose or dose thresholds for complications so we don't really know what, you know, there's an idea, but there is no established consensus on this.

If the shunting to the GI tract is identified, it can be managed, however, by, one, eliminating those vessels that you saw that could be shunt or put in a catheter way down into a vessel that will -- really, there's no other vessels around or identified that where this could occur.

And if it can't be eliminated, however, the consensus is that for most patients that this is contraindicated.

Here's an example in the first, you see the arrow on a vessel, it goes through the GI tract, all the other vessels are going to the liver. A catheter in to the right in Image B is put in. A coil, which will include that vessel, is put in and, as you can see, finally before therapy, it is looked at again and you

can see that vessel. There is no flow so there is no danger of placement in that instance into the GI tract.

So, once these two things are done, that is we know and can manage lung activity and we can manage GI activity, the catheter's placed and it's administered in terms of the treatment activity according to the equipment and instructions of those devices.

There is certainly ample peer review literature that shows that with these things in place, that -- and with these angiointerventional techniques, at the discretion of the interventional radiologist that these techniques have greatly reduced serious GI complications.

And the current complications in terms of the administered activity can be mitigated in the lungs by the percentage and by reducing the dose.

So, now, after all these things are done to compensate, the dose is infused, once it is reexamined to make sure it is just as the surgeon has -- that the interventional radiology has planned it, that it is really at the vagary of the blood flow.

Once it's injected, there is no more control over this after all of this is done. And these are distributed -- each device is distributed at random into wherever it's going to go and by all planning, this is

limited to the tumor, by the best of planning.

The treatment activity, and I want to point this out again because this is a key element in one of our recommendations, that, in general, it's based upon the activity that you order to administer. That's the way it's ordered and that's the way it arrives.

There is no routine pre-implantation that is before the treatment of lung or GI doses nor is there any routine calculation of doses after the administration.

So, the subcommittee in this instance unanimously agreed, and again, there was an evolution, that's one of the great things about the subcommittees and having the representations of this committee, is that it is a microcosm of what Lynne was talking about, the public and the stakeholders and in terms of this, that there was a very vigorous, over multiple and long emails, as the staff can tell us, as well as one conference call on June 24th, to evolve to a consensus.

And the consensus was that in order to align for this procedure to align with the unique characteristics of brachytherapy which was neither conventional brachytherapy or unsealed source therapy, in terms to align with what has happened in this procedure and all the very detailed safeguards now

involved and the current medical practice of authorized users and treatments, that some change in the guidance was necessary.

And there are two parts of that that I will address that deal with these non-target doses.

The first is the written directive. The current guidance states that maximum doses, again which are not calculated pre-dose, and activities that would be acceptable to the GI tract and lungs be put in the written directive.

Well, we're not sure what acceptable is simply because, you know, there is no threshold for the GI tract and doses are not routinely calculated.

In terms of the lungs, the pre-therapy doses again are not calculated. To review that, we do know the shunting, the amount, and we can calculate an activity, again, activity to the administered, not a dose, specific dose and if the shunting is excessive, then the procedure is not performed.

And so, our conclusion is that for the GI tract as well is that specification of a maximum acceptable GI tract dose is not based on any clinically relevant or consensus derived benchmark. The doses are basically thresholds or unknown.

The current practice guidelines state that

there is no acceptable activity. And the determination of activity dose based on the surrogate imaging are problematic for reasons I won't go into. They really show a sort of, where it's going to go, but calculating a dose with this is fraught with error in most instances in the deposition and localization volume and these measurements are inexact.

So, the other part of this, the guidance that we are addressing is that it's necessary in terms of the medical event criteria for reporting on any event resulting a dose to an organ or tissue other than treatment site that exceeds by more than five millisieverts to an organ or tissue and again, a dose not an activity, and by 50 percent or more of the prescribed activity or administration to the non-target tissues.

So, what about -- talking about the pre-estimation and how difficult that is in terms of the written directive, what about afterwards? What is the current state of practice?

First of all, Bremsstrahlung imaging is the way we do it. That is, Y-90 does have in terms of being a pure beta emitter does, obviously, generate Bremsstrahlung. The problem with Bremsstrahlung is that there is no peak; it's a continuum.

Imaging that images are very, how shall I say, not up to the par of what we're used to in imaging with our standard methodology. So these calculations of doses are difficult and they vary quite largely with whatever type of technology you happen to have. And although that's evolving for a PET-CT, that's not widely available for everyone to have.

And after the fact, you know, many of the clinicians feel that it's of questionable value because the procedure's been done. And we don't even know if we see an image there whether it's going to cause problems or not, particularly for the GI tract.

So, our conclusions were that the prescribed activity, an actual infused activity, are the most important metrics. You know, once we have a metric, the question is what, you know, what is the reportable portion of that metric? What is acceptable and what is not?

And like we do now, it should be based on the readily determined differential between the prescribed activity, what's in the written directive and what was actually infused into the patient.

So, our recommendations for the change in the guidance or the specification of an acceptable GI tract and lung dose activity in the written directive

prior to the Y-90 microsphere embolization procedure should not be required because for all of the reasons that I've given you, but instead, a total treatment activity to be administered should be the required compliance measure in the written directive.

Also, that implantation of the brachytherapy sources is considered to be in accordance to the written directive if the total administered activity does not differ from the written directive by 20 percent except in situations in which there is stasis. That is in the current guidance and that is something that we felt was important to this because stasis can lead to reflux when it's not expected.

And that these recommendations should be incorporated into the guidance and we've added that we feel very strongly that the NRC staff, if they're adopted in consultation with ACMUI, that you should compose and disseminate an explanation for these basically in detail to the authorized users and other stakeholders who may be using them to make sure that this information gets out.

We have multiple members of this Committee who are experts on each piece of the things that I've been talking about and so I'm sure that if you have questions, each of us may be able to answer them.

Thank you.

CHAIRMAN THOMADSEN: Thank you, Dr. Guiberteau.

Comments or questions from -- ah, Dr. Zanzonico?

MEMBER ZANZONICO: First, I must commend you, excellent presentation.

And I would endorse those recommendations enthusiastically. There's a lot of unknown and evolving science and technology in this modality that's clearly beyond the scope of regulatory governance.

And I think the metrics that you defined give current technology, current practice, current knowledge of the unknown biology so forth and so on, are moved along with practical metrics.

There's no doubt this is an effective treatment for patients in very dire situations and I think it would be inadvisable to say to these regulators to try and parse this anymore finely than the subcommittee has defined.

The technology is just not up to that at the moment. So, like I said, I would just wholeheartedly endorse these recommendations.

CHAIRMAN THOMADSEN: Thank you very much.

Dr. Suleiman?

MEMBER SULEIMAN: I think it's a really, really nice presentation.

For clarification, these are considered medical devices. They are not considered drugs, though it's always been interesting historically that when people are first introduced to these, I think they are, in fact, drugs. I feel their safety profile is much more similar to a radiolabeled drug than brachytherapy sources. But, it is what it is.

The term, you know, a rose by any other name is still a rose, so regardless of the color, you treat it appropriately.

My concern is the guidances are not binding and we need to push the field forward. I really like the fact that you're trying to drive home the point about dosimetry and the activity. I see this much more than I care to where people just constantly get activity and absorbed dose, you know, mixed up.

And I think at some point, I think all therapeutics are going to have to have patient specific dosimetry and I think you need to make sure that even if people don't do that on a regular basis, they're going to start thinking about doing that.

And I see value in after the administration is done to calculate the dose, otherwise you may -- that

could be important in assessing the patient's outcome later on. So, you know, we gave this patient more or less than we had expected.

I'm not saying you mandate that, but I don't know whether you could sort of soft sell it in the guidance and say this would be a good idea to do, you know, but it's not binding and nobody's going to come down and beat you over the head because you didn't do it.

But I think you want to educate the community and the people at this table are not the ones who always need the education, but the people out there who are doing this, it's always good to sort of, you know, point them in the right direction.

So, I wouldn't be afraid to add some additional things that could push the field forward short of mandating it at this point.

VICE CHAIRMAN GUIBERTEAU: I think to answer that, if you read the current literature, the field and the procedure are moving forward quite robustly in the sense that, as you say, there is virtue in being able to -- for people to continue to know how to calculate doses.

There isn't much value in calculating doses that are not meaningful. And in this case, sometimes

they are reassuring when they shouldn't be and alarming when they should not be. And that is an issue that we discussed very carefully and are concerned about.

Secondly, in terms of your feeling on the devices, that has become a major confusion with those dealing with these. And I'm not -- the only -- we're not dealing with that all. But, you know, in many ways, obviously, what we're proposing is somewhat similar to what we used in unsealed source therapy.

But then again, in terms of the ease of doing this and in terms of the understandability of this in the community and especially with respect to, you know, in terms of compatibility C, I do not believe that, you know, what we have advised in guidance has caught on with the community simply because many feel it is undoable because, for all the reasons that I gave you.

And we felt, after our discussions, that this was a way to be sure that the procedure, you know, that there is a metric for them to follow for patient safety reasons, but it's not one that is unreasonable.

And finally, if I may, and I do agree that, you know, it would be nice if we educate by intrusion, but -- and legislation, but to me, in terms of what's happening, there is already much of this happening in the community.

So, in terms of evolving technologies and, again, Part 1000, I mean in five or ten years, we may come back and say, you know, all this needs to be changed again and it could be sooner than that.

CHAIRMAN THOMADSEN: Dr. Dilsizian?

MEMBER DILSIZIAN: Great presentation.

We do a lot of brachytherapies and do a lot of imaging before. Most of the time, as you said, a diagnostic MAA can compute the lung shunt and if there is some gastric reflux, we tell them ahead of time. This is assessed and can be prevented by closing the gastric arteries clearly shown.

I guess the question here is the unintentional reflux that you brought up and how do you identify those? Based on symptomatic subsequently even though it would -- although the preventative actions were taken care of, but there can be some reflux of the gastric artery.

And what we've done recently is we are looking at pulse therapy and CT imaging to first identify that the therapy went to the liver and those identify was it reflux.

Now the advantage of PET-CT even though it has a very small portion of yttrium-90 is that it can give you the anatomical co-localization where we can

actually look at the stomach and we can see if there's any activity that went to the stomach post-therapy even though that wasn't the intention.

Now, you say well, what was the purpose if it's already there, what can we do about it? My question is that, as you know, the most common cause of the symptoms will be ulceration. And so, if we can identify that some of these patients have already had some reflux to the stomach, perhaps it will be just for information before the patient develops symptoms to have some palliative therapy.

So, my recommendation is that if -- as far as recording the event even though this is an unusual event, having some imaging that can identify reflux to the stomach and then treating it palliatively before the ulceration occurs may be something that we could think about.

VICE CHAIRMAN GUIBERTEAU: Well, you know, let me address that. I mean reflux is a consternation in performing any of these procedures, particularly with respect to SIR-Spheres that have much more embolic effect because of a number, I mean it's almost an order of magnitude different from the 1.2 million that you get with TheraSpheres and the size, although it's an excellent methodology that reflux is something that you

can prevent if you have modified.

But on the other hand, the vascular system, I mean you can't prevent the reflux but you can mitigate the effect of that. You cannot see reflux in an after the fact image. You only see the results of the reflux.

So, as many of you know, when the SIR-Spheres are injected, they inject it very slowly, very carefully in little pulses with contrast to see where it's going.

But, in my own experience and many people's experience, one puff looks terrific, the next puff is refluxed. It happens almost without warning.

So, a lot of this has to do with skill and preparation. I think most of the pre-preparations try to eliminate or they presume there's going to be reflux so let's not have anything near there.

But, I agree wholeheartedly with what you're saying. There is nothing wrong to imaging afterwards to see, not I'm not talking calculating doses because the doses may not be meaningful, but if you see that, you could institute palliative therapy. But the calculation of doses may not be worthwhile. In fact, our Committee felt it probably wasn't in most instances.

I might also add that most protocols now do have antacid in blocking therapy built into their

programs. They give this to everyone because it is really -- they're harmless drugs, you give it to the patient and you give it before you do the procedure.

So, I agree with you and, actually, I will agree with you more as soon as this procedure evolves to the extent that we have a lot more accuracy in terms of what we can do with Bremsstrahlung imaging.

CHAIRMAN THOMADSEN: Yes, Dr. Alderson?

MEMBER ALDERSON: Well, I also want to compliment you on a great presentation.

And the way that I hear this is, is what we're trying to do with the recommendations is to keep us from having too many misadministration reports that we have to make and then all the things that go on when one of those gets made.

So, in that sense, all the things that you said are correct, but, in fact, it seems to me that that's what you're driving at here and it's something that I think is appropriate and I will support it.

CHAIRMAN THOMADSEN: Thank you. Yes, Dr. Langhorst?

MEMBER LANGHORST: Can you talk about a little bit more, you mentioned it at the beginning of your talk, the interaction between the physician and the patient in regard to the practice of this therapy and

the risk associated versus how a regulatory body determines whether the administration was met -- has met the medical policy criteria?

VICE CHAIRMAN GUIBERTEAU: Sure. Well, you know, this is no different from -- and each State has its own requirements -- but in general, each procedure that may cause significant side effects to patients whether it's surgery or whether it's, you know, radiotherapies or some medical therapies, some new medical therapies that the patient is informed of the risks and benefits and the side effects.

And you know, this is -- in patients who are in these dire straits, there is no absolute even though the procedure may not be performed.

But, let me give you an example of a patient that I am familiar with -- whose case I'm familiar with and I'm not breaching anything because I'm not telling you anything about that patient.

That if some of these patients who are candidates for liver transplants are waiting and if there is something that can't be mitigated, the patient needs to help make the decision and say, look, we will be performing this on you against what we usually do and we see that you have risen to number ten on the list to get a transplant. It is up to you to help us make that

decision.

These are the sorts of things, and that's rare, but I'm saying that these are the sorts of things that you're dealing with in this situation that make it much more important for these interactions not to be disturbed.

And I can tell you the people doing these are -- I've seen the forms from various places and they're pretty uniform in terms of what is required. And as you know, not every -- these procedures are really limited to big centers, either big hospitals, free-standing hospitals, I mean large centers or academic centers. So we're not talking about these patients offices.

In terms of where we come in, that's the very interesting thing about what this Committee does is to try to determine where, you know, what does our policy mean in terms of regulating this? I mean what is best for the patient? What is not intrusive? What will protect the patient? And we think that those will be in place.

One brief thing I want to mention and I don't want to open it up to too much, but the original question was, are we not getting enough reports?

Well, and this is just speculation, but one

reason we may not be getting enough reports is that the reporting metrics don't fit with what's being done and unless we resolve that and align that, then what is the purpose of our regulating?

So, again, we felt very strongly that this would probably -- it might increase the number of reports we get. But on the other hand, the purpose here is to make this rational.

CHAIRMAN THOMADSEN: A follow-up from Dr. Langhorst.

MEMBER LANGHORST: And I think -- thank you very much -- I think that the fact that we don't have it in this regulatory guidance document as far as following up with what you're saying, that doesn't prevent the medical treatment to be doing exactly what it should be doing. It just isn't a metric that you can regulate on.

And so, don't feel that if it's not in this guidance document that everybody thinks, oh, they don't have to do it because it's two different things.

CHAIRMAN THOMADSEN: Mr. Fuller?

MR. FULLER: Yes, I just have a comment and a question.

The first comment back to our earlier discussion about 10 CFR Part 35 Subpart K. This is a prime

example of those things that while we might like to move things from the temporary parking lot to the rule, that this one would be extremely challenging, I think. And so, I guess it's good that we have been able to stay in an area where we could exercise some flexibility and be able to react and adjust to things.

My question has to do, though, with the recommendation for what would constitute a medical event that needed to be reported? I believe from reading the report and what you said, Dr. Guiberteau, that it should be limited to the amount of activity that is delivered, in other words, it should be limited -- the metrics should be limited to the activity that's delivered at the point of the catheter. In other words, where the catheter is placed.

So, my question becomes then what if the catheter is misplaced? So, we've had a number of medical events that reported over time where they actually delivered the activity, which we talked in terms of the dose, and I know how difficult that can be, but where the activity was actually delivered to the wrong lobe of the liver.

So, the way I read this, it would indicate or I would assume that even under those cases where someone misplaced the catheter, if they delivered the

activity to the tip of that catheter, then that would not constitute something that needed to be reported.

So, could you comment maybe a little bit on that?

VICE CHAIRMAN GUIBERTEAU: Well, I think that would be instance in which this would not have been administered in accordance with the written directive, certainly in terms of the amount it would be.

But in terms of, you know, any time you change the metric, you need to change the associated things such as your mentioning that, according to the written directive in this instance, would be according to the position of the catheter where the treatment was planned.

And, you know, those are things that I think the staff and the Committee need to consider when these are revised, just as reflux, nobody knew much about reflux when this first came out. Now we know that's something that if it is anticipated, then fine. But, specifically, in terms of the delivery, the delivery needs to be according to all the planning that has gone forward.

MR. FULLER: Thank you.

CHAIRMAN THOMADSEN: And I think an answer to your question, this doesn't change any of the medical

event criteria such as positioning the tip of the catheter in the wrong treatment site or the wrong patient or using the wrong isotope.

I think all of that would stay in place; this just clarifies the question about would a dose to the GI tract or to the lung be considered a medical event when it fell into the criteria as discussed in these recommendations.

MR. FULLER: Thank you, thank you.

MEMBER ALDERSON: So, I don't know what the parliamentary procedure is, but I would like to suggest that the Committee support this recommendation. I would move that.

CHAIRMAN THOMADSEN: I think that that's a good example of parliamentary procedure. We need to have a second. Actually, we don't need a second because this is coming from a subcommittee, we actually need the recommendation, although I will take that and we don't need a second, we will open the motion to a vote in just a second.

It is on the table for action now, thank you for bringing to action, it's what the parliamentary procedure would have been and we'll open the motion for discussion to approve these recommendations and Mr. Costello, you were about to make a comment.

MEMBER COSTELLO: Well, it's slightly off topic, but on this topic, you know, the Committee recommendations we've done, that's what I favored it then and I --

Excellent report, by the way. I mean you have great leadership with the subcommittee, we really did and I would vote in favor when it comes to a vote.

CHAIRMAN THOMADSEN: Very good, thank you for the support of the motion.

Dr. Howe?

DR. HOWE: Just two comments.

When you read the subcommittee report, there's going to be two underlying themes.

One is that you have fewer problems when you have more experienced physicians. That raises possible question in our regulatory idea of do the authorized users need additional training before they're authorized users? Is three cases enough?

The other is, you have put a lot of description into what is good medical practice before you do these -- that you do the embolization; that you do the MAA shunting; that you make a medical decision on whether to go forward with this patient or not to go forward.

But that doesn't show up, as Mr. Fuller was

trying to point out, in your final recommendation of what is a medical event. It's just based on activity in the body, that activity at the tip when the tip is correctly placed.

So, you're tying it back to your written directive, but we don't have a way of capturing in the written directive right now; the tip is where it was supposed to be and then you did the administration.

So, I think you need to kind of address -- I would hope you would address those issues.

VICE CHAIRMAN GUIBERTEAU: Well, we specifically did not because we wanted to keep this an undistracted change in the metric.

As I said, I don't believe that reflux was necessarily first addressed early on when people were thinking about this.

So, again, these are issues -- we did not address the dose to the tumor dose, the target dose, because that was not our charge and we wanted to move the ball forward. We do understand that any time you do that, there are other issues. But, we didn't want it to be a distraction.

And two, when you say experienced physicians, I believe most of the literature says this procedure complications have diminished as physicians

have gotten more experience.

Most of that applies to the evolution of the techniques, that is, people doing this in 1998 under research protocols probably did them less well than people who do today because we know so much more.

I think the training is very important and, you know, if that's felt to be necessary, you know, I don't have any issues with some reasonable, you know, alternatives of that.

But I think in terms of experienced physicians that that was really what the report and the literature primarily addressed.

Now, the procedure is maturing for the most part at least the performance of the aspects from the physician team. In terms of the imaging, that is still in dose calculations, that's going forward.

So, you know, I just wanted to point that out.

CHAIRMAN THOMADSEN: Ms. Weil?

MEMBER WEIL: From the logistical perspective, you said that these procedures were only performed in academic medical centers --

VICE CHAIRMAN GUIBERTEAU: Or large medical centers.

MEMBER WEIL: Large medical centers.

What's the likelihood that this might move out of that arena into smaller medical centers, non-hospital practices in the next couple of years?

VICE CHAIRMAN GUIBERTEAU: I think there are two issues at play here.

One is that the, you know, if you study penetration of technology, you know that it resists moving to atmospheres in which it is less well done, but inevitably, it moves into the community.

One thing preventing that here is the cost of the procedure, the relative rarity of the procedure in terms of where they are performed. Generally, doing these in the community that don't have access to transplantation teams, who don't have access to teams performing cryotherapy for these things.

I believe there is interest in doing this, but of course, I'm no crystal ball. But, I think at the moment, I think you're right to point that out, but I think at the moment, it probably is where it is for the time being. But, no guarantees.

CHAIRMAN THOMADSEN: Mr. Costello?

MEMBER COSTELLO: I have a comment. That has already -- to some small penetration, not into clinics but in the community-based hospitals and non-academic clinics.

And having said that, I think that -- I don't think we've seen any terrible thing resulting from that and the issues that have occurred in those hospitals would not be affected by this guidance. You know, we have a hospital treating people without a radiation oncologist on the license at all.

We had another hospital treating patients but not measuring the dose at all. They made the radiation measurements but they never made any calculations to know how much went out to the patient.

And none of these would be affected by the guidance. This is just, you know, bad performance regardless of what the guidance would be.

I have not seen it any place other than a hospital, I mean I've only ever seen it in hospitals. And most, as you say, in the large academic research places. But I have seen it outside of there, too.

CHAIRMAN THOMADSEN: Thank you very much.

Dr. Alderson?

MEMBER ALDERSON: Dr. Welsh was next.

CHAIRMAN THOMADSEN: You were deferring to Dr. Welsh.

MEMBER WELSH: Well, thank you.

Regarding the question of is three cases enough, I think that's a good question and my response

might be that what Dr. Guiberteau said about the technique, the technology evolving over the past decade and, therefore, the complications being much higher with the teams that were brand new to this and complications being much lower today because of the benefits of all that gleaned information is quite true.

However, there's also no doubt that somebody who's done this a thousand time is likely to be better than somebody who's done this three times.

That is most definitely likely from the interventional perspective where there is technical skill involved. And while it may not be as challenging as resecting a craniopharyngioma, there is a certain degree of technical skill required and not all practitioners are going to be equal in this particular aspect.

The people who have done it three thousand times have got more experience and are better than those who've done it three times have done it three thousand times because they may be gifted and have talent and be capable of doing this better than somebody who might have tried ten thousand times and just can't do it as well as the super skilled practitioner.

Having said that, from the radiation safety perspective and the authorized user perspective that NRC

is concerned with, that might be a slightly different aspect than the typical skill of the interventionalist and maybe three cases still is sufficient for authorized user status.

So that was one comment I might have. Other comments, though, I concur with everybody's compliments of Dr. Guiberteau's presentation. I feel like it was great and Mickey, I think you missed your calling, you should have a radiation oncologist.

But other things that were brought up was why do you do the imaging after the treatment? Well, although you're not going to get, there are some situations where if we had the excellent imaging we could better predict whether a patient would be candidate for a repeat treatment or if we actually give the dose that we wanted to and should there be a supplemental radiation therapy technique applied or chemotherapy supplemented here.

The more accurate our post-implant dosimetry is, the more likely we would be able to state such things that would benefit patients in the future. This is certainly not where I want [inaudible] brachytherapy is today, and if Bremsstrahlung imaging that we have currently is more in the same ballpark as the yttrium-90 PET potential could be.

But, although it was brought up, most institutions can't do the PET today. But I think that in the future, that will be where we evolve to.

Finally, I think Dr. Langhorst brought up a question of physician-patient involvement and speaking as a radiation oncologist, I think that this is part of the reason why radiation oncologists should remain involved with this team effort because it is good for patients with a consultation from a cancer specialist, in particular cancer specialist who has a lot of experience and knowledge of radiation related issues.

So, those are my comments.

CHAIRMAN THOMADSEN: Thank you very much.

Dr. Alderson?

MEMBER ALDERSON: Right, so, thank you.

In part, I'm going to make a comment about what I think this Committee is trying to look at and perhaps you can correct me since I am so relatively a new member of the Committee.

But, it seems like that the motion or the recommendations to focus on the safe and I'll say uniform application of medical radiation versus our ability to control which we don't have biological variability or the precision of medical practice. And I think that's

what some of the recent comments focused on.

So, I still believe having heard those comments, which are certainly good for patients, but I think are not exactly what we're trying to accomplish here. But I still support the recommendations of the subcommittee.

CHAIRMAN THOMADSEN: Thank you very much for the clarification.

Dr. Palestro?

MEMBER PALESTRO: A couple of comments.

Number one, regarding the number of therapies, the ones you perform in terms of experience, I don't know how you determine a number. I don't know that three is enough, that five is enough, I don't think there's any good way to come up with a number and be certain that that's the appropriate number. So, I certainly wouldn't advocate changing it.

And I also think the distinction between academic medical centers/large medical centers and community hospitals or smaller sites really is sort of irrelevant because the concern that we have is that at the moment, a medical event is based on the dose to the GI tract.

And yet, regardless of where the procedure is being done, we've come to the conclusion that with

current technology, at least, we don't have the ability to accurately determine the dose to the GI tract and even if we could, we're not certain that that dose is necessarily a dose that will precipitate an ulceration or reaction of some sort.

So, I think that that's, to me at least, that's less of a concern as to where it's being performed.

CHAIRMAN THOMADSEN: Thank you.

Dr. Suleiman?

MEMBER SULEIMAN: I sort of agree with the minimum three, first off, more for the newer members and some of the older ones, what's practice of medicine? What's the inherent variability associated with medical practice? And you trust your physician, that's what I tell people, if you don't trust your physician, get somebody else.

And you can't start using numbers and saying three procedures or five procedures, it could be somebody who worked in a hospital is now doing in the clinic. So, it's the same person now doing it in a different environment, so we want to categorize these things in such a simple bean counting way but it doesn't always translate that way.

So, I think the most important thing is

trust your physician and appreciate that this is an area of medicine that's extremely variable and has a high level of uncertainty.

Again, so people don't forget, I think until patient specific dosimetry becomes routine practice, you're not going to see any improvement in radiolabeled therapies, I think even here.

And I've seen -- and there's experience out there and there are trials out there where you do the post-patient imaging and you find out that the dose the patient received was much different than what you had predicted.

So, and with adjunct therapy where you may go in with a radiolabeled in the first place and then top it off a little bit later on, that's going to be of value.

So, the lesson here is, you have to start accepting the fact that you're going to have to do patient dosimetry on a patient by patient basis at some point if you want to get this close to radiation therapy type pieces on accuracy.

But, I think in terms of radiation safety, I think you guys have met the charge. You know, I think the confusion is let's not get into practice of medicine and this is -- I mean this was originally for

humanitarian use purposes, so this was just not a routine first run therapy.

So, we're getting into the weeds. These are interesting discussions, but I don't think they address the radiation safety issue. I think we're addressing safety issue big time.

CHAIRMAN THOMADSEN: Thank you very much.

Mr. Costello?

MEMBER COSTELLO: I have a question on the training and three or more than three.

At least most of the authorized users that I've seen while they can be interventional radiologists or not, but they're mostly radiation oncologists.

And of times, the procedure, the authorized users are actually out of the room for watching through a window. And the IR doctor is the one actually, you know, injecting the patient.

And in terms of under doses, overwhelming most of our medical events involving actual under doses, a number of them are caused by the/or related to the actions of the interventional radiologist, okay. It is a skilled thing putting it in there, well beyond my skills.

But, and whether or not the authorized user is not doing this, has had three or more three or five,

that will affect skill of the interventional radiologist and that actually does have an effect on how medical events you have, particularly under doses.

Or for that matter, if you go too fast, you're going to, you know, reflux them and other things.

CHAIRMAN THOMADSEN: Thank you.

Any other comments? I'm hearing none; we'll take a vote. The vote is to accept the recommendations of the subcommittee as those of the ACMUI. All in favor, please say aye.

(CHORUS OF AYES)

CHAIRMAN THOMADSEN: Opposed, say no. Abstentions? And it's passed unanimously.

Very good job on the work of the subcommittee. Good job.

Yes, Ms. Holiday?

MS. HOLIDAY: Just one final thing, I know that the committee just voted to accept our recommendations, but, you know, do I also have a formal vote to endorse the subcommittee report to become the full committee report.

CHAIRMAN THOMADSEN: Thank you very much for that clarification. I'm not sure I understand it entirely, but do a motion on the floor to endorse the subcommittee report?

Thank you very much.

Do we have any comments before we take the vote? None, in that case, all in favor, please say aye.

(CHORUS OF AYES)

CHAIRMAN THOMADSEN: And those opposed, say no. Any abstentions? Thank you very much.

I think that is now approved and endorsed.

At this point -- yes, Mr. Costello?

MEMBER COSTELLO: This is more of a process question. Now that we've done that, will sometime in the future they actually get back to us and tell us what they're doing with the recommendations?

CHAIRMAN THOMADSEN: I think that's part of the -- Ms. Holiday was saying at the end of the ruling of each meeting, the follow through of what actually happens with our recommendations. But, it's good to keep us on track.

With that, it's time to take a break for lunch. Please be back in position at 1:00.

(Whereupon, the matter went off the record at 11:40 a.m., and resumed at 1:01 p.m.)

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

(1:01 p.m.)

CHAIRMAN THOMADSEN: The first discussion in this session is the FDA's role in the global molybdenum-99 shortage by Dr. Suleiman.

MEMBER SULEIMAN: Thank you very much. We have been -- most of you have been aware of the global moly shortage, and the agency, FDA, has really been pretty involved with this. And after I did this last time, I'd better start telling people a little bit more about what we've been doing. And so that's really the purpose of this.

And I'm not going to have to read this much longer, but the opinions I express today may not necessarily reflect the official position of the FDA or Health and Human Services. And I want to clarify -- I think this is an important point -- since information on an investigational new drug application and a new drug application submission to FDA is considered confidential -- we are not even allowed to acknowledge that we received such applications -- I need to clarify that any information in this presentation has been obtained from public sources.

Similarly, the mention of any commercial products are neither an official endorsement or

criticism of the product by me, the FDA, or Health and Human Services.

As I said, we've been pretty much -- very much involved with this dating back to the middle of the 2000s. Clearly, we are aware of the other legislation that we intend to comply with, the American Medical Isotope Act of 2012, which essentially eliminates the export of highly enriched uranium in the use for molybdenum-99 production, which, as you know, decays into the tech-99m isotope.

We have been working with stakeholders to rebuild the fragile manufacturing infrastructure, basically aging reactors, for the production of moly-99, and we are very sensitive that we need to address security concerns and ensure a stable supply at the same time. And we have spent an awful lot of time working with industry basically to help them navigate the regulatory pathway to develop alternative technologies for the manufacturing of moly-99.

If people aren't aware, technetium-99m is the major medical isotope in the world. When I was in graduate school 40 years ago, I actually did my master's work with technetium. I was told it was a relatively new drug, new isotope, and it had some really unique advantages. And I think it's a testament to that

radionuclide that today it basically dominates the nuclear medicine community. It dominates 80 percent of all nuclear medicine exams; that's about 14 to 15 million in the U.S.

And the reason is basically physics. It has an optimal imaging energy of 140 keV. It has an extremely practical half-life. But aside from the physics, I think this is really the key. It has a great chemical state, and you can bind it with all sorts of drugs. And it's not the nuclide. The nuclide either -- is either a good imaging agent or a good therapeutic agent, but the -- where the drug goes is where the nuclide rides along. And so that's really what is -- what drives this.

And so when people say tech is going to go away, I doubt it. I mean, it's a case of when the right drugs that maybe seek certain smart probes, it will go to certain cancer, to certain sites, that will be the next major breakthrough.

And it's relatively easy to manufacture, so it's accessible, it's relatively inexpensive, and it's easy to use to label drugs with.

There are basically two ways that technetium -- excuse me, the major way that it's produced today is in reactors. You basically irradiate U-235

with neutrons and you get fission products, and you have this mass of very hot radioactive material. And so these are in the jargon called irradiators, so there are a number of reactors around the world that irradiate this uranium to produce the moly.

That center slide there is really often overlooked, but you have producers. These are the processing sites that actually take this fission material and then chemically extract the molybdenum from the mess of radioisotopes that have resulted. And this is a chemical separation process, and not all irradiators, you know -- you may have irradiating capacity, but you may not have the ability to process all of it.

For example, right now in Australia, their OPAL reactor was limited in terms of their processing facilities, but they are now -- they have broken ground and they are increasing their capacity to extract more molybdenum if they irradiate more uranium. And so then you separate the moly, and then you -- the third part of it is the traditional generator, and it's put into -- you put the molybdenum on the top and it goes through an Illumina column, and what you get out from the bottom is the radioisotope technetium-99m.

And that is really what FDA is concerned

about, the quality and the purity of the medical isotope.

There have been a number of alternative manufacturing processes. These are just two of them. One is using -- these use accelerators. One uses moly-98 as the target material, and it hits it with neutrons, you get a gamma off, and you get the moly-99. The other process uses moly-100 with high energy gamma -- X-rays from an accelerator. Again, you get neutrons off, and you get moly-99. In both cases, you take the moly-99, you pack a generator with it, and you get your technetium-99m.

There are some alternative methods that the Canadians are using that basically involves irradiating moly-100 with a two-proton accelerator, and they get the technetium directly, bypassing the moly -- the moly pathway.

So these are all being worked on, developed, and we will have to see how it all plays out.

Separate from that, because there are several pieces of this puzzle as this evolves, was that back in 1992, Congress passed this Energy Policy Act. And at that time, they really felt that you needed to eliminate highly enriched uranium, which is uranium that has more than 20 percent U-235 in it and is considered weapons grade, and so they basically restricted it from

being exported by the United States to all of these reactors that were using it for medical isotope production.

A few years later, in the Energy Policy Act of 2005, a different message was sent saying we are going to allow HEU to be exported for medical isotope production as long as it goes to Canada, the Netherlands, Belgium, France, and Germany. So the HEU was sort of being pushed or pulled from two different ends, and eventually the recent AMIPA, or the American Medical Isotope Act of 2012, with a different twist. They said, "Gee, we need to have production in the United States."

So one of the requirements of that act is to promote the production of moly-99 in the U.S., and finally put a deadline to phase out the export of highly enriched uranium for the production of medical isotopes effective seven years after the date of enactment. So it is either December 2019 or January 2020, the U.S. will no longer be allowed to export HEU for moly-99 production.

However, there are some emergency escape clauses in there that involve the Secretary of Department of Energy, the Secretary of Health and Human Services, where if a true crisis is going to emerge where this is the only way to produce it, they could invoke

that situation, if necessary. But it looks like the conversion to low enriched uranium is proceeding.

Now, this report is sort of a very definitive one. It was published in 2009, but basically the question that was being asked is, is it feasible to switch from highly enriched uranium to low enriched uranium? And that was a question that they hadn't answered, because you are using 97 percent enriched uranium and you are now going down to 20 percent. So my simple mind said, "Gee, you are going to reduce yield, you know, by 60 to 80 percent, you know, so a reactor is not going to be able to produce as much." Wouldn't that possibly create a shortage?

The answer to it was no, and there are -- they found out that you may use low enriched uranium, but you can pack more -- you can make a larger target and you can affect the density. And so what I understand is the yield drops maybe 10 or 20 percent, but it's not as dramatic. And so they irradiate more of it, and they can produce it, so that hasn't been the problem.

However, the report did raise some real concerns about HEU production not leading to a drug shortage. Some of these were technical, as I just described to you. Some of these were economic. Some

of the alternative ways cost more. And some of them were regulatory. There was concern over licensing, over transport of materials. There was concern about FDA regulatory requirements, which was actually my entree into this issue.

Now, this is a slide I've taken from National Nuclear Security Agency, who has sort of been leading this. The brown is the highly enriched uranium that is being used at these different sites, and the blue is the non-HEU. And you've got four or five major producers in the world. And as you can see, they are slowly shifting; they are converting to using highly enriched -- to using low enriched uranium.

But the real big 800-pound gorilla in the room is the Canadian reactor that will not convert to LEU. They are just ceasing production come 2016. So that takes a major player out of the game.

I took the next two slides -- I'm not going to go into a lot of detail -- but this was in the Nuclear Energy Agency of the Organization of Economic Cooperation Development, I will discuss them in a little bit more detail. The full report is available online, but these are the current irradiators as of April 2014. And this is their maximum capacity. This is not what they produce on a regular basis, but these are the major

players.

Now, you've got more players now than you did a couple of years ago. And if you look over in the right-hand column, you'll see that the United States is conspicuously, you know, absent. The two red dates under stop dates, 2016 and 2015, are associated with the National Research Universal -- that's the Canadian reactor -- and OSIRIS, which is the French reactor. They are both going offline permanently in the next two years.

The other slide -- and I just limit it to these two tables -- shows you potential, new irradiators that plan to be commissioned by 2020. With respect to the OECD, these are efforts that have broken ground, have put money into it. These are tangible initiatives to develop -- to produce -- you know, to irradiate and produce moly.

There are a lot of other players. I will discuss them again momentarily. But the only -- the main thing here, you can see there are several U.S. players in different phases. One you've heard of is NorthStar, and they have been working with the University of Missouri facility, and Morgridge-SHINE out of Wisconsin, and they have -- they have also been proceeding in their plans. So these are potential irradiators.

Now, getting back to the NNSA, as part of some of their initiative, they funded four cooperative commercial projects. The four are listed here. The two at the bottom -- Babcock and Wilcox and GE-Hitachi -- are basically on permanent hold. They felt, for business reasons or whatever, that they stopped their work into this project.

The two top ones are the two I referred to earlier, NorthStar Medical Radioisotopes, which actually has a new drug application in-house at the agency, and SHINE, the Morgridge Institute for Research. They are developing a method to produce moly-99. Since they will be producing the material, it may not be necessary for them to actually apply for an NDA, but they will have some interactions with us.

Now, to further make the scenario interesting, there was an isotope workshop back in June in D.C. sponsored by Argonne Lab and Department of Energy and the National Nuclear Security Agency. And this information is all online, including the presentations, but these are some of the additional players that have expressed an interest in producing moly.

Some of them are using existing technology, so it's not a case of developing something new. They may just use a classic reactor with uranium fuel. Some

of them have come up with some novel new methodology, and so there is a lot of talk, there is a lot of discussion, and some of these are in various phases of moving forward.

The point is there is a lot of interest in this. Currently, there are three FDA approved products in the U.S. -- Mallinckrodt, which makes the Ultra TechneKow, Lantheus TechneLite, and GE. I think last year we approved their health care Drytec generator system, which is actually manufactured in the United Kingdom.

Now, there can be no discussion of this without explaining what went on in Canada with -- that puts things in perspective. You have to appreciate the fact -- and why we didn't have a domestic producer was Canada is our neighbor next door, and they were producing an awful lot of moly-99. At certain times, they could produce as much as two-thirds of the global supply.

And this old reactor was built in 1956 at Chalk River and was to cease operation around 2005. And they had a plan. They were going to replace the NRU with two reactors referred to as the Maple reactors. And this is another interesting aside, but the reactors were built, they started to work, they found some design flaws; they had some positive coefficients of

reactivity; they were never licensed; they were considered too hazardous. How you could actually wind up building something like this and learning about it at -- you know, not getting it approved.

So not only did it result in some difficult decisions, there was some political fallout from it as well. At one point I think the Canadian government almost lost their vote of confidence over this very issue. So for a variety of reasons, they basically decided they were going to get out of the global moly-99 business. That occurred eventually.

But during 2007 and 2009, when this old reactor -- and a similar thing happened recently in Petten in the Netherlands, when they shut down for maintenance, they find other problems, and so they stay shut down for a longer than expected period of time. And what happened is this precipitated the first of several shortages and crises that eventually resulted in the establishment of what is referred to as this high level group of medical radioisotopes.

The Organization of Economic Cooperation Development is an outgrowth of the old Marshall Plan, but it is now an international agency. There is a Nuclear Energy Agency component of it. And as best I understand, Canada and the U.S. went to them and said,

"Look, we'd like for the OECD to take this issue and come up with a plan." So the HLG-MR is referred to as the high level group on the security of supply of medical isotopes. So their mission was to make sure there is a long-term stable supply of moly-99, at the same time there is security.

This is sort of where FDA gets into the game. One of our primary responsibilities is to mitigate and prevent drug shortages and ensure supply, not just for technetium, for all drugs. We have facilitated the development of new technetium labeled drugs. Any time there is an approved drug that requires changes, they have to come back to us and file a supplement. And of course, you know, we inspect these sites on a periodic basis.

Specifically regarding the moly-99, we have a drug shortage group that is very much in contact with the major manufacturers. And sometimes they get information before I get a chance to learn about it. So it has been pretty transparent with the companies.

We have spent an awful lot of time trying to provide specific advice on the correct FDA regulatory pathways. It is not very obvious to -- a lot of these reactors and producers are really not directly involved in health care. So they are very confused when they were

told that they may have to get FDA regulatory approval.

And we have participated in a number of outreach activities. We have participated -- I have been a member of this HLG-MR group, which has been meeting in Paris twice a year. The Office of Science and Technology Policy out of the White House has regular stakeholders meetings in the D.C. area. Department of Energy has had a series of isotope workshops. So there has been a lot of effort to get the word out about what is going on.

So how does this apply for moly? I will give you a few little specifics. When someone files a new drug application, the source and production of the moly-99 needs to be specified. That is just part of the application process.

If the product is already approved, but now there is going to be a change in manufacturing, this is really one of the focal points of some of my earlier interactions. Let's say they're going to convert from highly enriched uranium to low enriched uranium. They have to file a supplement to an approved new drug application.

Now, this was very daunting and threatening to some of the companies as they have never done this. So there was some confusion in those days. There were

rumors that we could slow the whole process down by as much as three years.

If the protocol isn't spelled out, the -- you could file what's known as a drug master file to ensure confidentiality. I'll explain that very shortly. And this drug master file, which I refer to as a safe deposit box, specifies how the moly is produced, including the composition of the target material specifications, the irradiation process, the chemical separation of the moly from the fission material, and so on.

So it's your entire production process has to be spelled out. So this is the cookbook. So you take this cookbook and you put it in the safe deposit box, and you file that drug master file with the FDA. Nobody has access to it, not even FDA. And the reason you create this drug master file -- and we get -- I was surprised to learn we get about 6,000 of these filed on a monthly basis, so this is pretty routine. It maintains confidentiality of proprietary information. And, specifically, it permits the efficient review of the information by FDA reviewers to support the application.

So in this example, let's say producer C -- let's use one of the real -- the Australian reactor, OPAL; they produce moly-99, but they don't tell you the

composition of their target material. They don't tell you how long they -- that's proprietary. They don't tell you how they extract the moly. That's a chemical separation process. And they are now going to sell it or provide the moly-99 to these two companies, A and B.

They don't need to provide any of that information to companies A and B. What they do, however, is they give a letter of authorization that says FDA reviewers can review this protocol that is filed away in this drug master file in support of any submissions or applications by companies A and B.

So it is pretty efficient. Companies A and B don't need to get me information. They just say, "We are getting it from producer C, and here is the DMF. And oh, by the way, the company has given us a letter of authorization allowing the FDA to look at this on behalf of our application."

And so an experience today -- when I got summoned to the National Academy here, it was actually in 2007, we were accused of possibly delaying this as much as three years. Well, it was really great when we finally looked at these and cleared them in five days.

So from that point on, my credibility, you know, improved. But I wasn't sure how long it was going to take. But basically DMFs, we don't approve them per

se; we just say, "This looks like it's acceptable, because we don't approve the subpart of the application. We approve the entire drug application."

So, but we looked it over, we said this looks acceptable, and that was it. So it was a pretty benign and painless experience. Ultimately, how long it takes to review or clear some of these things really depends on the quality and the scope of the submission.

So where are we right now? My take as of today is we are probably 30 to 40 percent LEU globally. I think the trend -- you are seeing a number of reactors making the transition the next few years. You are seeing a lot of interest with alternative technologies or existing technologies in terms of producing moly-99, and they are all in various phases of development.

And the concerns -- this is sort of my negative slide. Although moly seems to be stable for 2014, there are some challenges in the 2015 to 2020 period. In 2015, the Belgium BR-2 reactor will be shut down for a year and a half. The intent is to refurbish it and get it back up online before the Canadian NRU shuts down. So it is a coordinated effort. But they will be out of commission for a year and a half.

The French reactor shuts down permanently in 2015. They are supposed to be replaced by I think

the Jules Horowitz reactor sometime around 2020. Those usually don't come online when everybody predicts, so there will be some delay there. But that's not a large reactor, but it's still an ongoing site.

And in 2017, the reactor will still be operational -- they will be using it for other types of research -- but they will cease producing moly-99, and they have stated this, you know, publicly on several occasions.

But there are some positive sides as well. The production capacity has actually been increased recently, because you've seen other reactors, like Poland's MARIA and the Czech Republic's LVR-15 reactors enter the pool. So you've got more diversification.

The Australian reactor, which is really relatively new -- I think it went online in 2008 or 2009 -- they found out that their producing capacity was limited, so they have broken ground to increase their production capacity. And I think 2017 is not the case; it may be online as soon as next year, 2016.

There are numerous -- and I referred to some of those earlier -- alternative both international and domestic initiatives to produce moly. And there are the countries that have never exported to the U.S., and they have mentioned they would be interested in selling to

the North American market.

So my -- you know, people -- there is a list, so you can't say we're not concerned, but what I say is, if there are -- we can handle a single unplanned outage. But if there are multiple unplanned shutdowns, you know, you see a high risk of creating a real tight or shortage situation.

But the situation today is really more stable than in the past, primarily because of the addition of the European reactors and the current increase in Australian capacity. The 2015-2020 period is going to be very, very tight. There is concern in the 2016-2017 period. There is also concern quoted not only by the OECD but by an NNSA review of the program that there could be an overabundance of moly-99, if everybody who says they are going to produce in fact get online.

As far as FDA, we will continue to interact with the regulated industry to help them navigate what they need to do. And, you know, our primary concern is to make sure that the drug quality and the purity are maintained.

That's it. Any questions?

CHAIRMAN THOMADSEN: Thank you. Questions from the Committee? Yes, Mr. Mattmuller.

MEMBER MATTMULLER: Steve Mattmuller. A couple of comments, and then a question or two. You mentioned the cost -- what the original cost estimate in the 2009 NEA report was, and in the more recent one, they actually admitted that their earlier estimations of what the cost would be for the conversation of HEU targets, the LEU targets, and processing, and the additional waste, was far greater than what they actually anticipated. So that has complicated the efforts for this conversion to full LEU production of moly-99.

And just another comment in regards to how difficult and the length of time it takes for some of these new reactors to come online. There is a French reactor under construction right now, and it's -- the containment vessel has been capped. But they are still three or four -- no, excuse me, five or six years away before they can actually produce anything. So it's just -- from our perspective in nuclear medicine, it is incredibly frustrating to see them appear to be so close yet so far away.

And, likewise, even with -- there is a relatively brand-new reactor in Germany that was never originally designed for radionuclide production. It was just for testing, materials testing and such. But

they have been trying to add a radionuclide production capability. And you think, gosh, if you've got neutrons, that would be easy, but it's still taking them -- their estimate is not until 2017 where they will actually be able to produce some moly-99, so it's frustrating.

And for those of us who used to get nervous about the three letters called the NRC, we now pay attention to something called the ORC, which is the outage reserve capacity, for when a reactor goes down. Hopefully, most of them are planned, as in the case for when the Belgium reactor goes down. But once that goes down, supply is going to be very, very, very tight. So if there is any additional unplanned outage from another reactor, it could get to be very ugly, again, like we have experienced in the past.

And to put -- so my first question for you. For the big Canadian reactor, 2016, is that going to be January of 2016 it shuts down or December of 2016?

MEMBER SULEIMAN: October.

MEMBER MATTMULLER: October. Okay. That's 10 more months than I thought. Okay.

And then, from publicly available documents, I know that the NorthStar generator system has been submitted for an NDA application that you can't

talk about or even acknowledge. But in my mind, that would be -- because in some sense moly-99 is easy for the FDA to look at as far as radionuclidic and radiochemical purity. We really don't care where it comes from; that's easy to incorporate into someone's manufacturing process.

But this is a whole new generator-type system that could take several years to review and approve. And what can I ask you that you can answer in public? So has the FDA allocated additional resources for an expedited review?

MEMBER SULEIMAN: Well, we don't -- when people talk about expedited review that means they have done everything right. And so recently I offered a suggestion that I think if people go through the regular process and do it right, it will get approved well in advance. So it's in the system, and that's all I can say, you know, at this point.

I mean, there have been some delays, but they have broken ground. I mean, they have shared that information.

MEMBER MATTMULLER: Right. Right.

MEMBER SULEIMAN: They are actually getting their moly using the University of Missouri [Reactor]. They are using neutrons, but they are using

reactor neutrons. So at one point I thought, are they using LEU? No, they are actually using the neutrons, irradiating the moly-98. Okay?

There are other production facilities that are going to be using their accelerator methodology to generate the neutrons to irradiate the moly-98. So they are going to get the neutrons one way, you know, or the other. And they sort of -- I think they are also talking about producing moly-99 using the moly-100 as a target material.

CHAIRMAN THOMADSEN: Other questions? Obviously, very clear. Thank you very much for the update.

And, Dr. Zanzonico, who will be talking about the ACMUI bylaws.

MEMBER ZANZONICO: Good afternoon, everyone. So we're going to take a little detour, hopefully brief, from some of the scientific and technical issues we have been talking about to address a rather longstanding -- surprisingly longstanding parliamentary issue, namely the revision and approval of the bylaws of the ACMUI.

And I don't have any slides to present on this topic, but you see being displayed some of the pertinent sections of the draft bylaws that still

require attention.

Now, as you know, the Bylaws Subcommittee and the ACMUI overall have been working on its draft bylaws for some time now, and we -- that included holding a teleconference past this August. And it became clear at the conclusion of that August teleconference that there were two -- there are only two issues that still were not able to be finalized.

One of these was on possible language on extension of the two-term or eight-year limit of ACMUI members, and some language on recommendations of the ACMUI for exceptions to those limits. And there were a lot of compelling reasons that were put forth for that. For example, there may be ongoing issues being addressed by the ACMUI that could be disrupted if one of the members who is rotating off happened to rotate off in the midst of those deliberations, and so forth.

So that was one issue, possible language on extending or exceptions to the eight-year term limit.

The other was on the definition of a voting quorum. And the current language -- that is, the language in the current bylaws, indicated that decisions could be made by a majority vote of a quorum, which in turn could mean that a minority of the ACMUI membership could make a decision, and there was a general uneasiness

with that fact.

So in the -- other than those two issues, there was general agreement on the bounds of the bylaws.

Now, the subcommittee, the Bylaws Subcommittee, has been working on this for a surprising amount of time and expending a surprising amount of effort via email since our August teleconference. And our current recommendations on those two points are as follows; namely, the subcommittee decided to leave the language in Section 3.1 -- can you just navigate to 3.1 first? I know it's out of order. But basically, if I can read that for you, the pertinent language is that "the term of an appointment for the ACMUI is four years, and the Commission has determined that no member may serve more than two consecutive terms, eight consecutive years, unless directed otherwise by the Commission."

We went through a lot of alternative language, none of which was satisfactory to anyone, really. And so we decided to leave that language as is, recognizing, as we have been told both by the NRC staff and the Commission itself, that there is an open door policy.

So if the ACMUI as a whole, or individual members, felt there was a compelling need for an exception to the eight-year or two-term membership, that

there was sufficient flexibility in just our general way of doing things to bring that to the attention of the NRC staff as well as the Commission itself.

So rather than trying to be overly prescriptive to the point of perhaps excluding certain contingencies, we thought it best to just leave this language as is and take the open door proclamations at their face value. So that's the first recommendation of the subcommittee, to leave this membership -- this language on membership as is.

The second point on a voting quorum was drafted in consultation with the Office of General Counsel, the OGC, of the ACMUI. And the new language is specifically designed to address this unease with the possibility of decisions being made by a majority of the ACMUI membership.

And so the language on this point, which is highlighted in yellow on the screen is, "Decisions shall be made by a majority vote of the current ACMUI membership. Should one or more members be unavailable for compelling reasons, such as extended incapacity or recusal, the current membership shall be regarded as reduced accordingly."

And so that language, number one, would avoid a decision being made by a minority of the

committee membership, but it would also avoid the possibility that a decision would be postponed indefinitely. Should a member be unavailable again, either because of recusal, illness, injury, imprisonment, whatever the case may be, they could -- that person would be no longer part of the current membership, the voting membership, and so a decision could subsequently be made in short order.

So what I would like to do is ask someone to make a motion to first -- if there is no discussion or comment, but that aside, someone make a motion to approve the recommendations on these two points specifically, assume that's approved, to then have a vote on approving the overall current version of the bylaws.

CHAIRMAN THOMADSEN: And I assume that the subcommittee is making this motion.

MEMBER ZANZONICO: The subcommittee is making the motion. And if I didn't say it, I should say the subcommittee has unanimously approved both of these points, the language on both of these points, Section 1.3.5 and Section 3.1.

CHAIRMAN THOMADSEN: So since that is the motion of the subcommittee, it is on the floor for discussion at the moment. Comments? Yes, Dr.

Alderson?

MEMBER ALDERSON: I think you have done a great job, considering the controversies that were involved here. And I think that we should support these recommendations.

CHAIRMAN THOMADSEN: Thank you. Ms. Weil?

MEMBER WEIL: No, no. I was just -- I was pointing to --

MS. DUDES: I just -- I would just request, with all the work that has been done, that if the Committee would also consider -- and this is just an administrative change. But as I'm reading this, it has the acronym for our office, FSME, in there, and if you would also consider approving the staff member to just make a blanket change to reflect the merge that will occur next week. No wording other than any reference to FSME with that -- that would be replaced.

CHAIRMAN THOMADSEN: Are there any objections?

MEMBER ZANZONICO: That strikes me as the least controversial --

(Laughter)

CHAIRMAN THOMADSEN: Very fine. Hearing no other comments, all in favor please say aye.

(Chorus of ayes)

Those opposed say no. Any abstentions?

In that case, we will move on, since we have now approved -- we have accepted, and I assume endorsed, the report, we now need to, as a committee, adopt the recommendations of this committee as our bylaws. And I'll ask, are there any comments before we take a vote on that? I assume not, or there would have been comments before this.

All in favor say aye.

(Chorus of ayes)

Opposed say no. Thank you very much. Great job.

(Applause)

Now, returning to something more substantive, also from previous meetings, we will have Dr. Howe talk about iodine patient release. Welcome, Dr. Howe.

DR. HOWE: Thank you. Now you can hear me with a microphone I hope.

CHAIRMAN THOMADSEN: Not very well. You're going to have to --

DR. HOWE: I'll move it closer. Is that better?

CHAIRMAN THOMADSEN: It's a little better.

DR. HOWE: Okay. Iodine patient release is

a continuing issue with the NRC and with the medical community. And on April 28, 2014, the Commissioners gave us staff requirements for Commission Document COMAMM-14-001, and then the other COM from Commissioner Magwood, 14-0001, also.

And the title of this was Background and Proposed Direction to the NRC Staff to Verify Assumptions Made Concerning Patient Release Guidance. Now, we have brought to you several times another Commission SRM, Staff Requirements Memorandum, that dealt with: where do patients go after they are released; and do they have adequate instructions; and are they allowed to go to hotels and other public places?

This one is different. In this particular case -- and I'll go through what the Commission directed us to do -- is much more patient information oriented. So the Commission directed us to consider developing a website that would provide access for patients to clear and consistent patient information. So that would not necessarily be just radiation safety information, but it would be general information that patients would want to know if they are having, in this case, specifically I-131 treatments.

A standardized set of guidelines to provide instructions to patients, there was concern that

different licensees have different levels of instructions to patients, and that causes confusion and there is no standardization. So they directed us to do that.

They also want us to determine whether we or a medical organization has a brochure that can be used for nationwide distribution that provides patient guidance. They also want us to determine if there is a significant -- if we need significant regulatory changes to our patient release program, and I'll go into that in a little more detail.

And as a part of all of this, if we do devise new guidance, if we do major changes in rulemaking, then we need to revise our Reg. Guide 8.39, which is the regulatory guide for patient release. And also, in conformance with that, our Appendix U in NUREG-1556, Volume 9, which right now is almost identical to the guidance that's in Reg Guide 8.39.

So what has the Commission directed us to do? First of all, they want us to get information from a wide spectrum of stakeholders -- the public, we always get public comment; patients, we are supposed to be trying to get down into the patient level; patient advocacy groups; physicians; professional societies; licensees; ACMUI members; and Agreement States.

For us to get that wide spectrum of stakeholder input, we are going to have to get an Office of Budget and Management clearance to be able to collect information from more than nine sources. So that is going to be a major component of what we are doing.

We are planning on going out to collect this information using a Federal Register Notice. And when we use a Federal Register Notice that means we also put it on our medical list server, and we try to go out to professional organizations also to maximize the exposure of what we are looking for, so we can get as much input as we can. And we are also planning on having public meetings.

Now, this initiative is going to take quite a while. I mentioned earlier that we have a Commission paper about where are patients going when they are released, what is the frequency, what kind of guidance are they getting. That has a contract that is associated with it, and the contract will take a number of years to collect the information.

And so we won't be making any final guidance changes or rulemaking decisions until we have the results of that contract, in addition to the results of the work on this -- as a result of this staff requirements memorandum.

So let's look at it in a little more detail. You can break these things into a general perspective. One is guidelines that licensees can use to provide instructions to patients. The Commission wanted to make it very clear that these were not supposed to be new requirements; they are voluntary. They can be adopted as best practices.

This is kind of an opposite direction than we normally go. We normally go to the medical community and say, "Well, what are your best practices?" and then we kind of work our regulations around those. In this case, the Commission wants us to provide more uniform guidance, and the medical community can use it. And the whole purpose is to reduce the variability and eliminate uncertainty with the information provided to patients.

And as a result, as stated earlier, if we do develop new guidance, that guidance will be eventually implemented and put into Reg. Guide 8.39.

One of the things that it addressed is the potential for a model patient acknowledgement form that they envision as a form that is fairly simple that the patients can read and sign and also the licensees would sign. And one of the things that they are looking for in this patient acknowledgment form -- there are really three big categories.

One is that the patient understands the instructions as communicated. Two, that the patient acknowledges, for example, that they've gotten information on certain key topics -- an explanation of the treatment process, understanding of the need to reduce exposures to others, and how long they need to take special care.

And another major topic is that they work with the licensee to develop plans for their release, once they've left, how they're going to get to where they're going, the arrangements to protect others, minimize exposure, manage biological waste. Many, many trash trucks go to the dump and get turned back because there are chicken bones from an I-131 patient or some other contamination material that should have been held but wasn't.

And the patient knows what to do if they need emergent care, emergency care, and who they contact if they have any questions. So these are all basic concepts, but they are not necessarily radiation -- some are radiation safety, some are not.

In asking us to develop a website, what they really want us to do is if somebody else has got a good website, has this information already, that we can use our NRC website to link to that information, so that we

don't have to start from scratch. But if there are some things that we don't find that we've got good websites for, then we'll have to develop the content.

The website is going to have basic components, which radioactive iodine, that's something NRC can probably address easily. The radioactive iodine treatment -- this is more medical, so we would not expect NRC to be developing this information but going out to other sites to find it. And that's, how do you prepare for the treatment, what to expect before and after receiving, and what side effects.

Basic radiation safety -- we have a pretty good handle on most of this. This is the precautions to take after receiving a treatment, the risk to others, the appropriate statements regarding risks to young children and pregnant women.

And probably the most controversial thing that they have asked us to do is make a determination of whether we need significant regulatory changes to the patient release program, and to see if they are warranted for an activity-based patient release threshold under which patients could be required to be maintained in a currently sponsored facility. We didn't say "hospitalized"; we just said may be held for a period of time, and it could be minutes, hours, before their

release. And to clarify whether the current dose limits in 35.75 apply to each individual administration or they apply on a yearly basis.

NRC believes it knows that it -- the answer to this question. The ACMUI does not agree with the NRC.

They want to see if we need regulatory changes for the current patient release standard. The current patient release standard in 35.75 says that you can release patients as long as the maximally exposed person does not exceed 500 millirem. That is higher than the public dose limit in Part 20. And Part 20 currently says that Part 20 does not apply to doses received from patients. So the question is whether that limit should be reduced to the Part 20 public dose limit or not.

And also, whether we need to develop specific requirements for releasing patients that are going to be in contact with young children or pregnant women, and whether those limits need to be above the current Part 20 dose limit, which is the current 500, or whether they need to be dropped down to the Part 20.

So those are questions that we are going to be asking out in the public forum as we develop a Commission paper that recommends either that we go forward with a major rulemaking or we not go forward with a major rulemaking.

How long do we think that it will take to respond to this staff requirements memorandum? We have actually got timelines out that go -- certain items are going to be out in 2015. Those are the easier ones that we can address -- whether there is a brochure out there, whether we can come up with a website, whether we can standardize guidance. But some are going to be out in 2019, and that's because we've got to wait for the information to come back from the other staff requirements memorandum and the contract.

So, what are we going to do for a path forward? We're going to have extensive outreach on U.S. and international practices. That was another question that came up in a slightly different Commission briefing, and so we are going to find out, what is really going on in the international practices, how do we match up with it.

We have started some preliminary work on that. We are also going to have extensive outreach to professional societies, patient groups, and the medical community as a whole. And that is -- we are intending to go out with our Federal Register Notice to ask for a lot of input on the questions on guidance, on websites, and the basic information that we can collect.

And then we will also have public meetings

to go out on -- whether we should go forward with proposed rulemaking and the issues that we are going to be looking at to see if we need to address.

In the short term, we are developing -- or going to develop a Federal Register Notice to solicit patient-focused information from all stakeholders. But before we can send out a Federal Register request for information, we have to develop an OMB clearance to have the ability to get that information, collect that information. And then we are also going to be looking to the ACMUI for assistance in all levels of this effort.

So that's what we are thinking of. We've got a timeline out to about 2019. And if we go to rulemaking, the rulemaking probably wouldn't happen until our basic 2023 rule.

So do I have any comments or questions from the ACMUI?

CHAIRMAN THOMADSEN: Thank you, Dr. Howe. I think we do. Dr. Langhorst?

MEMBER LANGHORST: Thank you. Dr. Howe, the direction of the Commission referred to iodine patient release or all patient release?

DR. HOWE: Most of the specific information that they are looking for -- is I-131 related. But they also asked us when we revised the guidance for 8.39 or

NUREG-1556, that guidance has to be more general in global and --

MEMBER LANGHORST: Right.

DR. HOWE: -- encompass all patients.

MEMBER LANGHORST: Because 10 CFR 35.75 is not limited to just iodine patient release.

DR. HOWE: No. But right now they are focusing, because they've had more experience, they've been out to the thyroid patient conferences, and so they are focusing more on I-131. That is our largest group of patients with patient release issues.

MEMBER LANGHORST: Right. Right. And I have just one comment, and this is a comment that I have -- I have made to NRC staff in the past. There are two locations currently for patient release guidance, and that's the Regulatory Guide 8.39 and this Appendix U and 1556 Volume 9.

And I love the 1556 series. As an RSO who has to write license applications, they have been fabulous in my opinion. However, I think I was asked a few years back about whether Reg. Guide 8.39 should then just be rewritten to reference Appendix U. I recommended that it not, because I think the general public would not know to look for the 1556 guidance documents and would be lost in the amount of information

that is there.

I think that it would be better to have one guidance document, and that should reside in the 8.39 guidance document with the Appendix U referencing it, because I think those who use that 1556 are much more knowledgeable and know where to find the regulatory guides, whereas the general public I think could find the regulatory guide a lot easier. So I just wanted to make that recommendation again from my own personal opinion.

DR. HOWE: And our intent is to maintain Reg. Guide 8.39 as the patient release. There are a number of things that go into developing 8.39 that is -- and 8.39 is -- our NRC Office of Research is responsible for it, and it has the ability to do contracts and other needs of updating the information out there that our local medical team doesn't have the resources for. So NRC's intent is to keep 8.39 as our document.

Having said that, we are in the process of revising NUREG-1556. We have gone out with some risks that provide guidance on patient release -- hotels and infants and pregnant women. And that information may be incorporated into 1556 before we get to our final revision of 8.39. So there may be a period of time in

which 1556 is a little more up to date on guidance, because it is incorporating things that we have already said, but we will be catching up with 8.39 for the really technical stuff.

MEMBER LANGHORST: Thank you.

CHAIRMAN THOMADSEN: Yes. Mr. Costello?

MEMBER COSTELLO: Dr. Howe --

DR. HOWE: Yes.

MEMBER COSTELLO: -- in anticipation for this meeting, I sent an email out to all of the Agreement States of what our agenda was going to be, and the topics, and the only topic I got any comments on was this one, and not surprisingly.

And I think the States in general are not looking for changes in the basic rule. I think people have accepted that. However, there are two points that I think the States want to make. One is -- and you already talked about both of them already -- patient instruction. And the issue with patient instruction that they want help on is how to handle their waste, and you have that up there.

The States spend, including Pennsylvania, in fact maybe more in Pennsylvania than any other State, an incredible amount of time following up on alarms at transfer stations and landfills. We probably average,

just in eastern Pennsylvania alone, maybe one a day during the working week, every day. Philadelphia has a lot of big medical institutions, constantly.

In addition to that, we have also had a phone call from the mother of a thyroid cancer patient whose waste hauling company is threatening to fine her thousands of dollars if their waste set off any alarms at the landfill, because in this county the landfill is not permitted to receive any -- any radioactive materials.

DR. HOWE: That's not unusual.

MEMBER COSTELLO: And that the hauling company, when this happens, they are threatened with fines by the landfill. They plan to pass these along to the patient.

Now, the woman who called our office says, you know, "I've got this daughter who has got thyroid cancer, and now I'm being threatened with fines." And she was complaining that she didn't receive sufficient guidance from the medical institution that sent her home.

Well, calling a regulatory agency like us, there is not much in the way of relief that we can give them. We have, in some cases, given all the relief that we can give, that this waste can be disposed of as normal

waste and there is no safety or regulatory reason whatsoever that it can't be sent to a landfill.

But these landfills oftentimes -- and the hauling companies are private corporations, private companies, and they -- I mean, we contact them, but they don't have to do what we tell them to do. They don't have to accept the waste if they don't want to.

Now, this particular issue was resolved. They worked it out that they would notify the waste hauling company in advance, and they will then make a special run to pick up their waste from this residence and hold it for decay for a while, and then send it off.

So, basically, what we'd like is when we do have these instructions, that they explicitly help the patients, so this doesn't happen to them, and help maybe the States so we can do, like, real radiation safety things instead of responding to an incredible number of alarms.

Pennsylvania has got alarms everywhere, okay? I think, you know, Pennsylvania has alarms at the transfer stations, we've got alarms at the landfills. We're a state of alarms, right?

So we hear about these all the time. I'm sure other States hear about them, and I'm sure you hear this from other States. But we would like the guidance

to be comfortable for the patient. We don't want to hear about patients being threatened with fines for doing nothing wrong, and these are cancer patients. Okay?

The second issue, and you've touched on this as well, is that doses of 100 millirem versus 500 millirem -- question as to what should the dose be to family members when these patients are sent home. And I have not heard from a large number of States -- a few -- but I think the ones that I have heard from, they would urge 100 millirem, because 100 millirem is a safe dose for members of the public in other circumstances. Why wouldn't it be a safe dose in this circumstance?

Now, I went back and read the statement of consideration when the rule was changed back whenever that was --

DR. HOWE: 2007.

MEMBER COSTELLO: -- but -- and they explained that, that the 500 millirem will be for an occasional situation, whereas the 100 millirem public dose limit is something they would expect to be repeated over and over again. And I understand that. I'll send you a link. It may have been earlier than 2007.

DR. HOWE: That doesn't sound familiar from the patient relations side of it.

MEMBER COSTELLO: But I think of the States

that I talked to; I think they would understand the rationale better for larger millirem rather than 500 millirem. Okay?

Now, the third issue that I hear from the State -- my own State -- and which I don't know if you can do very much about -- I hope this will call it to your attention -- is that EPA has very, very low standards I-131 drinking water, because they have very low dose standards for dose to the public from that pathway.

Well, there is a creek -- there is a very small creek. We have a place that draws from the water from there, and sometimes we have -- EPA has made measurements which exceed this level of I-131. Okay. And we've talked about this.

I don't think that the patient release rule actually affects this, because patients are going to be, you know, releasing their I-131 going into the sanitary sewer, whether they're doing this in the hospital or whether they're doing this at home or whether they're doing this in a hotel. I'm just saying this is a pathway. I don't know actually if it has been looked at. And it is a pathway for population dose from this treatment.

So I was asked to call this to your attention, and so I have.

So none of this -- you've got, you know, pathways that go to 2019, so you have plenty of time to work on these.

DR. HOWE: Yes. And we really are looking forward to getting comments from the States that are specific to the things that they are interested in. And Laura Weil brought up a number of the points in the ACMUI discussion with the Commission, and we think the general philosophy is patients want to do the right thing. They -- we need to make sure they know how to do the right thing, and the medical licensees need to make sure they know how to do the right thing. So I think this is more of a reinforcement of that concept.

And I-131 released to the environment, everyone assumes dilution of the solution, but every once in a while you end up with re-concentration.

MEMBER COSTELLO: And so, also, I think EPA's limit is unreasonable. You know, they are talking about it's either three or four millirem in a year, which is, you know, not a significant dose. But they have their rules, and we have ours.

DR. HOWE: Yes. And I think most -- I mean, the guidance I have seen so far is we've got -- the patients are told to hold onto their trash for a period of time before they put it out on the street, whether

they're doing that or not, and that's causing additional alarms.

But you never want them to stop looking at alarms because every once in a while that is really something important.

MEMBER COSTELLO: Yes.

DR. HOWE: Although the I-131s and the technetium dye, there is no substantial --

MEMBER COSTELLO: We approve all requests, all requests, when the I-131 is identified. If they find cesium-137, it might be different.

DR. HOWE: Right.

CHAIRMAN THOMADSEN: Dr. Welsh?

MEMBER WELSH: Being a member of that Patient Release Subcommittee, I have a number of comments. First, regarding the Commission direction to create a model patient acknowledgement form, initially I was thinking that, well, maybe I'm not in favor of that, because it sounds like it could be an encroachment upon medical judgment.

However, after you explained it, I'm not convinced of my counterargument -- that I would be in favor of this, particularly because I hear over and over again that patients weren't told this or they misunderstood something and this is what happened with

the trash, for example.

And I know that all patients have to sign a consent. Maybe if that consent was standardized and produced by the Federal Government or endorsed by the NRC, and the language is crisp and clear and everybody can see it, this controversy about, "Well, I was never told this" might go away. However, the possibility is that Agreement States might not follow this particular recommendation.

So that's one thing that I would make a comment on, and I'm in favor of the patient acknowledgement form.

But other points are extremely controversial, and one root cause of the controversy is the adherence in this country and many other countries on the little or no threshold hypothesis, which I think I've said many times at this -- in this venue I'm not a big fan of, because it's not supported by the science. However, it leads to tremendous consequences, and those consequences can be quite severe.

And people tend to underestimate the severity of these consequences. The radiophobia that the general public has is actually quite alarming and quite concerning and detrimental, I think, to the welfare of the general public. For instance, when we're

talking about, should it be 100 or 500 millirem, both of them are below the annual exposure from natural background radiation depending on where in the world you live.

So if it's okay to live in the Rocky Mountains or if it's okay to live in parts of India or Iran, why shouldn't it be okay to receive exposure from a radioisotope in New York City, for instance. The health consequences are unlikely to be very different.

Therefore, when the NRC goes forward with all of this, I might recommend that when you -- I think you said you might explore international standards and possibly attempt to match them, I would caution -- maybe I misinterpreted the words, but I would say do not -- I would advise not trying to match international standards, because some of these other countries are even more radiophobic than the United States. And the consequence of this general international radiophobia is perhaps in the best interest of patients and the medical care that we would like to give to patients.

So those are my general comments.

DR. HOWE: And we've gotten some preliminary information. We wanted to go directly to the countries and ask them what their standards were and what their release practices were, and most of them are

much more conservative than the U.S., and most of them have -- some of them have implemented release standards after our 1997 rule, but they are still more conservative than what we have. We seem to be the least conservative of any of the groups.

So I don't think the staff's intent is to go and match the international, but we -- the Commission has directed us to see how we fit in with the international community.

MEMBER WELSH: So I guess my point there is that, although the other countries are more conservative, perhaps they are not correct. And for us to get in line with the international community might be a move in the wrong direction. And I would say that the NRC is quite smart, and the United States generally is an intelligent country and can probably make its own decisions. And I would caution against getting in line with the conservative international opinions on this particular issue.

DR. HOWE: Thank you. Point well taken.

CHAIRMAN THOMADSEN: Mr. Fuller?

MR. FULLER: And I think I can respond to that, too, just to kind of give some perspective. At this point in time, we have been instructed to collect information and to look at things. This would

definitely require a change in the rule. And before a rule would be changed, we would go through that long process I was referring to this morning.

It is a very deliberate process with a lot of public interaction, and so -- and, you know, the risk associated with the various limits for dose to members of the public, all of that would have to be deliberated on in several different venues. So it would not be something that the staff could just say, "Well, this is what we are going to do." So, but we do appreciate that perspective.

CHAIRMAN THOMADSEN: Thank you. Dr. Suleiman?

MEMBER SULEIMAN: I'm not 100 percent comfortable with my memory, but I was involved with an IAEA document leading up to the basic safety standards, involved with surveying the different countries. And as I recall, they're all over the place. I didn't perceive that we were the most conservative, and I found it a surprising inconsistency. I mean, so I would -- I would reinvestigate that and be more careful.

We were surprised at the range of recommendations. The two things that sort of stuck in my mind was in Germany they hold urine. They don't dump it down the sewer. And as I recall, everybody -- they

tried to figure out why. That was considered a much higher risk, because you are concentrating all of this radioactivity. And numerous studies have shown that with the decay and dumping it in the sewer system it was really the safest, you know, way.

And we could never find out why the Germans did it this way, except that once they had adopted it, and the local building codes had adopted it, they were doing it a standard way, and by God they were not going to change it. So, except for that German practice of collecting all the urine, so you had a hotspot in the hospital when you walked by those tanks --

DR. HOWE: I think we found more than one country that holds the waste in holding tanks and then releases it later after decay. So we are seeing that variability in the information we are getting back. The one good thing about the European Union and some of the other countries in Europe that are kind of going together is they are adopting more standardized guidance and regulations on what they're doing.

So we are not having to see -- when we go to France, Germany, Belgium, The Netherlands, we are not seeing as -- we are seeing -- we agree with HERCA, or we agree with some other IAEA document. So we are seeing a consistency among some of the countries. They are much

more conservative than we are.

CHAIRMAN THOMADSEN: Yes, Dr. Zanzonico?

MEMBER ZANZONICO: I just want to make a couple of points. First, I think there is a lot to criticize in the Commission directions. I mean, it's, frankly, based on a political reaction and not very much on science. So I just wanted to say that.

The other issue is I am really troubled by the possibility of an NRC website. That strikes me as a regulator interposing itself between the physician and the patient. I can see providing information, resources, and so forth to hospitals, to physicians. But as I say, I'm really troubled by the possibility of a regulator communicating directly to patients and, in effect, bypassing the caregiver.

So those are just the points I wanted to make.

DR. HOWE: And that's certainly an area that we are not in today, but it is an area that our Commission is asking us to look at. And I think they see it more as a reference document.

MEMBER ZANZONICO: But I think the NRC, being a federal regulator, and having their logo on the website, it is not as innocent as it sounds. It is going to be interpreted --

DR. HOWE: Totally understand.

MEMBER ZANZONICO: -- by individual patients as the final word, and they are going to go back to their patient -- to their physicians and say, "What you told me was wrong, because the NRC on their website says XYZ." I think it's just a bad idea and a bad precedent.

DR. HOWE: And one of our -- if we do go ahead with the website, one of our intents is to put links to more medically oriented websites that do provide more patient-oriented information. We don't want to develop the content ourselves, because that is not our level of expertise.

MEMBER ZANZONICO: I should say, having said that, I agree completely that the instructions are very non-uniform and very poor in many respects, and very poorly communicated. My problem is not with the concept of a standardized set of recommendations and safety precautions. My problem is with that originating with the NRC, with the regulator, and being communicated directly to patients.

CHAIRMAN THOMADSEN: Dr. Guiberteau?

VICE CHAIRMAN GUIBERTEAU: I have the same concerns as were just expressed. I do think understanding how government agencies, whether they be

State or Federal, have a reluctance to basically appear to endorse any sorts of documents from links, that this would have to be handled very carefully.

But I do like that idea, and it might be part of the work of this Committee to induce a consortium of those professional societies involved in this, such as the Endocrine Society, the Society of Nuclear Medicine, the ACR, et cetera, to work on a -- you know, a set of, say, minimum safety precautions, or however you wish to word it, so that you would sort of be working from the back side in, because I think if you have a whole list of these listed there, I mean, someone could say, "Well, it was recommended" -- and they will, they will say, "It was recommended on your website, and I just happened to hit the wrong one, because if I had done this one, then, you know, I would have been better off about controlling my waste."

But I think that's something that we have talked about here, and we haven't really -- if you are going to outreach in the communities, and this would be the perfect community -- this would be the perfect Committee to do that.

Second of all, if you don't mind, I have some questions, but I don't want to conflate them. So the second -- my second question is on this model patient

acknowledgement form. I presume -- it says model form read and signed. I presume that you mean a model for patient acknowledgement that this -- these would be elements that would be in your form.

But, for instance, at our institution we are very conservative, so we might want a form that was even more conservative than what this model would be. But I presume by "model" it is something that would be used but not mandatory. Is that correct, or is that not the intent here?

DR. HOWE: The Commission's intent is not to have this be a required form, but a model form that people could pick up and use. We are having a difficult -- and we will have a difficult balancing act. Our previous process has been to be more performance-based. The guidance we are getting in this particular staff requirements memorandum is more prescriptive.

And in the end, how do we balance that performance-based with the prescriptive? In other words, if it were performance-based, we might say, "It would be beneficial to have a form patients could sign," and just list the bullets. Have you talked about these elements with the patient and the patient talked about these elements with the physician? And they would be

in very general global terms, but we may be directed to be more specific than that, and I don't know. But we are going to be working that balance.

VICE CHAIRMAN GUIBERTEAU: One of the things in my career has been the decidedly beneficial movement of regulations nationwide, but particularly with the NRC, from moving from being too prescriptive to being performance-based. So I would hope there would be a balance here. And I do understand sometimes that prescription is needed, but I do think that just what I hear from all of my colleagues that this is something everyone appreciates. So I would hate to see -- I would hate to see a movement back in the other direction.

My final question is here on your path forward, because it says short term, and for any government agency short term is usually longer than one would like. But in terms of what do you mean by short term, particularly with respect to a Federal Register Notice soliciting patient-focused information from all stakeholders, and what does that mean, patient-focused information?

DR. HOWE: Well, if you went back and looked at some of the earlier slides, that I have a standardized set of guidelines. We are looking for, what do people have now? What do the medical facilities have now for

guidelines? And we'll look at those and see what looks really good, and some things may not look quite as good and they standardize and make that. So that is the kind of information we are going to be looking for.

We are also going to be looking to see if people have other things that they think ought to be part of that dialogue between the patient and the physician for a patient acknowledgement form. And we will also be looking for, you know, the things that are discussed and our website information.

So we are trying to collect a lot of information that we could be using for the general guidelines, and we could be using for the website, and we could be using for developing the model standard patient form. And that's what that Federal Register Notice is. It's to collect a lot of information from patients, physicians, facilities, Agreement States, societies, so that we have a very broad perspective of what the community wants and what the community has available to it.

VICE CHAIRMAN GUIBERTEAU: And this begs the question, once all of this -- and this will be a lot of information --

DR. HOWE: It will be a lot of information.

VICE CHAIRMAN GUIBERTEAU: -- and it will

be large bell curve, that -- who will be the arbiter of what is the proper -- you know, what is the proper level for -- and position for the NRC to take? Would that be part of this Committee's duty?

DR. HOWE: Certainly, this Committee would be a big part of that. Sometimes it is very easy. We go out for public information, and we get formal letters. Okay. Five thousand people said this. Okay. We don't have one document we've got to read. Other times we get little variations and we have to meld it all together. That's what we normally do.

But we will be coming back to you for guidance, and I'm hoping I'm going to get some assistance from the ACMUI.

VICE CHAIRMAN GUIBERTEAU: And so that we will be forewarned, when do you anticipate such a call for information?

MR. FULLER: I'm sorry to interrupt. Just to clarify, because we had an earlier discussion. There is actually two things. Very, very early on when Dr. Howe starts working on drafting this Federal Register Notice, we are going to -- we are seeking some volunteers, if you will, not the whole subcommittee, to get back and forth and go through that formal process. But just some folks on the Committee who could review

and work with Donna-Beth and make sure that we are getting the right message in this Federal Register Notice and also that we are focused on the right audience.

So some early involvement with some key folks from the ACMUI would be very, very helpful to us as we develop this. But certainly anything that we then draft or work on or get to some point where it's ready for review, that will definitely be coming right back to this Committee.

And we have the timeframes worked into the time -- that's another reason why it seems like we should do things quickly, but it takes a year or more. We have built in those timeframes where we know that the ACMUI and the agreements, probably subsequent to that, would have an opportunity to look at these drafts, tell us if we are headed in the right direction or if we are way off course, or what have you, and so this body, through the Patient Release Subcommittee and other ways, will have its normal opportunity to work with us and help us get it right.

VICE CHAIRMAN GUIBERTEAU: So those are very welcome comments. Thank you.

CHAIRMAN THOMADSEN: Ms. Weil?

MEMBER WEIL: I'd like to comment on Dr.

Zanzonico's concern about the NRC as a regulator interposing itself between patient and clinical team. And I think we need to twist that a little bit, because what is being proposed really doesn't affect treatment and treatment decisions. It -- what is being proposed will protect the public health, non-patients, family members, the general public, from radiation exposure.

So it is not really sticking its nose into the clinical decision-making. It is after the treatment is completed, how do we protect the public health?

CHAIRMAN THOMADSEN: Dr. Dilsizian?

MEMBER DILSIZIAN: It's just -- this discussion reminds me of inappropriate use of a lot of procedures when society has had to take charge rather than regulators of creating appropriate use criteria.

And I think this falls into the same category for me. I think that we have several societies here represented, a lot of members. I think that the societies already have some of these guidelines on their website. What we need to do is come together and propose our societal guidelines to the NRC, so that it will be from us to the regulators instead of from the regulators to us.

DR. HOWE: And part of our going out for

information is asking what you have out there that is available. We don't want to reinvent the wheel.

CHAIRMAN THOMADSEN: Mr. Mattmuller?

MEMBER MATTMULLER: In regards to the website, I am almost embarrassed to say that I caught this, but in the -- what is it called? A COMWDM, which is some sort of MO from the Commission -- when they talk about the website, they say develop a joint website or a link with relevant medical organization and patient advocacy links.

But then, when Mr. Satorius describes the website, he leaves out the word "joint." So I think that would allay a lot of Dr. Zanzonico's concerns and other concerns that we all have that it will be a joint website. It's not going to be a pure NRC website.

DR. HOWE: What this website looks like at this time is premature. Clearly, it has to be something that melds with our regulations, and so we will need some degree of control to make sure that what is out there does agree with our regulations. But most of the stuff that we're being asked to bring together for this website is beyond our regulations. It's medical treatment and other things, and we won't really be looking at that part.

So we are hoping to work in partnership with

a number of groups, individuals, et cetera. We aren't excluding that at all.

MEMBER MATTMULLER: Well, I guess at some -- from a regulatory walk perspective, that the Commissioners said it must be joint, but the -- Mr. Satorius says it doesn't have to be joint. So --

DR. HOWE: And Mr. Satorius' memo is the memo that brings together -- the Commission had a paper, and all of the Commissioners looked at it. Two of the Commissioners sponsored it. All of the Commissioners looked at it, and they provided comments. And when all of their comments were melded together, that was put in the form of a staff requirements memo.

So that is still coming from the Commission, but it is sent to us through SECY and Satorius. So it does represent the Commission view, but after the initial paper was written. So it's a more consolidation of all five Commissioners on what they want the staff to do.

MR. FULLER: I think the key -- if I may, I think the key here is that we -- the staff feel very confident that we are clear that we are not to do this by ourselves, that we are to do this with as much help, if you will, and appropriate participation.

You know, a number of us, I know over the

years have seen the presentations in various venues about the Image Wisely campaigns and the Image Gently campaigns. And if we could model similar type efforts, if we could model this after similar type efforts and with similar type of organization, and so forth, we think that is probably -- or something akin to that would be sort of the ideal situation.

CHAIRMAN THOMADSEN: Dr. Alderson? Yes. You. You're the Dr. Alderson I'm calling on. Yes.

MEMBER ALDERSON: Thank you very much. So the thing that -- a well-intentioned proposal, unfortunately, my concern is that there is enormous potential for misunderstanding as you pull all of this together. And in the ability of -- and I'm not being pejorative about the general public, but the ability of the general public to correctly understand these kinds of issues is, you know, appropriately limited because they haven't been educated in any of these issues. And the fear potential that is associated with radiation is well known to everybody.

So it seems to me that the real challenge here -- and this will seem axiomatic initially, but I'll expand on it -- is to do it right. And if you can really do it right, that would be great, but I think that is going to cost a lot of money. I think to really do it

right you have to really get a lot of groups together, not just medical organizations but groups that are sophisticated in how they market and project to the public. And it would cost a lot of money.

I don't know anything about the appropriations side of the NRC or how that happens, but I think this -- to do it right is going to cost a lot of money. I just hope that somebody is really committed to doing this right, because I think if you don't, it could go wrong.

DR. HOWE: Point well taken.

CHAIRMAN THOMADSEN: Yes. Thank you for that comment. Ms. Fairobent?

MS. FAIROBENT: Thank you, Dr. Thomadsen. Lynne Fairobent with AAPM. Dr. Guiberteau, just to follow up on your point and perhaps let you know what staff has been doing from the association standpoint. Society of Nuclear Medicine and Molecular Imaging has convened a group of medical association staff who have already had an initial phone call, taking a look and talking about a strategy going -- collective strategy going forward from the medical side.

So we will be looking at this issue collectively and coming forward with some unified recommendations.

DR. HOWE: And we look forward to that.

CHAIRMAN THOMADSEN: What was that?

DR. HOWE: And we look forward to that.

CHAIRMAN THOMADSEN: Thank you. Thank you both. Other comments from the Committee? Yes, Mr. Mattmuller?

MEMBER MATTMULLER: Steve Mattmuller. I was inspired by your radioactive chicken bones comment. Is there any talk of providing some guidance to poor individuals, such as Mr. Costello, and the States, that when these landfills find a minute amount of I-131 in their trash, that they just -- it's below -- be classified below regulatory concern and they can dump it and not save it and call out the teams to measure it to say yes?

I mean, because it's my understanding these sites that had the sophisticated detector system can also have handheld multi-channel analyzers, so they can readily identify it right there on the spot.

DR. HOWE: One of the big issues is we don't regulate them. They handle non-radioactive material, and many localities, when they put in a landfill, they say, "Okay. We'll accept the landfill if it has no radioactive material, no bio-hazardous waste," and they list all the things that they don't want, and they put

the level at zero. And then we don't regulate them.

And, in many cases, they get detectors because they are trying to comply with their local standards. But it's difficult for us to reach them. It's easier for Mr. Costello to reach them in his state because he is also part of the State regulatory --

CHAIRMAN THOMADSEN: Mr. Costello?

MEMBER COSTELLO: Yes. Some of these places have incinerators, and sometimes the public, you know, prefer this stuff not be incinerated even though the dose to them is zero basically. Even with non-spatial assumptions, it's still zero.

We get phone -- we get requests coming in where they're measuring 20 microR per hour or 10 microR per hour background and asking us approval to send them. I mean, it would have to be more than trivial. But because of the situation we spend an inordinate amount -- not just in Pennsylvania, but many States spend a lot of time on this.

And they would find that if the patients were instructed such that this wasn't happening that would be a good thing, because I know in Pennsylvania when they chased down this one individual whose daughter had -- you know, was threatened a fine of thousands of dollars, well, we knew the hospital that this patient

was treated at.

So we would contact the hospital. You know, "Why is this happening? Why are you -- is your patient, you know, being threatened with thousands of dollars of fines because she didn't receive any instructions really at all what to do with her waste?"

So it -- something needs to be done, because otherwise you wind up with having States imposing requirements on hospitals, so they are not hearing from patients calling, because a patient can just as well call up a legislator and then it would even be --

DR. HOWE: And my understanding is back when they started putting the detectors on the landfills, the hospitals, all their stuff was going back and they -- in self-defense, they had to put radiation monitors at the door where the trash was going out, and pull aside certain items, so that they could then successfully send them off to the landfill.

MEMBER COSTELLO: And I -- of course, all of this stuff is deregulated. All of this patient waste and the risk from this patient waste is not regulated. But we spend a lot of time working on it.

CHAIRMAN THOMADSEN: Dr. Welsh?

MEMBER WELSH: I'd just like to chime in and agree with what Mr. Costello has just said, because if

taken to its logical but absurd extreme, if we have very, very sensitive devices, and we continue to have this inordinate and inappropriate fear of radiation, then what is going to happen when there is a bunch of bananas or a can of Brazil nuts or a batch of oranges that have been thrown in the dumpster and people worry that it's radioactive. Well, it is. But is there a threshold below which you really are concerned or not?

And I think we are all in agreement that the low doses that we're talking about presently are of no health consequences, but you could continue this argument until you wind up doing things that are just totally inappropriate. And I think there does have to be some common sense and reason imposed along the way. So I agree with Frank.

DR. HOWE: I think you have a public comment.

CHAIRMAN THOMADSEN: Oh. Thank you very much. Please identify yourself.

DR. GOETSCH: Steve Goetsch from San Diego Gamma Knife Center, Dade Moeller Associates. I was teaching a course at Dade Moeller Academy in Las Vegas in June, had four students who were learning radiation safety who are actually New Jersey State highway patrol officers. I learned as much from them as they learned

from me, I think.

They were telling me they have a device that they use on the New Jersey Turnpike, sit on the side of the road with a very sensitive detector, multi-channel analyzer, and they can watch passengers in the cars going by and spot technetium-99 and iodine-131, fluorine-18, and can just watch people going by at 65 miles an hour and identify the isotopes.

I asked, "What do you do when that happens?" "Well, we very rarely stop -- you know, if we saw a huge amount of, say, cobalt-60, we would be more interested." But the power of that technology is out there in all the states. They see it all the time now. I had no idea they could do that.

CHAIRMAN THOMADSEN: Yes, Dr. Suleiman?

MEMBER SULEIMAN: I mean, just a refresher, you know, a couple of years ago two people were coming across the border, and they got detected by portable detectors. And the protocol of Homeland Security -- they have these little gauges. If I remember right, the maximum scale on that is barely what would be defined as a radiation area, and their intent was just to say if you pick up something, you bring in somebody who knows more about the topic. But anything you detect is a pretty safe level unless it's the maximum.

DR. HOWE: Well, they all did -- they had a multi-channel analyzer, and what they saw wasn't the normal peaks.

MEMBER SULEIMAN: Oh, no. Yes, I'm talking about -- they have like these little devices. But the portable detector thing, I was surprised, because one came in from Niagara, drove in, and the other one flew into one of the international airports. And for those of you who don't remember, they picked up -- these patients had the nuclear medicine scans two and four months previously, and they had had a CardioGen -- it's a rubidium, 75-second half-life agent. So what were they detecting? They were detecting the parent nuclide, which was strontium, which stuck on the bone. And so this eventually led to a recall of the product.

So those are low here. I mean, and it wasn't handled irresponsibility. I mean, Customs picked it up, deferred it to Homeland, because they have an inventory of materials that they couldn't identify this nuclide, because it wasn't a commonly used nuclide. Actually, went to a Los Alamos group whose job is to look at the spectra and they nailed it. They actually said, "This is a medical isotope contaminant."

And by then, we got -- you know, FDA got involved and the NRC got involved, so it was one of the

few times where this detector system, you know, picked up something that turned out to be -- resulted in an important outcome.

DR. HOWE: And I think that builds on the idea of the State troopers. They see fluorine-18 go by, or there is a -- "I know what that is. They see technetium go by. I see thallium go by. Oh, I see something here. Oh, I don't know what that is."

MEMBER SULEIMAN: I mean they're not looking for medical isotopes.

DR. HOWE: No. They are just looking for things that they know they don't have to worry about, and then they get concerned about the others.

CHAIRMAN THOMADSEN: Any other comments? Mr. Mattmuller?

MEMBER MATTMULLER: I'm not sure anyone in New Jersey drives 65.

(Laughter)

But to go back to the radioactive chicken bone idea, I know you don't regulate landfills, but -- and maybe I'm just very naïve, despite my years on this Committee -- but would it not have -- I guess it's more directed to Mr. Costello -- have any effect with the States that the NRC had a memo of some sort, a notification, that this I-131 you might be seeing in

your landfills is coming from patients that we have regulated. But it's -- if you're finding it in landfills, it is below regulatory concern. So --

DR. HOWE: We never use the word "below regulatory concern." I mean, we used that in the '90s and were severely punished for it.

MEMBER MATTMULLER: Oh.

MEMBER COSTELLO: In the building I work in, are radiation people -- and then there are people who regulate waste facilities, or -- they are aware, and they are very aware, that the radioactive chicken bones are not a hazard.

The problem is there are some landfills that deal with people other than us. You know, they have populations around them who are -- they are permitted, they have local organizations and things, and we can say that it's perfectly safe that these things are in a landfill or an incinerator for that matter.

But we can say this until the cows come home, okay, but we aren't the main people who are worried about it. And so if they have told the population we are not going to put any radioactive material in there, then we can't make them do it. You know, we can allow them to do it, and, if they asked me, I would encourage them to do it. But that's as far as we can go.

DR. HOWE: And it's also the radioactive kitty litter.

CHAIRMAN THOMADSEN: Let's talk about biohazard. If they could detect biohazard as easy as radiation, they would just be collecting stuff from garage sales.

Any other comments? Thank you very much, Dr. Howe. Very interesting topic.

Dr. Langhorst, would you like to -- you are next on the list. I'm sorry. I got ahead of myself. Ms. Holiday. I'm obviously getting ready for the break.

(Simultaneous speaking.)

MS. HOLIDAY: Actually you guys discussed a lot of what I was going to talk about, when you were talking about international practices of patient release. So, this should go very quickly.

So, I gave -- I'm giving this presentation at the request of Dr. Langhorst. She said she kind of wanted to discuss the May Commission meeting that we had on May 9th. So, I'll kind of set you up for her presentation right after me.

So, of course, the topics that were discussed were Dr. Thomadsen gave an overview of the ACMUI's activities. Dr. Zanzonico gave a presentation on the Committee's position on patient release. Ms.

Weil gave a presentation on the reliability of radiation safety instructions for patients released following Iodine-131 therapy.

Dr. Thomadsen gave a presentation on the Committee's view, which was to not make any revisions of NRC's Medical Policy Statement. Dr. Suleiman gave a presentation on FDA's radiation role responsibilities, and then lastly, Dr. Langhorst gave a presentation on her view of the regulation of the medical use of byproduct materials. So, as a result of that Commission meeting, the Commission issued what is known as a staff requirements memorandum, an SRM. That SRM came down on June 5th, 2014, and basically the task that came out was they requested staff to provide information to them on the international practices of patient release following Iodine-131 therapy, and to provide a CA briefing to discuss our experience with the Medical Visiting Fellows Program.

The first half came, of course, as a result of Dr. Zanzonico and Ms. Weil's presentation. Then the last half came as a result of Dr. Langhorst's presentation.

So, just very quickly, staff provided a memorandum to the Commission on August 29th, and the ML number, which I will also distribute this to the

Committee, is ML14217A350.

So, basically the gist of the memorandum was to inform the Commission that staff worked with the Office of International Programs, where we solicited responses from countries. We asked them specifically, "What are your requirements or your regulations for the release of patients who were administered Iodine-131 therapy?"

"In addition to your requirements and regulations, what are your standard practices? Are you keeping them in a hospital? Are you keeping them in a separate hospital-owned facility? Are you releasing them to hotels?"

Then we also asked them, "What is the typical activity that is administered in a procedure, and what was the date of the latest revision to your regulations?"

So, actually what we got was similar to what everybody has said: that the response from those countries is varied. The majority of them, their responses were that what they have is regulations and requirements, and some even say that they don't have set forth requirements.

In fact, their release permits are either at or below NRC's pre-1997 release criteria. That

pre-1997 release criteria is that patients may be released if their dose rate is less than 5 millirem per hour at one meter, or their retained activity is 1,110 megabecquerels or 30 millicuries.

So, I know that Dr. Suleiman mentioned the BSS, IAEA's Basic Standards of Safety. I think I'm saying -- Safety Standards, excuse me.

IAEA published guidance in 1996 that had this guidance level of 1,100 MBecquerels, or close to the 30 millicuries. They also listed a good practice of 400 MegaBecquerels.

Then we also found out about this organization called HERCA, which is the Heads of European Radiological Protection Competent Authorities, which is -- which was spearheaded by France, and they set a guidance of 800 MBecquerels.

So, we got a total of 17 responses. Seventeen countries responded to our request, and we found that Germany, Australia, Japan and South Africa typically adhere to IAEA's '96 suggested guidance level of 1,100 MegaBecquerels.

China and Lithuania went with a good practice limit of 400 MegaBecquerels. Then for the countries that followed HERCA's guidelines of 800 megabecquerels was France, the United Kingdom, Poland,

Spain and New Zealand.

Then we found that there were also countries that were more stringent than these set forth requirements. Germany, while they did adhere to the 1,100 MegaBecquerels, they said that they hold their patients for at least 48 hours, and they have to have a local dose rate of 0.35 millirem per hour at 2 meters.

Philippines don't release until there's 300 millirem. Japan is 500 MegaBecquerels. South Africa holds their patients until it is 2.5 millirem per hour at 1 meter.

There were countries that talked about this isolated waste treatment system. There was another country that talked about how no matter how much they administered their patients, they require their patients to stay in the facility for at least three days.

So, there is a varied amount of responses that we got. This was just information gathering. So, we did share that with the Commission. As Dr. Howe mentioned, as a result of this Commission SRM for the patient release project, staff will be looking into and working with international community to better understand what they do. Not necessarily adopt what they do, but just to get a more well-rounded perspective of what's going on in other nations.

For the second task, staff was requested to provide a CA briefing, or Commissioner's Assistance briefing, to discuss the Medical Visiting Fellows Program.

As it turns out, there are maybe two staff in the NRC that have a recollection of this program, Dr. Howe being one of them. And so, this program actually came in 1990. It was pre-1990, as a result of a request from the medical community.

We currently had a few rules that were coming up: Quality Management rule, the Patient Release rule and the Pharmacy rule. A solicitation was sent out in the Federal Register, similar to how it is for the ACMUI.

So, we requested a nuclear medicine physician. What we got was actually a nuclear pharmacist, and Dr. Myron Pollycove as our nuclear medicine physician. What actually happened was the nuclear medicine physician was on loan to us from NIH. I'm sorry? Yes, the nuclear pharmacist. Did I say physician -- I'm sorry.

The nuclear pharmacist came to us from NIH, and after the radiopharmacy rule was passed, he returned back to NIH. Dr. Myron Pollycove was here during Patient Release rule and the Quality Management rule, and then

after that he kind of went on to pursue other things.

So, from there on, staff didn't really see a dire need for another medical fellow. I think we would like to think that over the past decade or so, our interactions with the ACMUI have greatly expanded, and there's so much more open communication in terms of subcommittee reports that are submitted, or general recommendations that are put forth.

I know that every two years, we do an evaluation, and it seems that the ACMUI is very pleased with our current reporting structure. So, we kind of agreed with this position that there's no real need for a medical fellow at this time.

The Committee has 13 positions on it, of which we get a varied amount of perspectives and expertise that we need to properly promulgate our regulations. So, that just summarizes those two tasks that the Commission directed us with.

Then lastly, that SRM mentioned the open door policy that has been mentioned a few times at least during this meeting. The Commission, as well as Ms. Dudes has reiterated numerous times, has an open door policy here.

When Dr. Malmud was here as the chair, I know that he mentioned the Commission had always offered up

to him that if he ever wanted to come into town and drop in and just talk with them, he had the option to do so. The same option is here for the Committee.

So, if there are ever any issues or items that you would like to discuss with the Commission, they have this open door policy. If you have issues that you don't necessarily go to the Commission with, you can always come and speak to Ms. Dudes, or any one of us if you don't want to talk to me.

[Laughter]

Now, I have to say, do you have any questions?

CHAIRMAN THOMADSEN: Yes. Is it possible then to get a list of phone numbers and emails of the commissioners?

MS. HOLIDAY: Absolutely. Absolutely. It is available on the website, but I can submit a list.

CHAIRMAN THOMADSEN: Thank you very much.

MS. DUDES: I just wanted to be reflective on what Dr. Welsh said earlier, in looking at that first item we talked about, which was the memo on international practices and not necessarily get distracted by that information.

We will make sure that it's a healthy, open informative exchange, but we have very important work

to do. You saw Dr. Howe's timeline, and hopefully we can do some things in short order working with the communities and the societies to get the guidance documents on a website or some linkage to that, develop brochures in conjunction with the societies and this committee.

I'm always worried when I see papers that say, "This country does it this way. This country does it this way." Because then you're not comparing the entire system. You're comparing a release practice not in context of the medical system and other things, other societal factors.

So, I think it's valuable information. I think you should always be aware of it, but I think our focus going forward is to try and get some of the tasks that we can really accomplish safety and make an impact on the safety of the patient release, and then continue to be aware and inform internationally.

It is -- you know, when we wrote that up, it was a separate request. It was a result of your meeting, rather than part of the overall requirements memorandum we got on patient release.

So, we gathered the information. We didn't do a lot of analysis of this information. So, contextually it may not be as useful, but I just wanted

to share that point with the Committee.

MEMBER COSTELLO: I just had a suggestion on members of ACMUI going to meet with Commissioners or the Commission. I would think the members would share this with the rest of the Committee. If -- if someone is going to talk to the Commission, let's say, it should be clear that they're representing themselves; they're representing the whole ACMUI or just what is it they're doing individually to seek appointments with the Commission or Commissioners without doing this collegially I don't think is the best way of doing it.

CHAIRMAN THOMADSEN: I think if you talk to the Commissioners, it would have to be as individuals and not representing the ACMUI, unless the ACMUI is officially sending somebody, in which case I think it's probably not a good idea to recommend people let everybody know that they're going to. They may want to discuss with the Commissioners something about the Committee that they feel uncomfortable talking to the Committee about.

MEMBER COSTELLO: It would be uncomfortable.

CHAIRMAN THOMADSEN: I would too. That could happen. Any other comments? Thank you, Ms. Holiday. Now, Dr. Langhorst. With great anticipation,

we've been waiting for your comments. Safety culture: Interactions between licensees and regulators.

MEMBER LANGHORST: Well, for those new members and soon to be new members, when you're asked, "What kind of topics do you think need to be discussed at our next meeting?" be prepared to discuss those topics as the leader. I didn't expect to do both, but that's okay.

So, as you said, I felt it was important to bring up some issues that had been discussed at the May 9th Commission briefing by the ACMUI. I'm leading the discussion but not the total discussion. So, I hope you all feel comfortable in jumping in at any point.

So, my goal was to do just that, and discuss how interactions between medical licensees and regulators may or may not support a positive safety culture.

So, I think NRC is to be commended on keeping up the evaluation of safety culture and what it means to them and what it means to licensees.

So, just this summer or spring - I can't remember exactly - they've updated their safety culture brochure. In looking at the brochure, there's lots of good information in this on safety culture. But there's no real specific mention of medical uses, and you all

may have heard me say that those medical uses can be different than other uses of radioactive material.

So, NRC's definition of nuclear safety culture: Safety culture is the core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment.

Nine positive safety culture traits have been developed, and this didn't just come from NRC. This came from a concerted effort of reaching out to various licensee communities, including medical use in developing these safety culture traits.

Now, I'm going to focus, because I only have a half hour but maybe not even that anymore. So, problem identification and resolution; issues potentially impacting safety are promptly identified, fully evaluated and promptly addressed and corrected commensurate with their significance.

So, what is meant by safety? We may have some different perspectives on that. I think we were just discussing perspectives on safety. And what is the perspective on what is commensurate with their significance? So, there are those topics to be looked at.

Work processes: The process of planning

work activities as implemented so that safety is maintained. Again, I'll point out that word safety.

Environmental raising concerns. A safety conscious work environment is maintained where personnel feels free to raise safety concerns without fear of retaliation, intimidation, harassment or discrimination.

Safety? I'll come to that. The retaliation, intimidation, harassment and discrimination.

NRC can look at this in regard to an individual's fear of how their licensee will treat them in raising issues. But I think we discussed in our Commission briefing how an individual may be influenced on how the regulator responds to an issue being raised, and what that could do to the potential impact of any use of radioactive material for that licensee.

I will point out that yes, NRC is a regulatory body. Agreement States are regulatory bodies. But I think we need to discuss how these influence people in raising concerns.

Effective safety communications; communication maintain a focus on safety. Again, what do we mean by safety?

So, I searched for a definition for safety

on NRC's website, and was not fully satisfied with my search there. Under the glossary, there are definitions for safety limits, safety-related, safety significance.

So, the best I could find was in regards to radiation protection, where Congress has charged the NRC with protecting people and the environment from unnecessary exposure to radiation as a result of civilian uses of nuclear materials.

I did find a definition for safety that comes from the Canadian Nuclear Safety Commission website. On that website where they talk about how they utilize the definition of safety, they reference a Canadian court definition for safety.

Safety is not measured. It is judged, and it is judged according to an assessment of an acceptable risk. An acceptable risk is essentially a value based proposition determined by policy and or those authorized by the government to judge safety and/or those exposed to the risk.

That's the best I found on a definition for safety other than, "something that is safe." So, let me come back to our cardinal principles of radiation protection and how they relate to medical use.

Any decision that alters the radiation

exposure situation should do more good than harm. That's the basis of medicine. Optimization, "A likelihood of incurring exposure, the number of people exposed and the magnitude of their individual doses should be kept as low as reasonably achievable, taking into account economic and societal factors."

This principle seems to be the basis of some of those special exemptions or limits that we apply for patients administered with radioactive material. You were just discussing a few of those.

Then the application of those limits. Any individual from regulated sources in planned exposure situations other than medical exposure of patients should not exceed the appropriate limits specified by the Commission.

This one specifically points out medical use of radiation is different than other uses of radiation and radioactive material.

Now, the healthcare arena has been working on safety culture for many years, and I know NRC has looked at these references. So, the National Academy began their endeavor in this with these two reports. "To Err is Human," in 2000, and "Crossing the Quality Chasm," in 2001.

So, healthcare needs to be safe, avoiding

injury to the patients from care that is intended to help them; effective, providing services based on scientific knowledge to all who would benefit and refraining from providing services to those not likely to benefit.

Timely: reducing waits and sometimes harmful delays for both those who receive and those who give care. Efficient: avoiding waste including waste of equipment, supplies, ideas, energy. You were talking about wasted energy.

Equitable: providing care that does not vary in quality because of personal characteristics such as gender, ethnicity. It's the end of the day. Ethnicity, geographic location and socioeconomic status.

So, let's go to our traits. Respectful work environment. Trust permeates the organization. Trust and respect. Trust and respect has been an issue that healthcare has had to deal with. Some of you work in a medical environment. There can be some issues of personalities sometimes, but that endeavor the medical community has been addressing, and perhaps this could be an area of a case study for NRC's education efforts to look at how this trait could be communicated to others.

Questioning attitude, individuals avoid

complacency, and continually challenge existing conditions and activities in order to identify discrepancies that might result in error or inappropriate action.

So, I feel like I might have challenged that existing condition in giving my viewpoints to the Commission. I think the community and the NRC need to work at how discrepancies might result in other errors.

The most common barriers to reporting of an issue is, "I just don't know what to report or how to report it." "Oh my gosh. I can't believe that just happened. I don't even want to think about it anymore, and I'm just going to forget it. No one will notice."

"Why should I even bother? Nothing is going to change." Or, "I may not trust who I can tell." Or, "My gosh. Am I going to have to start writing some reports? This is not going to end for a long time?" Or, again, that fear of reprisal.

I would hope that there's not a wall erected across the table of the regulator and the regulated community, which inhibits these kinds of discussions on how people -- how the two groups interact, and how this can impact the safety culture, in particular in the regulated community.

The perspectives of the NRC -- did I skip

one? The perspectives of the NRC? A lot of the focus on safety culture is on fuel cycle safety culture. NRC licenses 100 percent of these licensees. Also applies to medical or radioactive use, but NRC licenses only in 13 States and 4 US territories.

In medical licensees, NRC only applies to radioactive materials used in clinical settings. It doesn't apply to radiation producing machines.

The NRC has again put together a really nice NUREG on safety culture common language. If you take a look at that, you'll notice it is heavily focused on non-medical use. It doesn't really address -- it is much more focused on reactor and other material uses, and not on medical use.

That's the majority of licensees. So, versus that influence are medical licensees, positive safety culture, caring for our patients and our employees.

We have a big influence by the Joint Commission on other accrediting organizations that have their own set of criteria we have to meet or utilize NRC in Agreement State criteria in their own inspections.

They're the Centers for Medicare and Medicaid Services and insurance companies. Those are a big driving force in a medical licensee. There are

other regulators, and one thing I keep looking at here because I forgot to put in there is HIPAA. A big one.

There is the competition for business, and that is not only between hospitals or clinics. It is also within hospitals. It is one service versus another service, and who is allowed to provide that medical care and the legal liability, especially involved in malpractice and so on.

Healthcare is increasingly complex, and this is one of the themes of the National Academy of Science. At my location, at Washington University in Saint Louis, there are lots of condemnations. There are PET-CT's that we routinely use now.

We now have a PET-MR unit that is going to do great things, especially for our pediatric patients, and we also have the ViewRay™, which marries up the real time imaging, MRI with teletherapy sources.

So, this is a complex environment. I'm missing something here. So, if we -- I think I had things moved around.

So, during safety culture talks, I did find AAPM comments very helpful in this regard in the medical community trying to state that one size does not fit all. It is applaudable to try to have a single definition, but it is equally important to note that implementation

of the traits and behaviors as they apply to specific licensee categories may differ.

In medical uses, nuclear safety does not preempt or override patient safety especially in emergency situations. For example, life saving measures should always preempt the need to decontaminate a patient in an emergency room.

So, I offer up those comments to the Committee, and welcome your input, your discussion.

CHAIRMAN THOMADSEN: Thank you, Dr. Langhorst. Comments from the Committee? We have a comment from --

MS. TOMLINSON: Hi. I'm Cindy Tomlinson from ASTRO. I just wanted to let the Committee know that ASTRO had a meeting a couple weeks ago in San Francisco. We had one of our keynote speakers, Dr. Sidney Dekker, who is a human factors guy.

You could actually access his presentation on our website. And what I'll do is I'll send the link to Sophie, and she can send it out to you. I think it is very timely in terms of this discussion. He talks a lot about safety culture and how it works both ways; not just those reporting but those being reported to.

So, I think you guys will find that useful. So, I'll send the link to Sophie.

CHAIRMAN THOMADSEN: Thank you. Yes, Ms. Dudes?

MS. DUDES: Thank you. Thank you for the presentation. That was good. I appreciated that. Maybe this will come in your next presentation, because I guess I wouldn't be looking for ways -- or things that we can take away that would do more positively influence. So, I try not to look too far ahead, but if that's coming after the break, then I'll reserve my question until then.

MEMBER LANGHORST: I did have a question. During the Commission briefing, I was asked whether my comments were supported by the Committee. I know there was a great wave of nodding heads behind me, but I think I will ask that question of our Committee right now, as to whether am I -- am I being representative of the committee's views? Am I just my own views being voiced here?

MEMBER ALDERSON: I think you've expressed a complexity and subjectivity associated with this subject matter, and that's why in the previous session it isn't good enough just to have content experts. You have to really be able to see the big picture about how you communicate these ideas to people from different backgrounds, and how you can make an impact. That is,

at least from my experience, very difficult.

CHAIRMAN THOMADSEN: Thank you, Dr. Alderson. Mr. Costello?

MEMBER COSTELLO: I would have to actually go through your whole presentation again to say whether for me or not. For the most part, I tend to agree with what you talked about. I think, just speaking for myself, I think there might've been some implementation that the Commission itself needed to have someone on it with medical experience.

I think that's a little beyond what the ACMUI would likely be commenting on is the make-up of the Commission itself. I think you made your claim. I'll make this claim. I think it is true that staff needs all the help it can get at this point because you have the numbers up there.

The declining number of non-Agreement States and the -- and the aging of its own staff, the NRC's core experience is a challenge. It's a management challenge. This area, I think, is getting here -- you're importing some new talent, and that's good. But the fact is it only regulates a small fraction of licensees, and so the NRC's experience really needs to be supplemented with experience from industry, experience for the States, and so forth.

I think you have said words along those lines, and if you did, I would agree with that. But the idea that we comment on the make-up of the Commission? I probably wouldn't.

CHAIRMAN THOMADSEN: Dr. Suleiman?

MEMBER SULEIMAN: I think I'll hold back my opinion. I don't remember the details, but I generally agreed with pretty much everything you said. I think the message was, and we had a discussion beforehand, where I thought -- this is my recommendation. If you look at the economic value of medical care, and compare it with nuclear power generation, the ratio may be much more different than the weight of the Commission membership.

The only good thing is they are all consumers. So, in some way, they are all participating in the healthcare and delivery system, but professionally, it would be nice to have somebody who could relate with us a little bit more. I agreed with your message.

CHAIRMAN THOMADSEN: A member of the public?

MS. FAIROBENT: Thank you, Dr. Thomadsen. Not an answer to this specific question, but just a comment on the safety culture process that NRC went

through. AAPM was very much part of that process, and at the initial meetings, it was very much heavily weighted towards nuclear power and the fuel cycle.

I do feel that not only the staff but the other licensee categories, nuclear power, fuel cycle, research reactors, et cetera, did hear and listen to the concerns from the medical community. We were successful in getting the language changed to be more reflective of the diversity of the licensees that NRC regulates.

So, from that standpoint, I do want to compliment the staff and the process that we went through, and also that so far would've been successful in keeping safety culture at a policy level, and not down into the regulations.

CHAIRMAN THOMADSEN: Dr. Guiberteau?

VICE CHAIRMAN GUIBERTEAU: I think your presentation at the meeting with the Commission did us all a favor. Very much so. I think it is easy when -- I know the Commission has many lofty things to think about. I know they have other directions, but I think the less we express the fact that, as you said in this talk, one size does not fit all, that medicine is not a clockwork orange and you can't -- and you have to take into consideration what we were talking about earlier about

performance versus regulation by precision more or less, that these are things that we need to bring to the forefront because we are different.

I think the litany of things you said in your talk were important for them to hear. I know when you do that, people on the other side may have taken those as criticisms, but I didn't take it that way at all. I took them as being just a reminder that there's some things that this division needs and that this -- that this group needs that they may not remember. So, I applaud you for doing that.

CHAIRMAN THOMADSEN: Dr. Welsh?

MEMBER WELSH: Your question, whether or not we agree with you. I would say that I personally do agree with you. I agreed with you back during the Commission briefing. A number of years back when there was a vacancy on the Commission, I personally wrote a letter to the President, suggesting that the Commission have a member with more medical expertise than has historically been the case.

I think a professional society, at least one, wrote a similar letter. Now, I've heard estimates of anywhere from 5 percent to 20 or 25 percent of what NRC is involved with has to do with medical uses of byproduct material. I don't know what that figure truly

is, but if it is anywhere near 20 percent, then one could argue that at least one of the five Commissioners should have a good deal of medical background or expertise.

I don't know that the professional societies had the opportunity to comment before the vacancies have been filled, but I do think that going forward, it'd be wonderful for at least one member of the Commission to have general medical expertise or background.

So, it's a long way of saying, yes, I agree with you.

MEMBER LANGHORST: I will clarify that I did not, in my talk there, say, "They needed that." I just pointed out that very few over the history have had that.

CHAIRMAN THOMADSEN: Dr. Suh?

MEMBER SUH: Clarifying question. It's the President though who appoints, right? You guys just sort of sit back and watch.

MS. DUDES: Yes, the President will nominate, and the Senate will confirm.

CHAIRMAN THOMADSEN: Well, at the moment, I think we will take a break and come back to hear about enhancing interactions between the NRC and the medical community, which we've already been discussing.

(Whereupon, the above-entitled matter went off the record at 3:25 p.m. and resumed at 3:45 p.m.)

CHAIRMAN THOMADSEN: Dr. Langhorst.

(Pause.)

MEMBER LANGHORST: Here I am again. Thank you very much.

(Laughter.)

MEMBER LANGHORST: Okay. So, another topic that we talked about at the Commission briefing May 9th of this year was what could be done to enhance interactions between the NRC and the medical community, and I probably should say also the Agreement States.

So, my goal here is to explore ways to enhance the relationship and to engage interactions between all of us and to discuss the challenges we need to bravely face together in fostering this relationship and continuing interactions.

And I put that "bravely" in there, because it's not easy to hear people talk about, no, they don't think like Sue does.

Well, that's okay. I want to hear that. That's part of the safety culture and figuring out what is it that causes stresses, causes issues. And so, that's part of what we do here.

The ideas presented here are mine. And

they're presented to you all for the purpose of stimulating the discussion of this group, NRC staff, members of the public. And what order I put them in was the order I put them in and should not reflect my preference or what I feel is their importance.

So, radioactive material regulations. We have NRC and we have this group called Agreement States, but it's not just two situations. There are 37 different Agreement States.

MS. DUDES: I'm so glad that got bigger, because if that graph -- if the Agreement States saw that graph, I'd be hearing about it.

(Laughter.)

MEMBER LANGHORST: Don't worry. I had to have space on my slide. It was not intended, but those all stem from NRC-regulated authority. So, I have to say that.

So, there can be 38 different ways to do things depending on the level of compatibility and so on.

There are things called Master Licenses and I know the VA Hospital has that. I can't remember who else has that.

MEMBER COSTELLO: Navy.

MEMBER LANGHORST: The Navy.

MS. DUDES: And the Air Force.

MEMBER COSTELLO: Air Force.

MEMBER LANGHORST: And the Air Force for medical use?

MEMBER COSTELLO: Yes.

MEMBER LANGHORST: All right. Thank you.

And there are few, from what I understand, like city-based things for the larger cities like New York, Los Angeles. So, there's a lot of different players in this situation.

There are 17 of us. And I say "us," because I'm from Missouri. And, yes, that is how you say it.

(Laughter.)

MEMBER LANGHORST: 17 NRC States and territories. We all face other regulatory bodies in dealing with radiation, radioactive materials.

We have this thing called the Joint Commission that keeps getting involved here. A very important organization. So, there are a lot of players. A lot of different perspectives.

The National Academies just recently released a report this summer regarding the promotion of a culture of safety.

And from that report, I got this quote: "It is especially important for improving the exchange of

safety-related information, fostering collective mindfulness and sense-making, empowering workers to speak up and to share what they know, and creating a learning and improvement focus."

This report was focused on academic chemical programs. There have been some issues in the academic realm and chemical safety. And this report committee brought together expertise and outlooks in many areas.

One member is a university provost, has been a dean, a chemistry department chair chancellor. There are environmental health and safety officials from academia, from industry and national labs.

There were senior faculty chemistry members. There were young, junior faculty chemistry members.

There were experts on safety culture and behavioral sciences and the quote that I just quoted was from the second reference here.

Now, for full disclosure, the chairman of this report, that provost is my provost at my university.

So, we have a very strong light shone on our safety culture not only in chemical labs, but our entire safety culture at our university.

So, I want to talk about the regulatory

environment of Agreement State medical licensees. And so, this is off of NRC's website and you can see my State is an NRC State surrounded by Agreement States.

And in Agreement States, they have the oversight for medical licensees of the use of radioactive materials in medicine.

They also regulate x-ray machines and other radiation-producing machines. There are levels of medical licensing for physicians, for nurses, for techs, for sometimes physicists.

And maybe there is an opportunity to take all of that information to judge the relative risk of those uses of radiation, radioactive materials within medical licensees.

It tends to be a smaller regulated community within a State. Maybe perhaps an allowed development of licensee/regulator relationships.

I think that's particularly true when it involves a university medical center for a State -- for an Agreement State.

It can be influenced by the State and their radiation control program safety culture within the State.

There can be differences of how each of the Agreement States handle things and that -- and NRC that

can cause a challenge for those licensees, medical licensees who have branches in many different locations.

And so, what might work in one State is not allowed in another State or there are slightly different requirements. And so, that can be a challenge especially when if you have people moving between those two locations, well, why is it this way and how do I keep track of what I'm supposed to do?

And perhaps that Agreement State, that smaller community can provide a level of a safe environment to discuss safety and compliance issues with the regulators.

I will have to say I have never been an RSO in an Agreement State. So, I've always been an RSO in an NRC State. That's what I know.

This is NRC's Mission off their website: "The NRC licenses and regulates the Nation's civilian use of radioactive materials to protect public health and safety, promote the common defense and security and protect the environment."

And in their value statement: "In achieving our mission, the NRC adheres to the principles of good regulation, independence, openness, efficiency, clarity and reliability. The Agency puts these principles into practice with effective, realistic and

timely regulatory actions consistent with our organizational values and our open, collaborative work environment."

I feel we are a poster child for that in this committee. So, our Committee is one of those focal points for medical uses of radioactive material and also in regard to radiation-producing machines.

That level of expertise was added to the Committee when Dr. Guiberteau was brought on first as a consultant, and then as a full Committee member.

And I think that has been essential for our combined modalities that are more and more in use these days.

We comment. I'll let you guys read that. It necessarily doesn't need to go into the record, but this is some of what we do in our advisory of the NRC and of Agreement States to look at the issues to be brought to the attention of the Commission.

We are, as we said before, 13 members. We have two in-person meetings per year. There are various teleconferences on special topics and we have the subcommittee structure that is used to work on these special topics and develop the recommendations.

So, here are some of my ideas beyond us as a focal point. So, Sophie already talked about this in

regard to the Visiting Fellow.

I raise this as a potential way of the NRC having a more onsite medical expertise readily available to them.

Here's another suggestion that I did bring up at the meeting that perhaps there could be a periodic regulatory information conference devoted to medical use issues.

There is already a regulatory information conference that happens every year. And that is involving the reactor and fuel cycle licensees.

This is an annual three-day meeting here in Washington, D.C. They have a website on the NRC's website.

March of this year there were by my count, and it's a rough count, about 2,400 registrants. About 50 percent of those people were US licensees, contractors and so on.

There were about 40 percent of the individuals were NRC or Agreement State individuals. And out 10 percent were international.

I found very important on that website is that the dates for March 2015 and 2016 are already on the calendar.

So, people who are interested in coming to

this conference know when it's going to be and it's here in DC.

Here are some of the topics that I pulled off of that conference: Agency efforts to address cumulative effects of regulation, interacting with NRC. Medical radioisotope production was a topic. Safety culture journey: Lessons learned from culture change efforts.

These are topics that could go right into a medical use conference, but think of what we've discussed here today. I-131 patient release issues comes to mind. Again, the production of medical isotopes.

Now, the NRC and Agreement States work jointly on developing guidance. And I was glad to hear that Dr. Suh had been involved in helping on guidance for ViewRay.

So, technical teams, you can see this is some of the make-up that was suggested. And I think it's good to include an ACMUI member or perhaps to reach out to other medical experts in helping work with those technical working groups.

And that source of those medical experts could perhaps be the organizations that support these specialty board for certification that are recognized

by NRC.

That could be a way to be inclusive of some of those groups and to develop people for potential service on ACMUI potentially. And as I say here, perhaps that could be used with the 35.1000 guidance too.

As I said, NRC is working on safety culture and you guys are continually looking at what can we do to promote this, how can we do this.

And so, there are brochures that have come out. They're called Trait Talks. And they are being developed to focus on those nine safety culture traits that we talked about in the previous presentation and to give some real world situations and so on.

Perhaps because medical use can be different, perhaps NRC, Agreement States and medical community could help develop some of these that are pertinent to medical uses of isotopes.

Because of our focus of medical uses in discussions here, maybe we could add another ACMUI in-person meeting a year with the focus on having the medical community come in and give us presentations and focus discussions on issues they're concerned about.

This might not be as needed if we have a regulatory issue conference annually, but maybe we could get started in this way.

The ACRS has procedures to augment expertise and bringing in additional people to help with subcommittees and so on.

Perhaps some of our subcommittees, let's say, on our Y-90 microspheres subcommittee, it might have been very helpful to have an interventional radiologist available for that perspective.

On Gamma Knife, it may be very helpful to have a neurosurgery representative to have that perspective.

Remember I used the word "bravely." Fostering a positive safety culture takes people working with people.

It's really helpful when people understand why is this regulation in place and how does its risk that it's trying to mitigate relate to this risk, because we want to try to minimize our confusion of what needs to be done by having consistent and compatible expectations for regulations.

And when you're talking about radioactive materials, the use of radiation for medical uses, it is a different perspective.

Implementing these ideas takes additional resources. That means people. That means dollars. The NRC medical team as it stands now could not possibly

try to do a regulatory issues conference. They wouldn't do anything else, but it takes people and dollars from the medical community too to be participants in this and from the Agreement States.

And that may be asking a lot of our Agreement States given economic issues involved with state funding and so on.

We all need to lend leadership and demand respect in raising these concerns and be able to identify problems and talk about the challenges that exist in light of all of the patient safety issues and not just those related to radioactive material use.

You can't talk safety culture if you're only going to take one little slice of the pie. You have to look at it in the whole picture. Thank you.

CHAIRMAN THOMADSEN: Thank you, Dr. Langhorst.

Reflections from the Committee?

MEMBER DILSIZIAN: Enjoyed your presentation.

The part that I'm a little bit confused about is when you said to involve other specialties of physicians to present to us.

I'm new on the Committee, but I feel like as a nuclear cardiologist I'm representing the nuclear

cardiology community.

So, when I'm at the AHA/ACC meetings, anybody who has any concerns or any issues, I am their representative, I feel.

And, therefore, I would feel it's not necessary, if you will, or if someone does have a point, I would feel that why wouldn't I have been approached as a person rather than coming here separately and having to. So, I'm a little bit confused.

Again, I'm new. Maybe you can teach me what I'm missing about that point.

MEMBER LANGHORST: From my perspective--

MEMBER DILSIZIAN: Yes.

MEMBER LANGHORST: -- and you mean involved with like having a regulatory issue conference where you bring in -- I know that NRC has been excellent in the past several years of outreach to various parts of its community, but it tends to, okay, go to the Health Physics Society meeting and present there, and go to the CRCPD meeting and present there to the State folks, and go to your organization, but maybe there's some value in bringing some of the organizations together, too, in a focus of the regulatory environment rather than everybody just talking on their own and not coming together.

So, I present that as a possibility.

CHAIRMAN THOMADSEN: Dr. Suleiman.

MEMBER SULEIMAN: The lines are blurry, okay, because I think -- this is my perspective. I happen to represent FDA, but I have to, depending on what part of my career I'm either a health physicist or medical physicist, but I think most of the people here at this table are professionals in their own light.

They may have been nominated by a society. Do they really represent that society at this table, or not?

I mean, so, are we professionals constituting a Committee to give our best opinion and we happen to be associated with a variety of organizations, or are we in fact representing those organizations collectively at the table? So, which is it?

And I think sometimes, sometimes I think we forget that responsibility ourselves. Are we representing the public health? Are we looking out for parochial interests from our societies? Which hat do we have on, I guess, when we speak?

Maybe we should have three hats so when we say, this is me, this is my organization, or this is the society I happen to belong to.

CHAIRMAN THOMADSEN: Mr. Fuller.

MR. FULLER: I think I can answer that question and it may have been more rhetorical. But just so that everyone is clear because we go over this each time we select a new member, it's very, very clear in that process, but sometimes maybe people forget our expectation for all the members. Just so everybody knows, all the members represent yourselves.

You represent what you know and what you believe and what you think is in the best interest of the ACMUI and that's the perspective we expect you to bring.

You cannot know what you know. We understand that. You're members of various professional organizations and so you will have that perspective.

But any time you're here as a group, our expectation is, is that you are representing yourselves and that you are not here to promote a position of a particular professional organization.

CHAIRMAN THOMADSEN: Mr. Costello.

MR. FULLER: And that goes for the organizational groups --

MEMBER COSTELLO: Yeah, I know.

(Laughter.)

MR. FULLER: -- as well, because that has been a bit of a point of confusion.

MEMBER COSTELLO: You and I have discussed this before. I've got a few comments on your presentation which I thought was very good.

But to start with the last, I do reach out to the Agreement States, not to the Organization of Agreement States. Although, I might use them as a vehicle because they have more email addresses than I do. So, I know what the States are thinking.

So, the agenda for today, I wanted to know if they had any positions or things they were interested in.

In fact at the OAS meeting for those who were there, I threatened people who did not get in touch with me, you know.

I want to hear from them so I can do a better job. I'm keeping track of all the States who talk to me during the year and I'll pull out bells and never hear from them, but I'll do my job better if I know the issues that are going on out there.

Okay. I've worn lots of hats over the years. The hat I've had on the longest is health physicist, but I'm a regulator and I'm a patient. I do a lot of things, but mostly I'm me and I try to do the

best job of being me as I can.

As far as a rep for medical licensees, this is a logistical thing as I think about it. I don't know how many people would come, okay.

For the reactors, these are well-funded organizations. There's big pockets out there and NEI and so forth. You all know better than I do, individual hospitals, are they going to be sending their radiation oncologist to take a week off to come to Rockville and talk about - I don't know. I have no idea. I would like to think they would, but I think it might be a challenge.

I was intrigued by your idea of an extra meeting where you invite whoever you invite to basically educate us, you know.

We're supposed to be doing that, but I imagine some of these medical organizations might want to come and give us a presentation. I just don't know how it works.

As far as supporting it goes, I won't go to individual States, because no individual State is going to -- times are hard.

I think if you were to go to particularly CRCPD, you know, because they cover, you know, x-rays and everything else, and asked them for help for supporting some sort of meeting, you know, they might

listen.

And they actually have some, you know, paid staff that might be able to help, but you're asking a hard thing to do for Agreement States because basically what we are paid to do is do things for safety in our own State and we don't got a whole lot of budget for national issues.

And Pennsylvania is very, you know, nice enough to let me do this, but you all realize we are not going to leave.

So, I love the concept. I just don't -- maybe if you do a poll and ask people if they'd be interested, I don't know.

MEMBER LANGHORST: This is Sue Langhorst.

I think that it is going to be very dependent on how worthwhile those types of meetings are and it's not going to be something that will just necessarily catch on immediately.

Maybe one of the things that could be discussed is how quickly can regulations in this realm move forward, because that's one issue that we were talking about that needs to be discussed.

I don't know -- it will be dependent on how successful a meeting like that could be. Maybe it is starting out with an extra ACMUI meeting.

CHAIRMAN THOMADSEN: Dr. Dilsizian.

MEMBER DILSIZIAN: Yeah, just regarding organizations I've noticed that in the public a lot of organization representatives are here voicing their opinion officially or unofficially.

So, I think that if there are issues, I would think that they would be here. They know the meetings and I've seen two or three of these organizations represented.

CHAIRMAN THOMADSEN: Doctor -- Ms. Holiday.

MS. HOLIDAY: Dr. Holiday.

(Laughter.)

CHAIRMAN THOMADSEN: Doc Holiday.

(Laughter.)

MS. HOLIDAY: I just wanted to remind the Committee that during the May 2014 ACMUI, Dr. Zanzonico presented the Bylaw subcommittee's report that did include that question about the ACMUI meeting for an additional meeting.

And I believe that it was a consensus among the full Committee that you did not want to go with more than two face-to-face meetings.

However, I will also note that in a meeting prior to that, there was discussion about possibly having another in-person meeting for specific topics,

for example, with the Part 35 rulemaking.

And of course with such a meeting we have said before that there are budgetary constraints. But as long as we put that request in early enough, because I don't know about your institutions, but NRC has to submit their budget request at least a year or two in advance.

So, that would be something that we would have to go ahead and put in at least on the Commission's radar in order to do that. Thanks.

MEMBER COSTELLO: If I could, I think the budgetary impact of a third issue would be than another reg.

MS. HOLIDAY: Absolutely.

CHAIRMAN THOMADSEN: Dr. Alderson.

MEMBER ALDERSON: Thank you. I think this, you know, as an idealistic approach, this is -- it's a great idea and I think education is a wonderful thing whoever gets it, but I think this is practically very hard to achieve.

And I think if you had another person-to-person meeting, I'm concerned about the high likelihood of it failing.

And depending on who you bring in, how far you extend it out, does it go just to the medical

community and what part of the medical community, the experts, the physicists, do we go to societies?

And then we get societies with, frankly, we all recognize those who have been in societies, their agenda is to come talk about do we go to the public? Because the public wants to hear about all this and where do you cut it off? And so, I think there's just a lot of organizational problems.

One way that you might think about turning it around or if I want to try to think about it, which I am not now.

(Laughter.)

MEMBER ALDERSON: It would be to think about maybe putting on a video conference, a national video conference because, you know, you can project your ideas out. The expense of the people who have to attend, minimal. All they have to do is get on their computer.

And people do these things now and, you know, you can have, you know, call-in lines and all sorts of things, you know.

You might be able to try that. And if that -- nobody likes it, well, they won't dial in the next time or you'll get some feedback as part of your meeting. So, I'll just suggest that as a possibility.

MEMBER LANGHORST: As I tell my researchers,

if it was easy, it would have already been done.

CHAIRMAN THOMADSEN: Absolutely.

MEMBER LANGHORST: And so, that's why I put that word "bravely" in there.

CHAIRMAN THOMADSEN: Dr. Howe.

DR. HOWE: Well, we kind of discussed, you know, very informally internally about a medical RIC and one of the things we keep coming to is it's very difficult for the medical physicians to get away from its practice and come to NRC, but it's easier for us to go to a society that's maybe more therapy-oriented for the therapy-type discussions, a society that's more nuclear medicine-oriented for the nuclear medicine-type discussions.

And then I think we might get more bang for our bucks as far as actually having physician participation.

So, that's just one of the thoughts we've been batting around.

MEMBER COSTELLO: Next week is the Penn State Roundtable in which RSOs from the region, not just Pennsylvania, but all around --

-- RSOs from all around the area come together for I think it's a three-day or two and a half-day meeting this year. And for one day they invite

the regulators in. They fear if they're too long they'll be taking names and --.

(Laughter.)

MEMBER COSTELLO: And wearing my Pennsylvania hat, I finagled my way on the agenda. Basically have a discussion between the regulators and I'll have a very short presentation on how the RSOs can do better and then I expect to hear from them on how I can do better.

And I assure you I know most of these people forever anyway and we'll reach out. You go to OAS meetings, you have HPS meetings and other ones.

And maybe we can't do a whole lot better than that. I don't know. Health physics is a way to get a lot of information, not just medical, but a lot of non-medical.

And maybe as you talked about, it's hard for them to give up their medical practices and maybe us going to them may be a better way.

CHAIRMAN THOMADSEN: Mr. Mattmuller.

MEMBER MATTMULLER: Yes, to follow up with what Mr. Costello was saying, I too was thinking that instead of the NRC putting on a RIC, given the 37 Agreement States, that a group like the CRCPD would be a more appropriate organization to sponsor such a

meeting.

Plus, it also has the advantage that their meetings move around on a national basis giving people in different areas of the country a chance to attend because travel budgets are basically nonexistent in a lot of hospitals.

So, then if it's within an easy drive, a lot more people have a chance to attend than coming to Rockville, not that Rockville is bad.

MS. DUDES: But it's an expensive place to come, yeah.

MEMBER MATTMULLER: Yes.

MS. DUDES: I understand that.

CHAIRMAN THOMADSEN: Yes, Mr. Fuller.

MR. FULLER: I'll just add on my perspective when it comes to our meetings and things to consider, and of course we'll do whatever we can to support the ACMUI in any way that we possibly can.

The one thing I remind folks is that any time the ACMUI gets together and deliberates, it must be publicly noticed well in advance, the agenda posted, the meeting has to be a public meeting and so forth and so on.

So, as we think about the outreach that we do especially with the issues related to release of

patients with iodine-131 therapies and so forth, we're putting the plan together.

Donna-Beth described some of it today, but part of the logistics of that is a lot of public interaction.

We have some workshops in mind at this point in time that we're sort of starting to plan around and we will appreciate it and we will be asking for participation from the ACMUI in those sorts of public outreach meetings as well. So, I see these as other opportunities.

When we go to some of the professional societies, for the last few years we've been primarily in the attendance mode because early on with the rulemaking which was the last big thing we worked on, we were doing presentations. But then we found that, you know, it was better to listen than it was to talk sometimes.

And so, the model I think will be back on that note of explaining and sharing sort of what we're planning to do and again trying to encourage more and more participation by the public and the professional organization.

So, interacting with the medical community is something that we will always rely upon this body to

help us with, but we do not plan to wait around. And we will not be bashful in asking certain folks of this Committee to work with us as we start on this next big effort.

CHAIRMAN THOMADSEN: Thank you. Ms. Fairobent.

MS. FAIROBENT: Thank you, Dr. Thomadsen.

Lynne Fairobent with the AAPM. I know it probably surprises you all to think I might have an opinion on this, but I've been around far too long.

And going back to 1977 and '78 when I started with NRC, I think that it's time to try a regulatory issues conference for medical or perhaps for even materials.

It's been bounced around a number of times over the past 30 odd years. We don't know that it won't work unless we try it.

A key difference that I see in a RIC versus when we have a roundtable discussion based on an advance notice of proposed rulemaking like we have done with Part 20, like we did with Part 35 back in 2002, is the general nature of the dialog in the discussion topics.

It is not focused on a one-way discussion. NRC is holding a public meeting on an active proposed rule that is out for comment. There is give and take

in the dialog.

The difference in the presentations, the difference in the interactions, the availability of the commissioners to attend and listen to interact with the licensees in a non-enforcement or regulatory environment, I think, is very different.

I think there are ways that we could look at perhaps tracking the first RIC. And if it was not a standalone, perhaps we look at attaching it to the OAS meeting, which is a regulatory conference, versus CRCPD, or perhaps we look at doing it as part of one of the professional society's meeting as an extra day.

The difference that I see in doing a RIC in an open discussion and forum not only with NRC, but with the Agreement State representatives versus inviting NRC or a representative from the Agreement States either as the Organization or a particular State to come to, say, an AAPM meeting and give a talk, is that is a talk. It is a presentation. It is not a give and take. It's not open dialog.

Even when we give an hour-long talk if it's at our annual meeting, you have competing sessions. We have 15 parallel tracks at AAPM during our annual meeting.

The need for our members to get continuing

education credits towards board certification or recertification is great.

Oftentimes the regulatory sessions are not going to be the draw for that interaction. So, I do think that perhaps it's time to take a look at let's see what we can put together, let's see what we get as a turnout and then decide that, okay, it's not worthwhile. But if we don't try it, we don't know what the likelihood of the support of the benefit will be.

CHAIRMAN THOMADSEN: Thank you very much.

Dr. Ennis.

DR. ENNIS: Ron Ennis again. I want to just go back to Susan's presentation, but change the focus a little bit to an area where I think maybe there is need for work, but not from personal experience, but just from things that I hear from others.

And that is developing a culture of safety and collaboration and being able to talk honestly and openly for the benefit of the public when it comes down to the enforcement level.

And the actual regulators who come into the departments and the relationships that they may or may not have with the physicians, for example, that culture, my sense is, is not a healthy culture or not as healthy as it could be and maybe there's work that needs to be

done at that level involving Agreement States and NRC States to really improve so people are really working in a collaborative kind of way.

My own personal experience has been very positive with my regulators, but -- and I really will throw this out for discussion because I don't have any data. I don't really have even good anecdotes, but it's the sense that what you're talking about is really an issue, but at a lower level than ACMUI versus NRC.

CHAIRMAN THOMADSEN: Thank you.

Yes, Ms. Dudes.

MS. DUDES: Thank you. I just wanted to sort of echo, Lynne, your comment. And I think you're correct that we may want to try adding some sessions to some existing forum and see what we get.

I had an individual who was a vendor with a poster at the Organization of Agreement States meeting in Chicago say something very similar to me is that we were very happy that the regulators are meeting and discussing these issues. When do you bring the larger community in to discuss these issues?

And that resonated with us. And so, I think we'll at least, you know, try and see what small step could be taken, you know.

To undertake a two or three-day event, not

knowing what kind of reception we would get, may be a big step, but some level of effort in that area I think you're correct that it's timely and if we could tack it onto an OAS meeting.

And the reason I would like to tack it onto an OAS meeting rather than a society meeting or a CRCPD meeting is because you do have the Agreement States there.

And so, you have the regulatory body of the National Materials program in one place that would be probably the better venue to take the next step and then include licensees.

Of course we'd do that in a public way. So, anyone would be available or able to attend and that dialog would be open to the public as well.

CHAIRMAN THOMADSEN: Any further comments from the Committee or the NRC?

Yes, Ms. Langhorst.

MEMBER LANGHORST: I just wanted to say that my intent is to throw pebbles in the pond to send out ripples and for you all to take the ripples and see what you can make of them and again come back to this questioning attitude about how do we look at avoiding complacency and challenge existing conditions and activities.

I think this is never going to be, oh, we got to safety culture, okay, we're done. It is a continual dialog.

And so, I offer up my ideas and I hope you take them as inspiration to figure out what you think might work.

CHAIRMAN THOMADSEN: Well, I'm hoping you're going to offer more than your ideas, because I'm going to -

(Laughter.)

CHAIRMAN THOMADSEN: -- ask you and one other person on the Committee, a volunteer if there is one, to work with somebody who is designated by the NRC to come up with a very concrete proposal not just for the first meeting, but possibly for maybe up to three or something that would include some idea of the cost that they could then put into a budgetary item for the future to at least give this a try in the beginning and how it should be organized.

Do I have a volunteer to work with Sue on this? We do. We have Mr. Costello who is willing to also serve on that. I think that's great.

Where this goes, we'll find out. As has been said, we won't know until we try it and let's see.

Thank you very much, Dr. Langhorst.

MEMBER LANGHORST: Thank you.

CHAIRMAN THOMADSEN: Now, we have Dr. Welsh talking about the medical events for the fiscal year 2013.

(Pause.)

MEMBER WELSH: Thank you, Dr. Thomadsen.

Much of what I'm going to say here today is going to sound like a rehash of things I've said in years previously and that is in part because we have some new members and we will have future members and I will rotate off shortly as the subcommittee chair and somebody will have the honor and pleasure of inheriting this role of putting together this annual report.

So, much of what I'm saying here today is for the benefit of the subcommittee members and the Committee members as a whole regarding use of the NMED database.

When you look at the events in the past fiscal year, you can review them and identify them for a variety of different approaches.

The approach that I prefer personally is to go to NMED under Advanced Search, event type, medical, and then plug in the dates reported.

And when you do that, you come up with a total of 62 events for the year in question and they are

described as tabulated here.

None in the eye applicator brachytherapy. None in the brachytherapy of intravascular, et cetera, et cetera.

I won't go through the detailed list. It's in your handout, but I'll throw in some comments right now because for those who are not familiar with NMED, you'll see that there are some categories that remain poorly defined and they're still in the menu.

For example, linear accelerator and x-ray, which we know the Nuclear Regulatory Commission doesn't regulate, and then the undefined NA/NR categories, but the NMED team has listened to some of our concerns and has changed a good deal of what's in the NMED database.

For example, Zevalin didn't previously have its own category - did have its own category, but Bexxar did not. So, that was hard to understand.

Well, part of this was self-rectifying because Bexxar has bit the dust and is no longer available as a product, which I think is most unfortunate for our patients, but the Zevalin category has been eliminated. And also radiolabeled antibodies as a separate category has been eliminated. Zevalin is now listed in radiopharmaceuticals T.

So, things do change and it's obvious that

the NMED team has listened to some of our suggestions, but there are some things that are very difficult, if not impossible, to change.

And when you're going through the NMED database, you'll see that the events are not in chronological order. And this is because some events from months, maybe even years previously get reported and eventually logged during the period in question.

That means that some events from the period in question are not entered for many months and, therefore, the only way to practically do a search is to focus on the events reported during the time in question.

When you do that, you'll see some discrepancies. For example, in our spring meeting when Dr. Howe gave her report, there were 43 events. And now, we're saying that there are a total of 62.

So, there's a difference of 19 certainly not because Dr. Howe isn't counting as accurately as we are. If there's ever a discrepancy, I personally would side with Dr. Howe every time -- but there is a difference of 19 here even though the searches were done only a few months apart.

And this is not a phenomenon unique to the current fiscal year. For example, last year in 2012 we

saw that in the spring there were 52, and in the fall we tallied up 61. So, we saw the exact same pattern of a number getting popped or logged later on in the year.

Even though we're talking about the previous year, the previous fiscal year, things get logged a bit late.

And I bet you if we do this again for the same fiscal year, there could be a different number, but the important thing is at the bottom there that this year's total is virtually the same as previously, 61 versus 62. So, the current fiscal year is not anything alarming.

Another comment that I'll make at this early stage is that we've brought up many times in the past that it would be nice if the NMED database were organized by 10 CFR.

However, I don't think that's going to happen and I don't think it's -- maybe we don't need to insist that it happen.

We talked earlier today about some of the challenges. For instance, one Gamma Knife device is 600 and another Gamma Knife device is Part 1000.

And then for manual brachytherapy Y-90 is categorized in NMED as manual brachytherapy, but it's listed in Part 1000. Are these things going to stay

1000?

So, 1000 might be the right number or could be. In practice I think it's not proved to be the case, but the point is that it can be challenging to try to organize things along 10 CFR.

But this begs the question do we really need to categorize things along the Code of Federal Regulations categories, because this makes our -- our effort to do so adds significant burden to this task and some of us might not find it as enjoyable because of the burden that we place upon ourselves trying to organize things in accordance with 10 CFR.

So, perhaps during this report in the future just according to what's in NMED rather than trying to translate it into 10 CFR might be more constructive and educational.

So, getting into some of the details we saw that there were two in the Part 300. One of them was a Zevalin case which the calculated dose for the patient would have been higher than a standard dose.

So, they intended to give the typical maximum activity of 32 millicurie, but the written directive had transposed the numbers and the number 23 rather than 32 was written.

But then they gave 32 millicuries, so it

didn't follow the letter of the written directive and is logged as a medical event even though the intended activity was ultimately given to the patient.

Another case involved mIBG, metaiodobenzylguanidine, for metastatic neuroblastoma. I presume this was a pediatric case. The age of the patient wasn't given in the report.

One millicurie was administered. The Foley catheter leaked and eventually this was discovered. The patient was cleaned. The catheter was removed and replaced and the sheets and clothing were changed and the patient was discharged with no evidence of skin irritation, but a few weeks later examination for consideration of the second possible treatment revealed skin irritation consistent with radiation injury.

It was estimated that the patient's skin received 1,000 centigray due to that urinary contamination that was unaddressed for a bit.

So, the report says the patient and the doctor were notified. Again, I think this was a pediatric case. So, I presume that it was the patient's parents who were notified.

Corrective actions include procedure modifications and providing additional training to

personnel.

The next event of note was a situation which technetium cardiac stress test was administered despite the order being cancelled.

The procedure was changed from a stress test to an echocardiogram, but the technologist allegedly failed to notice the change and the procedure was performed.

A small dose was administered to the patient. No adverse health effects are expected, but it was a medical event because this procedure was cancelled and byproduct material was nevertheless administered.

So, corrective actions include going forward using a computer to schedule and cancel orders, encouraging physicians to write more legibly, moving from handwritten to electronic orders.

This next one was a most unusual event. Cardinal Health reported dispensing 34 unit doses of 12 millicuries each of technetium-99 sestamibi.

At the hospitals, the radiopharmaceutical was found to be taken up in the soft tissues rather than the heart.

So, this investigation led to the conclusion that the material contained only

technetium-99m rather than the radiopharmaceutical technetium-99m sestamibi.

So, how did this happen? It appears that the doses were incorrectly labeled, the technetium-99m was diluted and then incorrectly labeled as technetium-99m sestamibi. So, it seems like a manufacturing or perhaps a compounding problem.

It was concluded that Cardinal Health failed to follow established procedures. So, Cardinal Health completed and passed erroneously the QA testing which should have demonstrated that these were mislabeled.

So, corrective actions include providing additional training to the personnel, but it sure begs the question of whether or it's not just Cardinal Health who's totally at fault here.

Could or should the local hospitals have caught this error? And that's hard to answer. One bit of information that we don't have the answer for is exactly what was the activity that was sent?

Was it truly the 12 millicuries? And if it was not, could the clinics have possibly caught this? Although, given that these were unit doses, perhaps that wouldn't have happened regardless.

Another question that comes up is, is this

really -- should this really be in the category of medical events?

One could argue that the authorized users and the facilities did nothing wrong, but we've had many conversations about what a medical event is supposed to be and what that definition should encompass ideally.

And even though maybe they didn't do anything wrong, maybe we need to still categorize it as a medical event.

However, this one is just unusual enough that it begs the question of whether it would be an abnormal occurrence rather than a medical event.

Another case involved sodium iodide in which the patient was prescribed a therapeutic dose, but instead received a diagnostic dose.

And without going into the details that are written here, I'll just say that a new electronic medical records system was implemented and there was a constellation of errors that led to a perfect storm culminating in this event which fortunately is extremely unlikely to have any medical consequences since a therapeutic dose was prescribed, but a diagnostic low dose was administered.

The order that was requested was a whole body scan, but it appeared to be something different.

And when the patient presented for the study, the imaging center was down and was sent to another hospital.

At that hospital after the procedure was administered, somebody identified that there was something unusual about that particular order and going forward they had some corrective actions that were pretty standard stuff.

Perhaps this is an example of a medical event that was due to implementation of a new electronic medical records system.

And as more and more institutions transition, we need to be on the lookout for such events and perhaps institutions will benefit from this happening to somebody else so it doesn't happen at their institution to their patients.

Moving on to the manual implant brachytherapy category, when you search for this using event type equals medical and then the dates and then plug in procedure, brachytherapy manual implant, you get a total of 32.

But because Y-90 microspheres are Part 1000, this means that only 14 were Part 400 classical manual brachytherapy, manual implant brachytherapy.

Here's how they are broken down. And compared to last year, this was a good year. There were

20 events in 2012 with 34 patients. But this year in 2013 there were only 16 events involving 19 patients.

And I'll comment more on that one on the bottom, because it's been very difficult to categorize exactly where this one really belongs.

So, I'd lump it with the 400 even though it's really 1000, but it's certainly not brachytherapy.

Two of these events were cesium-137 GYN cases. One was involving 450 centigray that was delivered to the skin of the patient because the packing came out early. Another one was caused because one of the two sources fell out of the applicator.

Specifically in that first event, a patient received an unintended dose to his thigh because at six o'clock in the morning the patient felt something move and probably that was when something, the material popped out and it was subsequently discovered at 9:15.

The physicist was the one who discovered that the implant was out of the patient. The team removed the sources. And the reason for why this happened most likely was because of some accommodations and adjustments that were made during the procedure to accommodate that patient's particular anatomy.

The next case involved a Fletcher-Suit, Fletcher-Suit ovoids. The text says that 30 gray to each

ovary was prescribed. Perhaps that means ovoid.

At the completion of the procedure, it was discovered that the sources were not present on the left side and the source was instead found on the IV monitor stand.

What happened, apparently, was that one of the sources was never placed properly and was on the bed. The nurse found it 12 hours later, didn't know what it was, apparently, and just put it by hand on that IV stand.

The nurse had an estimated dose to the hand of about 13 rem. This was an example of human error and inadequate training.

Moving on to the -- to that other unusual event that was listed in manual brachytherapy, probably technically it belongs as a Part 1000 medical event, involved a seed that migrated after being placed in the axilla and was not retrievable during axillary surgery.

If you look at the activity and the doses here, you can see that this is not a brachytherapy procedure, but it was listed under manual brachytherapy perhaps because it doesn't have a convenient categorization.

This was the event [that] occurred primarily because of scarring in that patient's axilla due to previous surgery and maybe there was no way that

that seed could ever have been removed easily without causing damage.

The corrective action at the institution was the decision to cease doing radioactive seed localizations for axillary node lesions.

Moving on to prostate brachytherapy, this again is the biggest single category. 14 medical events involving 16 patients this year.

Two events involved medical patients, 10 of these were underdoses, and a couple of them were reported years after the procedure itself.

One was an overdose. There were two seed migrations, two anatomical barriers and one has to wonder if the seed migration and anatomical barrier cases really should be labeled as medical events.

Should they be categorized as patient intervention? And that's something we might discuss later on if we have time. There was one plan error and four seed misplacements.

The breakdown in the isotopes is as follows: One of those palladium-103 cases was retracted.

Of course these categories that I just listed are not mutually exclusive. One hasn't gleaned a whole lot of earth-shattering information from reviewing these medical events this particular year.

It's the usual causes; human error, inadequate training, inadequate supervision, et cetera.

There was one palladium implant that was initially called a medical event because of underdosing, but upon closer inspection was retracted in 2013 because of perhaps edema causing the miscalculated underdose.

At least one of these cases it seems like the seeds were correctly placed and then subsequently migrated leading to an underdose, which again begs the question of whether or not such case should be labeled as a medical event.

There was one situation in which the wrong plan was used. Clearly a classic medical event. A monotherapy plan was used instead of a combined modality plan and of course corrective actions include modification of default settings for the treatment planning system.

There were two events listed this year in the anatomical category or anatomical issues because of pubic arch interference specifically.

In the first one, five seeds were implanted out of the planned 106. So, corrective actions that are listed include verifying that there are no anatomical obstructions. But I'm sure that as we all know when we

do these procedures, you always try your best to make sure that there are no obstructions that you're anticipating. This patient went on to receive external beam radiation.

The second event was similar. The procedure was aborted early on after it was clear that the pubic arch was in the way. Only 14 seeds were placed. And so, 65 percent of the intended dose was delivered.

The written directive was revised, but I was disturbed to see that the corrective actions were to discontinue the program.

I don't have any information about whether this was a top-notch program and it's a shame that this is not available for patients anymore, or if this is a program that really needed to be terminated, but thanks to our list of anecdotes, tough regulations or inappropriate regulations or medical event definitions possibly influenced the decision of practitioners to do this form of brachytherapy.

I've always argued that, yeah, I think that if you have an inappropriate definition of a medical event and you're going to get cited with a medical event and your competition might say we don't have medical events at our hospital, it might discourage you from doing this procedure in favor of the more lucrative, but

not necessarily better for the patient, external beam strategy.

So, I don't know exactly what happened, but I was disturbed to see that this program was terminated.

Moving along -- I'm finished with the commentary there. Moving along to the Part 600, we can see that it was a good year with nine events compared to 17 in the previous year.

Most of these were HDR with only one Gamma Knife and then one Perfexion™. This is how they break down in terms of the HDR itself.

The causes were the standard problems, length problems, wrong patient plan used, incorrect applicator placement, a source that got stuck in the transfer tube.

We talked about the Gamma Knife. One was a conventional Gamma Knife unit, the 600, in which case the wrong side was treated despite the fact that the AMP thought the coordinates looked odd, but didn't bring it up or didn't say anything before the treatment proceeded.

The next one was a Perfexion™ unit medical event categorized as a 1000. And this was a mechanical failure of the sensor resulting in only -- in an underdose, but this was fixed and the patient treatment

was completed. So, it's very questionable about whether this should be labeled as a medical event or not.

Moving on to 1000, you can see that 2013 was a good year. That upward trend going from 2011 to 2012 was reversed with only 14 medical events. And the 1000s were essentially all microspheres with the exception of that one Perfexion™ Gamma Knife case.

And you can see, and I'll bring this up again, that the ratio of resin to glass medical events was reversed this year compared to years previously consistent with what we have said here at the ACMUI.

Here are the specifics regarding the SIR-Spheres events. The usual causes, blocked catheter, leaky vials, leaky catheters, needles not in the optimal position. Shunts to the duodenum, one was treated, one was classified as a recording error.

With the three TheraSphere cases, two of them were blocked catheters and one was a procedural error because no other cause was determined.

So, the general observations we have are that as previously there's not a whole lot of detailed information available in the NMED report which is not a criticism, it's just a reality that we have to contend with.

So, it's a good source of tallying numbers,

but you're not going to get the specifics here.

The training and procedural changes are the most common remedial actions, but, as I mentioned, there was at least one situation which the program itself was discontinued. And that's always something that is disturbing or concerning.

The yttrium-90 microsphere medical events demonstrated a reversal in their preponderance with more resin than glass this time around.

And I recall a year or so ago I was charged with analyzing medical events in Y-90 microsphere brachytherapy in particular to see if there was a trend that was real. And we predicted that the perceived trend of more medical events occurring in glass was just a fluke. And I think that this observation of the reversal in ratio confirms our conclusions.

So, in conclusion of this year's report, we see no obvious trends, no patterns, nothing that's truly concerning.

And it's important to underscore the fact that there are maybe 15 million diagnostic procedures, 150,000 therapeutic procedures using byproduct material annually. And the tiny fraction that we're talking about here today is quite reassuring. It confirms the generally safe fashion that these materials

are administered to patients in this country.

One of the questions that did come up during our conversations, email deliberations was what constitutes patient intervention?

And that might be the most important question that arose during this year's discussion of the medical events report analysis, because patient intervention classically is perceived as something that's intentional.

But if the patient's physiology changes or if their anatomy changes, should this be a medical event, or could this be construed as patient intervention?

Specifically when there might be a change in pubic arch position or interpretation of pubic arch location and we find in the operating room that it's impossible to place those needles, should that be categorized as a medical event, or is that more appropriately considered patient intervention because the anatomy is different?

So, these are some of the questions that we had. Are there any questions for us now?

CHAIRMAN THOMADSEN: Thank you very much, Dr. Welsh.

Mr. Costello.

MEMBER COSTELLO: Dr. Welsh, you know, I

think I was the one who raised the question of patient intervention and I've raised it because I thought I saw a disconnect between what at least appeared to me to be the majority of medical opinion of our subcommittee and what I am called to be the view of the NRC patient intervention and I like to describe it like this, actually one or the other.

You know, if you look at the rule, patient intervention talks about being something active, either intentional or unintentional, because I think the rule allows for unintentional patient intervention.

And what means is if a patient pulls out something during HDR treatment or gets off their external beam treatment or for something like that, okay.

What was clear when we were discussing it, that what I would call passive patient intervention, you know, something that happens because of the anatomy of the patient or something like that, in my previous life I would not have thought of that as being patient intervention. Doesn't mean that I would have been right, it's just I wouldn't have thought of it that way.

So, it's sort of a battle in my head and I heard, you know, discussion and I think it was the majority of the subcommittee, actually, were agreeing

that patient intervention could be what is called passive patient intervention.

And just to complete my thought about that is and you have in one of your slides if the authorized user and the staff does everything correct, everything according to procedures, everything according to accepted medical practice, but the outcome is that the intended organ didn't get, you know, the dose intended or the unintended organ did, does that constitute a medical event, or does it not constitute a medical event because they could not have done anything to prevent it?

And my thought was that -- and I don't think we could possibly totally discuss it here, because -- and I'll leave this up to the Chair that this might be a good topic for a subcommittee to look at to make recommendations to the NRC just what do we mean by patient intervention and what do we mean by medical event.

If the regs cannot have prevented it, and I hear this in my own State, it couldn't have been prevented or how could it be medically prevented, I think that's a subject worth pursuing.

MEMBER WELSH: Well I would concur and I'm very appreciative of you bringing this up, because it's not something that was on my radar, nor was it on most

of the other subcommittee members' radars.

But I think now that you've raised this question, we realize that this is a crucial, important question that doesn't have an easy answer that will likely come up within the next five minutes.

I think that as I said, perhaps the most important conclusion of our exercise this year was just this question that doesn't have an answer just yet.

And with Dr. Guiberteau's presentation this morning on Y-90 microspheres, one has to wonder about what if the team did the MAA scan and did the angiography and everything was done according to the book and looks perfect, and then you do a lung scan and you find that there's more activity in the lungs than anticipated.

Has something happened in terms of the vascularity or the shunting that is over and above what could be controlled by the authorized user and team?

Should that be given the unfortunate marker of medical event which comes along with some negative connotations? But what do you call it?

So, I would agree that maybe this question does need to be asked in subcommittee form to specifically try to answer that.

CHAIRMAN THOMADSEN: Thank you for the

comment.

Yes, Dr. Zanzonico.

MEMBER ZANZONICO: Those two 35.400 MEs for the anatomical for the pubic arch, I'm not familiar with this at all.

Is that something that should have or could have possibly been detected by some pre-procedure imaging procedure?

MEMBER WELSH: So, in practice we often do a pre-plan a couple of days, weeks ahead of the actual case.

And in principle it could be identified, but that planning procedures is imperfect and is imperfect, in terms of determining the degree of pubic arch interference that you will actually face when you start placing needles.

An experienced team, experienced authorized user will probably get a good sense of whether or not there's likely to be anatomical interference or not and may be able to say, ah, we've just done this procedure, this planning procedure and we realize that the arch is going to interfere, we're not going to get to the anterior prostate, let's choose external beam instead.

But like I said, it's not as perfect as we'd

like it to be.

MEMBER ZANZONICO: Some follow-up questions. The numbers in some cases seem almost too good to be true, and I doubt they are.

I mean, at the end you estimated there were 15 million diagnostic procedures per year, yet there were zero, if I understood correctly, zero radiopharmaceutical diagnostic medical events since 2004.

Am I interpreting that correctly? I think it was on your Slide Number 4.

(Comments off record.)

MEMBER WELSH: That might be the NMED categorization of diagnostic radiopharmaceuticals. Like I said, there are, there's the NA that's there, there's the radiopharmaceuticals D, there's the iodide on the next page, et cetera. So, that might be an illusion because of the NMED nomenclature.

But having said that, yes, it is almost too good to be true, but I think it's true that there are very, very few medical events.

CHAIRMAN THOMADSEN: I think Dr. Howe has the answer to that.

DR. HOWE: Back when we did the radiopharmaceutical in 1994, we adjusted the definition

for a medical event for diagnostic nuclear medicine and put a dose threshold.

And so, and the intent was that 99 percent of the diagnostic, what were diagnostic misadministrations prior to that day, would no longer be diagnostic. So, the reason you're seeing zero is because of that.

And I'd like to also comment on the difference between the number of medical events that Dr. Welsh gets when he does an NMED search and the number I present.

I get the same number, 62, but I review each one of those paragraphs carefully and some Agreement States have not adopted the dose threshold for the diagnostic misadministrations.

And so, many of these like the sestamibi's and the technetium ones, they aren't medical events under NRC's criteria.

And so, I bring to the ACMUI the NRC-accepted medical events and that's why there is such a -- where you have a fairly large number, 16, 15, 14, that's the difference in reporting between Agreement States and NRC.

And then sometimes something will still be labeled as a medical event if it got retracted later,

and I'll take out the retracted ones.

So, I have essentially gone through and filtered the data so that you see only NRC medical events.

MEMBER WELSH: Thank you for that clarification.

MEMBER ZANZONICO: I just have one other question.

CHAIRMAN THOMADSEN: Yes.

MEMBER ZANZONICO: You indicate that the date associated with a medical event is the date of reporting, not the date of the incident.

So, to me, that means that any of these trend data, you know, are almost meaningless since the date, if I understood it correctly, since the date of the incident could be completely dissociated from the date of reporting, yet the dates in your tabulation presumably reflect the date of reporting therefore.

Am I interpreting that correctly?

MEMBER WELSH: I think so. I think that there is this hazard of over interpreting what's available to us in NMED and we have to be cognizant of the fact that as an example I think it was in Wisconsin, that the State elected to do a review of all prostate brachytherapy cases and started picking up cases going

back five, ten years and then tabulating them last year or the year before.

So, you have to be cautious when interpreting those trends.

CHAIRMAN THOMADSEN: Dr. Suleiman.

MEMBER SULEIMAN: I mean, these numbers, we've always said this, are so low that they, they're almost, I mean, they're insignificant.

And so, trying to track trends with such low numbers, I mean, the only encouraging thing is that they're low. Clearly they're probably underrepresented, but that's always the case, you know.

What happens if something gets reported and gets picked up by the community or the media? All of a sudden there's an increased sensitivity and awareness and we may see an uptick.

It's not necessarily there are more events. It's just that people are made more aware, but I just don't see any of these numbers as being suggestive of any major problem.

MEMBER WELSH: Well, I would agree that there is no major problem, but I would disagree that they're over-reported.

MEMBER SULEIMAN: Underreported.

MEMBER WELSH: Okay. Because, you see,

medical event criteria, in my opinion, might be a bit stern and it might be relatively easy for a perfectly good medical procedure to be labeled as a medical event and, therefore, we've had the pregnant implant brachytherapy medical event definition subcommittee, et cetera, et cetera.

But even with the increased sensitivity because of a definition that may be imperfect, there's still a very, very small number of these per year.

And if you're to compare these numbers to what we see in surgery, medical oncology, we see that this is a very, very safe procedure.

However, because what we said or I said earlier that I think in this country there is inordinate fear of radiation, even a dozen or a hundred cases per year when the denominator is tens of thousands or hundreds of thousands, it gets picked up by the media and overblown all too readily.

But the bottom line is that this is a safe and effective use of medical use of byproduct material.

CHAIRMAN THOMADSEN: Dr. Langhorst.

MEMBER LANGHORST: One thing I wanted to mention, too, is that even if you don't meet the criteria of a medical event, which is an NRC regulatory definition, doesn't mean that the medical community

doesn't investigate what went wrong there, because there are a lot of other of these organizations that require that investigation.

So, just because it doesn't reach the level of medical event doesn't mean that, oh, we don't have to worry about it, we'll forget about it.

There's a lot of investigation and review of what was the lessons learned there.

CHAIRMAN THOMADSEN: Any other comments or questions for Dr. Welsh?

(No response.)

CHAIRMAN THOMADSEN: If that's the case, thank you very much. And with that, we stand adjourned for today. Tomorrow we start at eight o'clock.

(Whereupon, at 5:18 p.m. the meeting was adjourned.)