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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

(ACMUI)

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MEETING

+ + + + +

MONDAY,

OCTOBER 28, 2002

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ROCKVILLE, MARYLAND

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The Advisory Committee met at the Nuclear Regulatory Commission, Two White Flint North, Room T2B3, 11545 Rockville Pike, at 10:00 a.m., Dr. Manuel Cerqueira, Chairman, presiding.

COMMITTEE MEMBERS:

MANUEL D. CERQUEIRA, M.D., Chairman

JEFFREY A. BRINKER, M.D.

DAVID A. DIAMOND, M.D.

DOUGLAS F. EGGLI, M.D.

NEKITA HOBSON

RALPH P. LIETO

LEON S. MALMUD, M.D.

COMMITTEE MEMBERS: (CONT.)

RUTH McBURNEY

SUBIR NAG, M.D.

SALLY WAGNER SCHWARZ

RICHARD J. VETTER, Ph.D.

JEFFREY F. WILLIAMSON, Ph.D.

C-O-N-T-E-N-T-S

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

(10:03 a.m.)

CHAIRMAN CERQUEIRA: Good morning. My name is Manuel Cerqueira. I'm the Chairman of the ACMUI, and I'd like to welcome everyone here to the open session.

This is actually the first time we've convened under the full implementations of the revised Part 35, so I guess that's quite an accomplishment. We have quite a full schedule today, and we'd like to keep on time so we can complete our business by the end of the day.

Again, I'd like to thank everyone on the committee for their input.

At this point, I'd like to turn it over to Mr. Essig, who is the designated federal official for the ACMUI.

MR. ESSIG: Thank you, Dr. Cerqueira. As the designated federal official for this meeting, I'm pleased to welcome you to Rockville for the public meeting of the ACMUI.

I'm the Branch Chief for the Material Safety and Inspection Branch and have been designated as the federal official for this advisory committee.

This is an announced meeting of the

committee and 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 October 23, 2002 edition of the Federal Registry.

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 or direct the actual decisions of the staff or the Commission. The NRC solicits the views of the committee and values them very much.

I request that whenever possible we try to reach consensus on the various issues that we will discuss today, but I also value the minority or descending opinions. If you have such opinions, please allow them to be read into the record.

As part of the preparation for this meeting, I have reviewed the agenda for members and employment interests based on the very general nature of the discussion that we're going to have today. I have not identified any items that would pose a conflict. Therefore, I see no need for an individual member of the committee to recuse themselves from the discussion.

However, if during the course of the committee's business, you determine that you have some conflict, please state it for the record and recuse yourself from that particular aspect of the discussion.

At this point, I would like to introduce the members that are here today: the Chairman of the committee, Dr. Manuel Cerqueira; Nekita Hobson, who is our patient advocate; Ruth McBurney, who is the state representative; and Dr. Alfredo Sanchez, the FDA representative; and new to the committee, Dr. Douglas Effli?

DR. EGGLI: Eggli.

MR. ESSIG: Eggli, I'm sorry. I have a typo in my notes. It says Eggli there.

And, Dr. Leon Malmud. And reappointed members that were approved by the Commission on the 27th of September: Dr. David Diamond, Radiation Oncologist; Dr. Subir Nag, Radiation Oncologist; Sally Schwarz, Nuclear Pharmacist; Dr. Richard Vetter, Radiation Safety Officer; and Dr. Jeffrey Williamson, Therapy Physicist.

That concludes my opening remarks.

CHAIRMAN CERQUEIRA: Thank you. Any questions for Mr. Essig?

(No response.)

CHAIRMAN CERQUEIRA: I guess if not, we can move on to the agenda. And the first --

MR. ESSIG: If I could add there, there is one item that is not on the agenda that we would like to insert next --

CHAIRMAN CERQUEIRA: Sure.

MR. ESSIG: -- which is a presentation by the General Accounting Office. They are currently in the midst of an audit of the uses of sources of radioactive material, and they have a PowerPoint presentation that will take maybe five minutes or so.

CHAIRMAN CERQUEIRA: Okay. Sure.

MR. ESSIG: So, if we could yield the floor to them and then we'll resume with the normal agenda.

MR. COLES: Good morning, Mr. Chairman, and members of the Advisory Committee. I appreciate the opportunity to speak with you today. I appreciate NRC and the Advisory Committee making time to hear our presentation.

As Mr. Essig mentioned, the General Accounting Office is in the midst of a review of the domestic uses of nuclear material. If I could have the next slide please, just to give you a brief

outline of what we're going to talk about today.

First of all, I want to give you a brief overview of who GAO is and what we do. The second, talk about the reviews we're currently conducting on the uses of nuclear material. Third, how we plan to accomplish our objectives. And then fourth, what are our goals for this survey.

Next slide, please. First of all, US General Accounting Office is often called the investigative branch for the Congress. We are an agency in the legislative branch at the government. We conduct unbiased, objective, nonpartisan reviews at the request of committee chairman, the Congress as a whole, minority and majority leadership, and individual members of Congress. In addition, we also conduct reviews at our own instigation that deal with issues that we believe are currently relevant.

We're an agency of about 3,500 people in Washington, DC and spread throughout six regional offices. Our current head is Comptroller General of the United States, currently David M. Walker. And our job is to provide information to the Congress on whatever issues they feel are of interest at the time.

Next slide, please. Our current efforts

on radioactive materials were at the request of Senator Daniel Akaka, who is the Chair of the Subcommittee on International Security, Proliferation, and Federal Services of the Senate Governmental Affairs Committee.

He sent us a request back in January of '02 that requested that we take a look at a --

CHAIRMAN CERQUEIRA: If I could just interject for just one moment.

MR. COLES: Of course.

CHAIRMAN CERQUEIRA: It would be useful I think for the committee if maybe we can get copies of these slides done afterwards since we don't have them now.

MR. COLES: Absolutely. We've prepared some.

Senator Akaka wrote to us in January and asked us to take a look at the problem of radiologic sources worldwide, a rather large task.

We have divided our effort into three sections. We are looking at material used domestically, internationally, and then we also have a third job that's an aeroscope review of the Department of Energy's Offsite Source Recovery Program that primarily deals with greater than Class C

materials, storing them at Los Alamos for eventual disposition.

We are in the midst of working with a variety of state, federal, and international agencies: the International Atomic Energy Agency to the Nuclear Regulatory Commission, the Commissions, the Office of State and Tribal Program, Nuclear Materials Safeguard and Safety, Nuclear Security Incident Response, the regions.

We are working with the Organization of Agreement States, the Conference of Radiation Control Program Directors. We will be meeting with the Food and Drug Administration, the Department of Defense, State Department, Intelligence Community. And we're also going to meet with a selection of licensees, manufacturers, users of material to get their view on this issue.

If I could have the next slide, please. The domestic review is divided into three primary questions. First of all, we're asking a very general question: What is the extent of the issue? For this, we're trying to get some idea of the number of licensees there are in the United States, what types of materials are being used, what uses these materials are being used for, and I'll go into how we're doing

that in just a moment.

The second question is: How effective is the current regulatory framework? And third: What activities have NRC and/or the states or other entities entered into after the September 11th terrorist attacks to change, improve, modify the regulation of nuclear materials in the United States.

Next slide, please. How do we plan to conduct our work? We will be sending surveys out to the agreement states, also the non-agreement states, and the NRC regions. In an attempt to put together a national database of numbers of licensees, combining those databases that currently exist at the NRC and at the Agreement State level to get some idea of the scale of the issue.

The second part of the survey is going to be more qualitative efforts to ask the states and the regions about how they go about enforcing regulatory framework that's in place, asking them what changes need to be made, where there are gaps, weaknesses, and really where the strengths are as well.

In addition, we plan to go and speak with a sample of licensees from every part of the regulations that are currently subject to license, concentrating primarily on byproduct. We'll also get

into source and special nuclear material as well, but concentrating primarily on Part 30 series.

We plan to conduct survey pretests in November, some post-testing in January, and do a lot of our fieldwork just after the first of the year of visiting licensees and speaking with people in the nuclear materials community. Our final reports are expected sometime in the late spring of 2003.

We're also going to be participating in several IMPEP reviews, the Integrated Materials Evaluation Program, that NRC conducts of the agreement states and also of the regions, to get some idea of how the NRC evaluates their own efforts, evaluates the Agreement State efforts at inspection enforcement of regulatory framework.

Next slide, please.

DR. DIAMOND: I'm sorry. What does the acronym IMPEP stand for again?

MR. COLES: Integrated Materials Performance Evaluation Program. Thank you.

Integrated Materials Performance Evaluation Program. That program is conducted by -- for the NRC regions, it's conducted by NMSS. For the agreement states, it's conducted by the Office of State and Tribal Programs. It's a review that goes

through methodically step-by-step of segments of Agreement State regulatory programs and evaluates them based upon some fixed criteria.

We're going to be observing some of those reviews and commenting on the criteria that are used to evaluate NRC and state regulation.

What are some of the goals of our review? First of all, we want to provide an education on the regulation of nuclear materials to the Congress by a neutral third party. In this day of concern over "dirty" bombs and other sorts of misuses of radioactive material, there's a lot of information going around out there and we want to provide the most accurate and unbiased source of information we can to our clients up on Capitol Hill.

The second goal of our review is to provide the Bush administration with some best practices of what's currently going on in the radioactive material regulation community, cooperation between the states and the federal government, ideas that can be extended to other areas of regulation. We want to provide the administration with some ideas.

The third thing, we want to identify some of the successes of the current regulatory framework and also identify some of the gaps and weaknesses and

make any recommendations for change.

You folks have been involved recently in major changes of Part 35. We want to discuss that. We want to discuss the process that you folks went through on the Part 35 regulations, your ideas of where gaps still exist or some strengths that could be extended to other areas.

And then finally, we want to examine the need for legislative changes. I put as an example up there, possible modification of the Atomic Energy Act to provide for NRC regulation of accelerator-produced materials. That's one idea. We're not advocating it. We're not not advocating it. It's simply an idea that been put forward to us.

And we want to go through some of those ideas and talk to the Hill and see: Are there changes needed of the Atomic Energy Act or the other authorizing legislation of the NRC?

Next slide, please. Finally, just some contact information. What we want to do is, over the course of the next five or six months, we will likely be in contact with most of you, if not all of you, on the Advisory Committee to sit down and talk with you about your jobs on the Advisory Committee and where you think the current regulatory program stands for

the protection of radioactive materials.

It's a very broad scope review, but we're interested in talking with anyone. And if anyone wishes to contact us with ideas, perspectives, things you would want us to communicate with our clients on Capitol Hill, we are more than happy to meet with you at any point in time.

I appreciate your time, and I wish you luck in today's meetings. Thank you.

CHAIRMAN CERQUEIRA: Do we have any questions?

Richard and then David.

DR. VETTER: Can you share with us the motivation for this exercise, other than the fact that a member of Congress has requested it?

MR. COLES: I don't want to speak for Senator Akaka and his individual motivations for requesting this work. But what I can say is this. Every committee up on the Hill that has an interest in this subject is being bombarded with information from a variety of sources on what radioactive material could be used for in a terrorist situation.

Senator Akaka wanted someone objective to come in, who didn't have an iron in the fire, to educate him on how radioactive materials are regulated

in the United States because there are very few people up on the Hill who have a knowledge in the non-weapons, non-power side of NRC's work.

This is really one of the first broad scope efforts that has been conducted to try to give the Hill an education in this issue. And so, they called upon us as someone who really doesn't have an axe to grind.

DR. VETTER: But it looks like it's much broader than security. The questions will be much broader than security.

MR. COLES: That's correct. I would say that security is probably the primary thrust, but we're going to be getting into a lot of different areas as well.

I think security will form the focus of our third objective. That is the measures that have been implemented since September 11th. But, the other areas are much broader than that.

CHAIRMAN CERQUEIRA: David?

DR. DIAMOND: Thank you very much for your presentation.

I did want to point out again that a lot of this will have very little bearing on security issues. But my question is this.

In the radiation oncology community and perhaps in the nuclear medicine community as well, we have a concern. And that concern is that with all of this new legislation being promulgated, an amount of regulation that is very difficult for these individuals or even for the societies to fully monitor, that there may be regulations established that may have an adverse impact on our ability to use nuclear materials for medical uses appropriately, and how can we go and monitor these reams and reams and reams of documents and comments and proposed legislation given our limited resources?

What advice do you have on this regard?

MR. COLES: An excellent question, and I think that's precisely the reason why we've been asked to sort of step into the fray.

Right now, there's so much information being thrown at the Congress that everyone is afraid that the Congress will act with new laws and NRC will be forced to act with new regulations that are not adequately informed by the true situation out there.

What we want to do is we want to provide at least a balanced perspective on this is where the threat is, these are the things we need to be concerned about, and these are the things we don't

need to be concerned about that will simply be additional burden upon the licensees, and try to convince our clients that a broad-brush approach is not going to work and that you need to be a lot more specific and a lot more focused in your efforts to address where the true threats are.

DR. DIAMOND: As a follow-up comment, we too as a committee need to be educated on these issues. And I was very disappointed that we did not have our planned security briefing today.

I would just like to direct these comments to Mr. Essig, saying that we need to be educated on these issues and I was disappointed, I am disappointed that that briefing did not occur.

CHAIRMAN CERQUEIRA: Those are good comments.

When your committee does this work, are they going to go back to look at sort of previous reviews like the Institute of Medicine report that was done in '95?

MR. COLES: We are in the midst of a literature search to see where previous reviews have been done, and we'll integrate those into our work as appropriate. There are a lot of reviews out there, and any suggestions that can be given to us as to

things we need to look at, please bring them forward because I have a feeling we will miss some things in the process.

CHAIRMAN CERQUEIRA: Well, I think that this committee and the members, who represent various factions of the regulated community, would be very happy and willing to supply input.

Now, I apologize. I didn't catch your name. Are you Ryan?

MR. COLES: My name is Ryan Coles, yes.

CHAIRMAN CERQUEIRA: So are you the person that should be contacted initially?

MR. COLES: I'm the lead GAO official on this review, subject to management approval.

(Laughter.)

MR. COLES: But I'm heading up this review, along with my two colleagues: Peter Ruedel and Heather Von Behren, who are sitting in the second row back there.

CHAIRMAN CERQUEIRA: Well, great. Again, I think the committee as a whole, as well as individual members, representing various professional medical societies would be very happy to help you with this effort.

Thank you very much.

MR. COLES: I appreciate it. Thank you very much.

MR. ESSIG: If we could resume with the agenda, there's just a minor modification. The briefing that we have scheduled on the updated status of the training and experience recommendations from the committee, we're still going to cover that, but maybe a little differently than we had earlier thought.

Tony Tse is in the audience. But as with so many things, timing is everything and the timing of this issue is that the recommendations that are currently with the EDO waiting for sign-up, ready to go to the Commission. So, there isn't much that we can discuss in the way of specifics other than I can say that the recommendations from the subcommittee occupy a prominent place in the paper that went forth.

We have suggested another option. Well, there are actually three options total in the paper. But for all intensive purposes, the principle options are yours and then a small variation that we made on your recommendation.

CHAIRMAN CERQUEIRA: So the designated federal office looked at our recommendations and proposed some modifications?

MR. ESSIG: It was primarily in one area, and that was where the accepted boards would be listed. Your recommendation had said that they would be listed in the regulations themselves, and we've proposed a variation on that.

CHAIRMAN CERQUEIRA: Jeff?

DR. WILLIAMSON: Could we get a copy of the final report?

MR. ESSIG: As soon as the Commission authorizes its release. That's what I meant when I said "timing is everything" because it's currently on its way to the Commission. And if the Commission -- when they authorize its release, it's --

CHAIRMAN CERQUEIRA: Well, I think it would've been good to send it back to the committee. I mean there was quite a bit of time and work on it. And certainly as an advisory committee, we spent the time and effort and --

DR. WILLIAMSON: Yes, and we all have security clearances and are quite capable.

DR. DIAMOND: Mr. Essig, once again I'm very disappointed by this lack of feedback and communication.

Under Dr. Vetter's leadership, several of us spent a lot of time this summer in a very, very

tight schedule devoting work to these issues. This is the time, this is the venue we're supposed to go and discuss it.

Why am I here?

(No response.)

DR. DIAMOND: I mean I'm just asking a very basic question: What is going on here?

CHAIRMAN CERQUEIRA: Well, I think we had a question.

MR. ESSIG: Well, you're here to provide advice. You provided your advice. We accepted it, and we made a recommendation to the Commission based on your advice.

DR. DIAMOND: But we don't have any feedback? We don't have any --

CHAIRMAN CERQUEIRA: Right. Again, we've gone through a whole process of Part 35 revision, which was an interactive sort of process with feedback and, you know, quite a bit of interactive with the staff level and with the support people for the Commissioners. So, this is sort of unprecedented in terms of the work that the committee has done in the past, to not have gotten feedback.

It does represent a break in the precedent. And I guess Dr. Diamond's question is: Is

there a reason for that?

MR. ESSIG: It's well taken. But I had checked with my management prior to coming here to see what I could say today, and basically that's pretty much it -- the fact that it will be soon with the Commission, either today or this week. And as soon as they authorize its release, then you'll see what --

DR. WILLIAMSON: Why couldn't we have discussed it in our closed session then?

MR. ESSIG: I'm sorry?

DR. WILLIAMSON: Why couldn't we have discussed the modifications made in the final report during our closed session? I mean why wasn't this -- I really share Dr. Diamond's outrage at the fact that the modifications made to our proposal were not shared with this committee, and we did not have the opportunity to provide any feedback.

CHAIRMAN CERQUEIRA: And the Chairman had specifically made the request to the staff to have this material discussed and made available, and it just wasn't done. So that's clearly -- you know, it's disappointing, and I think it does break a precedent that's been established.

MR. ESSIG: I apologize for that, and I don't know what I'm able to do about it at this

juncture.

CHAIRMAN CERQUEIRA: Ralph?

MR. LIETO: Two questions. You said you checked with management. Is that Dr. Kuo?

MR. ESSIG: Yes.

MR. LIETO: My other question is: When these changes were suggested, alternatives were being finalized and were going to be submitted to the Commission. Why could we not have shared that information?

In other words, why could not the changes that the staff was recommending have been sent to the committee? Is there some legal precedent why that could not have been done or some staff policy?

MR. ESSIG: Not that I'm aware of.

DR. WILLIAMSON: The other issue I think is we could use the time, we still can use the time effectively I think to discuss any remaining fallout from this proposal and determine if there are any weaknesses or concerns regarding our proposal subsequently.

CHAIRMAN CERQUEIRA: Right. Are you prepared to do that, to give us --

MR. ESSIG: The alternative that we had come up with that differs from the committee is where

the approved certifying bodies would be listed. You had suggested they be listed in the rule. We have suggested that it be on the website. That's the only difference.

CHAIRMAN CERQUEIRA: So that's relatively --

MR. ESSIG: That's what I'm saying. It's a minor difference.

DR. WILLIAMSON: Well, concerns have been raised by the community based I think on the proposal as it was presented at the public meeting. And you know, I think there was something in writing that was circulated to the public.

Certainly one area of concern is what types of board certification make one eligible to be a radiation safety officer. And concerns have been raised to me privately by one of the organizations regarding whether the boards in radiation oncology and medical physics can meet even our revised standard.

CHAIRMAN CERQUEIRA: All right. Other comments?

Dr. Nag?

DR. NAG: Yes. I think at the last meeting we had with the Commissioners, the ACMUI expressed our concerns that we are the advisory body.

We give our advice to the NRC, and we don't get adequate feedback back from the NRC staff to us. And, the Commissioners instructed the NRC staff to make sure that this concern is addressed.

I would like to reissue that in the public forum that the Commissioners have instructed the staff to provide feedback back to the ACMUI and that is not being done.

CHAIRMAN CERQUEIRA: All right. Well, I think it still would be very important to get feedback to certainly the subcommittee that was charged to make these revisions, as well as to the whole committee. Again, it was a fairly long and complicated and involved document.

It's still unclear in terms of the website designation verses in the text. There was a whole issue of the process of reviewing boards, which boards were approved. So, we still need to get some clarification on where that stands.

MR. ESSIG: Would it be possible to schedule a subsequent conference call? Would the committee be amenable to that?

CHAIRMAN CERQUEIRA: Would the committee?

(Chorus of yeses.)

MR. ESSIG: We're talking in the very near

future, as soon as physically possible to do it.

CHAIRMAN CERQUEIRA: Okay. Again, I think the preference of the committee would've been to certainly have discussed it during the closed session if you felt that there was some secret of nature to these things or things that weren't for public review. But, I think a conference call would be appropriate.

I guess with conference calls though, for the whole committee, you'd have to go through a process, which takes time and effort. And, I think it does have to be open.

MR. LIETO: One question about a conference call verses a closed session. A closed session, we could have the information in front of us to look at and then stays here with the Commission. A conference call, you're not going to be able to send us anything via email or any other means that we can have in front of us when we discuss this.

So, I'm kind of wondering what we're going to be able to discuss other than -- without having to see what's actually been presented.

CHAIRMAN CERQUEIRA: Jeff?

DR. WILLIAMSON: I don't think that's true. I think in a public meeting we can have classified materials before us as long as we don't

share our paper copies with the public. Certainly, we've had pre-decisional materials in our packet before at public meetings.

CHAIRMAN CERQUEIRA: Well, I think again -- and I'm still not clear whether this is sort of a lack of planning or just a lack of ability to share the material. It sounds like perhaps it was the initial because we have, as Jeff has said, we have had a lot of interactions in the past with Part 35 revisions, both before things went to the Commissioners and after they went to the Commissioners.

And so, this does sort of break a precedent with not being able to get feedback in review. I'd suggest that if a conference call is any way to do it, that we go forward with that. But it would be, I think, important for the committee to do its work to have that material ahead of time so we could review it rather than just hear it for the first time during the conference call.

MR. ESSIG: That would our intent, to get it to you ahead of time.

CHAIRMAN CERQUEIRA: Okay.

MR. BROWN: Dr. Cerqueira, could I speak from the side here? This is Fred Brown.

It's unfortunate Tom's covering this item because the paper has not been in the organization that Tom heads up, just for point of clarification in terms of shooting the messenger.

Your points were well taken and maybe if I could just recast what was said slightly differently. There were no changes made to the ACMUI's recommendation. And the staff that was involved with that paper very much appreciated the work that was done and has a lot of respect for it. And I think when you see the paper, you will see that that fundamental appreciate and respect for what you did is going straight to the Commission.

In the process of putting together an options paper, which is what the staff was directed to do by the Commission, we felt compelled process and regulatory process-wise to have not just the ACMUI's recommendation or a recommendation worked out with the ACMUI, but other options as well. That doesn't change what the preferred option is.

But, there was a process perspective that drove us to the point that we're at today, right, wrong, or indifferent. And I understand your feelings about that as a committee. As Tom indicated, we'll take those back and they're well noted and

understood. But hopefully when you see the outcome, you'll feel better about it.

CHAIRMAN CERQUEIRA: Well, I think we'd be reassured when we see. But I think you've kind of sensed our general unhappiness with the process. And it does break precedence that we've set in working with the designated federal official and the Commissioners.

To keep on schedule, just a few last closing brief comments. Ralph, Subir, and then Jeff.

MR. LIETO: Roger, I appreciate your comments in terms of reassurance. I guess the concern is that there are obviously options that went in, and it's not clear where the ACMUI recommendation was ranked in those list of options.

If you had five options and it's at the bottom, I think there would be a pretty high level of concern and I think we would've wanted to be prepared to comment at this meeting about that. But not having that information, we don't know whether to feel good or --

CHAIRMAN CERQUEIRA: Be reassured or just not know.

Subir?

DR. NAG: Yes, I think we would definitely

have wanted to know what the other options were. We would've liked to have known that.

CHAIRMAN CERQUEIRA: Last word from Jeff.

DR. WILLIAMSON: Yes. I would've liked to have had a more technical detailed discussion, where we go over it section by section with the staff members that have previously reviewed the credentials of the various boards to make sure that we've got it right this time.

I think we can't afford to get it wrong this time. To use a catch phrase, "The devil is in the details." If one word is wrong, it could potentially continue this dangerous situation where board certification is marginalized. So, I think we could've very productively used the time to go over it section by section to determine if we finally have it right.

And in fact, the major reason this subcommittee and the whole parent committee wanted the boards hardwired in the rule language, the intent was to force NRC staff to vet these proposed regulations against the boards as they currently exist to make sure there's not a problem.

So, that is major concern. I would've liked to have seen some of the time used to run

through the details one more time with the appropriate staff member who has the most knowledge about the operations of the boards.

CHAIRMAN CERQUEIRA: I guess as sort of the closing point on this is there some idea of the timeline for when you'll be able to share this information, when we could set up the conference call, and who on the staff will be setting it up?

MR. ESSIG: We can ask for a timely approval by the Commission to release it to the committee for its review. I don't have a good idea at this juncture as to how long that might take. But we might be talking on the order of maybe a couple of weeks or thereabouts, maybe a month, within the month.

CHAIRMAN CERQUEIRA: And will Angela be handling the details for the conference call?

MR. ESSIG: Yes. Yes. So we would set up a bridge and have folks call in to it.

CHAIRMAN CERQUEIRA: Okay. So that takes care of the presentation that we didn't get on the training and experience recommendations from the committee.

I guess the next item is the Agreement State compliance with Part 35. And Part 35, I guess Lloyd Bolling will be doing that. Mr. Bolling?

And I had requested this be on the agenda because with the current Part 35 and then the work of Dr. Vetter's committee, starting with the training and experience, there was still a lot of concern as to whether we would have a unified process or whether we would still continue to have a lot of fragmentation. We've had some concerns by people who run training programs and what they're going to tell their trainees or how they should instruct their trainees.

So Lloyd, you're going to tell us how it's going?

MR. BOLLING: Yes. Good morning, and thank you for inviting me.

CHAIRMAN CERQUEIRA: We've killed one messenger so we're --

MR. BOLLING: Ready for the next.

(Laughter.)

MR. BOLLING: What I'd like to do is just give you a brief overview of what the Agreement State Program is about and then I'll jump right into Part 35, the training and experience, and compatibility of regulations.

First, it was interesting when I got the invitation to come and speak, the title was "Agreement State Compliance with Part 35". That's an interesting

choice of words because generally we don't use the work compliance when we speak about states. "Compliance" is usually something that we use in the realm of licensees. But "agreement" is what we use with agreement states.

The Atomic Energy Act was amended to add Section 274. And that section of the Atomic Energy Act allows the NRC to relinquish, and at the same time the states pick up or assume regulatory authority over certain materials and certain activities. The materials are byproduct materials, source material, and special nuclear material in quantities insufficient to form a critical mass.

CHAIRMAN CERQUEIRA: These slides are in the agenda booklet. For those of you who want to follow them, you can.

MR. BOLLING: Next slide, please.

In order for a non-agreement state to transition to Agreement State status, there has to be an initial finding of adequacy and compatibility. And then once the state has signed, that is the Governor signs and the Chairman of the AEC/NRC signs, there is a continuing program to make sure that the agreement states maintain adequate and compatible programs. And I'll get into that a little bit further in one of my

other slides. That basically is the IMPEP program.

One way that we make sure that the agreement states are maintaining compatible programs is we review the proposed and final rules that are promulgated by the states by both the technical staff and the legal staff. So, that is for states that are entering the program.

Non-agreement states that would like to become an Agreement State, they submit their statutes and regulations to us, we review them, make sure their compatible, and then we hand them over to the legal staff. The legal staff passes judgment on them, and then the information is funneled back to the states on any issues that need to be resolved or fixed. And then when the final rules are adopted and in effect, a copy of those is sent to us and we review those as well.

Next slide, please. The compatibility determination process, it looks a little laborious but it isn't quite. The proposed rule or program element is reviewed according to this like a flowchart. And what we do is we take the rule or the program element and we ask ourselves whether or not the requirement is exclusive to NRC.

An example of that would be if there's an

import component or is this a reactor or a fuel fabrication plan, which the agreement states are specifically prohibited from regulating. If the answer to that question is "yes", then that rule or that program element is reserved to the NRC, and the Agreement State may not by law regulate that portion of the activity.

If the answer to that question is "no" it's not applicable, we jump down to the next criteria and we ask ourselves whether this is a basic radiation protection standard, an essential definition, a term, a sign, or a label. If the answer to that is "yes", then we assign a Category A to that rule or requirement. And, it must be essentially identical in the Agreement State regulations.

Now, "essential identical" does not mean verbatim. It means can the licensee read the Agreement State regulation and NRC regulation and come to the same conclusion as to what is required of them? And if it varies beyond some acceptable level, then we must insist that they change their rule to make it compatible.

If the regulation or element does not meet this standard, we jump down to the next one and we ourselves: Is there a direct transboundary

implication? I believe the term in our guidance on this is "direct and significant transboundary implication". If the answer is "yes", then it also must be essentially identical in the Agreement State regulation as it would be in the NRC.

There is basically no difference in the way the regulation must appear if it's an "A" or a "B". It's just that the reason is different.

If the answer to this is "no", we jump down to the next criteria. And in this one, we ask ourselves: Is there a conflict, gap, or a duplication of effort created if the state does not adopt this particular regulation? If it is, then they must adopt it and have a new term, essential objectives. The state must have the essential objective in their regulation. However, they may choose to be more restrictive.

If the answer to the next question is "no", we jump down to health and safety. If the regulation or program element has a health and safety component, then we insist that the agreement states have maintained the essential objectives in the regulation as the NRC rule has.

And if the answer to that is "no", that is if the new regulation or program element does not

contain any of the above criteria, then we assign it a Category D, and we do not insist that the agreement states adopt that particular regulation.

Yes?

DR. WILLIAMSON: What is the difference in implications of "H&S" verses "C"?

MR. BOLLING: The H&S is if the regulation does not have a compatibility component to it, but there is a health and safety requirement that we feel should be covered, then we'll assign that H&S. It will have to have the essential objective, although it does not have to be identical.

DR. WILLIAMSON: But they could be more restrictive?

MR. BOLLING: They could be more restrictive, yes. In that respect, the "C" and the "H&S" are similar.

Next slide, please. We come to the training and experience regulations.

When we were promulgating the regulations in Part 25 and we came across the T&E question, we realized that there were some disconnects. And that's the reason for the two-year transition period.

The T&E for authorized users is a compatibility Category B. And the reason for that is

that the Commission felt that we had to have some set of uniform standards throughout the country so that physicians trained in DC could go to Oregon and take their qualifications with them and be licensed just as they would in any other NRC territory. So across the United States, physicians would be able to be licensed in agreement states and NRC territory with the same criteria.

The Category B requirements have directed significant effects in multiple jurisdictions. That's what that means. Agreement states should adopt regulations essentially identical to NRC, and this applies to radiation safety officers, physicians, nuclear pharmacists, and medical physicists.

Next slide. The term "legally binding requirements" is something that you may not have heard before. When an Agreement State regulation is determined to be a matter of compatibility, the agreement states have three years generally to adopt a similar and compatible rule. Because of the way regulations are promulgated in agreement states, this may not be possible.

So, we have something called a legally binding requirement and that may take the form of an order or licensed conditions, which can be used as an

interim measure until agreement states have the opportunity to promulgate a rule.

These legally binding requirements by the way are generally applicable to entire categories of licensees. For instance, if a locking mechanism on a teletherapy machine was found to be defective, we could issue an issue, the Agreements States can issue an order which is legally binding on all licensees of that category until such time as the time is fixed or a rule is promulgated which will cover that problem.

Next slide, please. The IMPEP process is one of the ways we use to determine if the agreement states are maintaining the compatible and adequate programs that they said they would when they signed the agreement with the Commission.

In the area of non-common performance indicators, regulations and program elements are contained within that indictor. So, this indicator has three ratings that are applied to states and/or the NRC: -- the NRC actually does not get reviewed against this criteria -- satisfactory, satisfactory with recommendations for improvement, and unsatisfactory.

So when we do an IMPEP review of an Agreement State, we look at their regulations and we

determine how many regulations they have that meet the three-year requirement, how many have not met the requirement and by how long. And then if there are substantial numbers that have not met the three-year requirement, they fall into the unsatisfactory category.

Next slide. This slide is a timetable for the different Part 35 requirements.

As you know, in April the rule was published. Just last Thursday, it became effective and so did the two-year transition period begin for subpart J, and the three-year compatibility period began for the agreement states.

Two years from now on October 24, 2004, the subpart J two-year transition period ends. And a year later, the Part 35 compatibility period ends for agreement states. So, the agreement states have until October of 2005 to adopt a compatible rule and/or as an interim measure institute legally binding requirements.

Now, at the last ACMUI meeting, I guess it was in February, I indicated that I would poll the states to find out what progress they're making towards instituting their rule. Of course, at that time the rule had just been published and was not yet

effective.

But, all states responded to the survey. Eight states said that they would have a compatible rule by the end of 2003. In addition, two states said that they'd have a compatible rule by 2004. And the remaining 22 states said that they would have one by the end of the three-year compatibility period, October 24th of 2005.

CHAIRMAN CERQUEIRA: Now, was that for all elements or just the training? You asked specifically for the training and experience?

MR. BOLLING: No, no. This was for the entire rule, all right?

CHAIRMAN CERQUEIRA: Yes.

MR. BOLLING: That concludes my presentation. If you have any questions --

CHAIRMAN CERQUEIRA: That's really very good, Lloyd. I appreciate your coming here and sharing this with us.

I had hoped to get somebody from the OAS to come because I had heard that there was some rumbling that it may be difficult for training and experience to get full implementation, and there may still be. But because of funding issues, we weren't able to get anyone.

And Ruth, can you give us some insight?

MS. MCBURNEY: Yes. I think the main concern there was that most of the states don't want to do a two-step process. They don't want to do all the stuff except the training and experience. They're waiting to hear what's going to come out of any changes that may be made to the training and experience requirements before they adopt the whole rule, instead of taking what's "compatibility" now and putting that in place and then having to go back and change the training and experience requirements once this other rule is developed.

So, I think that's the delay on a lot of them. They don't want to have to do two rulemakings. They just want to do one.

CHAIRMAN CERQUEIRA: So they heard that Dr. Vetter's committee was working on something to fix some of the issues related to the medical physicists, the authorized medical physicists?

MS. MCBURNEY: Right, and the authorized users.

CHAIRMAN CERQUEIRA: And that's part of the reason why it was very important for us to get some idea from the designated federal official as to where that stood because we had hoped to get that

implemented so when the two-year extension of the old as well as the new standards were basically no longer effective, that this new rule would kick in. And that's why I think Dr. Vetter and his committee did such great rapid work.

Okay. So we're still uncertain is what the bottom line is.

Jeff?

DR. WILLIAMSON: What is the status of the suggested state regulations with regard to compatibility with Part 35, and what role does this play in the general acceptance of the Part 35 changes among the agreement states?

MR. BOLLING: Well, a number of NRC staff are advisors to the CRCPD Committee that is revising their equivalent to Part 35. It's my understanding that a peer review document has been forwarded to the Executive Board of the conference. And, they will review it along with comments from others advisors and then move it forward.

The second part of your question, how does that influence the agreement states in adopting a rule, in some states they copy the suggested state regulations almost verbatim. In other states, they prefer to use the NRC rule.

We've had some extensive discussions with the states over certain portions of the suggested state regulations. It appears as though, based on our review of the last document that we were presented with, that those questions and concerns have been resolved and the rule is essentially compatible.

CHAIRMAN CERQUEIRA: I guess I just have sort of a procedural question. Now, under 274 of the AEA, we've got the NRC published Federal Register Notice, and let's say Washington State because I lived there for 11 years. They don't always like to tow the party line.

Now, under the 274 AEA, if Washington State decides that in three year they're not going to change anything, they're going to go their own way and continue to use existing regulations or to have more restrictive requirements for position, does the law allow the NRC to impose compliance or "agreement" as you like within say Washington State?

MR. BOLLING: My boss is heading toward the microphone right now --

(Laughter.)

MR. BOLLING: -- to bail me out.

MR. LOHAUS: Thank you. Paul Lohaus.

Very good question, and it's a tough

question that we wrestle with particularly in the area of regulations. And the answer is it really is -- the answer is given through the IMPEP program and the IMPEP process. There are several different aspects.

One is there's a set of objective criteria that are identified in our management directive that provides a basis to address compatibility. And a part of that process includes a review of conclusions of that review team by a Management Review Board.

And the question that the board sometimes wrestles with is if you have a particular section of a regulation that may not meet the compatibility criteria, does that place the state in a not compatible regime? Generally, the answer is "no". It's different. It may not meet the criteria, but it's not of sufficient significance that it places that program in a not compatible status.

You could then carry that logic to an entire rule. And I'm not aware from my experience of a case where a state has not adopted a regulation. They may not in all cases have done that within the three-year timeframe. But I'm not aware of a state that has never adopted a regulation. There may be differences in that rule and the MRB is going to have to make some judgments on the significance of those

differences.

If you were to be faced with that situation, Dr. Cerqueira, the MRB would need to make a determination --

CHAIRMAN CERQUEIRA: I'm sorry. MRB stands for?

MR. LOHAUS: I'm sorry. It's a Management Review Board. It's part of the integrated materials, performance evaluation program.

And very quickly, what you have is a team that conducts the review against an objective set of criteria. Then, my boss heads up a Management Review Board. Karen Cyr, our General Counsel is on that board. I am, Mary Virgilio from NMSS, and we also have an Agreement State program manager that serves as a liaison to the board.

They hear the team's report, they listen to the program, and then they take a look at all the different aspects and they make the final determination relative to the adequacy and compatibility of the state's program.

CHAIRMAN CERQUEIRA: But has that ever been tested? I mean has the NRC ever taken action against any states?

MR. LOHAUS: We have found programs not

compatible on the basis of not having put in place in a timely matter, regulations. I'm not aware of any tests relative to a single rule that was not adopted.

From my experience, that rule may be adopted in a longer timeframe. But I'm not aware of any states saying, "We're not going to adopt that regulation." Now, there may be portions within that single rule. And so far, I think the test has been to look at the effect that that has on other programs.

In other words, when you're looking at the compatibility part, what's the effect of that state's action on NRC or other programs? And if it's significant enough, then the MRB would make a finding of not compatible and expect the state to make a change. If it's not, then --

CHAIRMAN CERQUEIRA: But whether they could do that -- again, just to sort of boil it down to the nuts and bolts. Representing the cardiologists who have not traditionally come in via boards in the past, there's some question how you're going to set up your training programs. And you hate to train people who may meet criteria in some states, but not others.

Some that may be resolved in some of these board issues, but it's still sort of a practical concern. Some of my constituents are still expressing

concerns and apprehension about it.

MR. LOHAUS: Yes.

DR. DIAMOND: Mr. Lohaus, if I recall correctly of Category B, compatibility category, it's not necessarily essentially identical. Isn't it of minimum standard that, again, the states have the purview to make the regulations more stringent above that?

MR. LOHAUS: No. For Category B, the state would have to have a rule that is essentially identical. There may be some subtle differences in the word, but the actions that are required and the actions taken by a licensee to comply with that rule have to be essentially identical.

CHAIRMAN CERQUEIRA: For Category C, they can be more restrictive according to what Lloyd said. But Category B means that because it does cross state boundaries --

MR. LOHAUS: Right.

CHAIRMAN CERQUEIRA: Dick?

DR. VETTER: Just to follow up on Dr. Cerqueira's question, and this perhaps more of an expression of frustration than it is a question, and it relates to compatible regulations verses compatible programs.

We live in a global economy, and more and more healthcare systems are operating in multiple states. And yet, we are seeing, as more and more states become agreement states, we're seeing significant differences among implementations of the programs.

Just to focus in on one, for example in Part 35, adoption into Part 35, I'm aware of one state that is incorporating into their new regulations all of the guidance relative to Part 35. They're incorporating guidance into regulatory space. That becomes very frustrating for licensees that operate in more than one state.

And I can give you other examples where there are significant differences, not in the regulations per se, but in how the program is implemented. So I guess my question is: What can you do about that? Perhaps there isn't much. It's more of a frustration I'm venting.

MR. LOHAUS: Yes. The guidance is not mandatory.

DR. VETTER: It is if they incorporate it into their regulatory space.

MR. LOHAUS: That's correct. And our recommendation would always be that guidance be what

it is, and guidance not be adopted into a set of regulations.

However, I am aware that in some states there may be statutory provisions that the completeness, if you will, of the set of requirements that a licensee would be subject to should be reflected in a statutory regulation, if you will, or other legally binding requirement. And it does create difficulties because it removes flexibility in terms of the guidance being one approach, one acceptable approach to meet the rules.

But, I think that's only in a few cases. Maybe Ruth, you may have some insights here too from your experience. But I think there are some states that do have some statutory requirements across the board for all states agencies that the guidance also needs to be reflected in their rules. And, it does create a more difficult situation. No question.

CHAIRMAN CERQUEIRA: Other questions for Paul or for Lloyd?

(No response.)

CHAIRMAN CERQUEIRA: If not, I'd like to thank you. Lloyd, you've done a great job on this and you've kind of been the one constant behind the program. Thank you very much.

We're ahead of schedule. That's great. Next item is discussion of the National Materials Program Working Group Report. And Paul, you're already seated there.

MR. LOHAUS: Okay. Let me first of all, thank you and express my appreciation for the opportunity to be here.

What I'd like to do is I have six slides that I put together. I'd like to use this to maybe pick from where we were at the last meeting. We talked about briefing you periodically to give you information in terms of where we are on the National Materials Program, and that's what I'm going to try and do today. And then, answer any questions that you have.

Can I have the first slide, please? I think you all have a copy in your handout as well.

I wanted to start out and really highlight that we have a National Materials Program today. It basically reflects the NRC and the collective Agreement State programs. This program has evolved and will continue to evolve. But today, we do have a National Materials Program. And basically what the program is is the collective NRC Agreement State programs.

I wanted to highlight four background or reference documents and we can talk through each one. The first is an earlier Commission paper, which we talked about at the last meeting. But that provided to the Commission, the working group report for the National Materials Program Working Group, which contained a series of recommendations for Commission consideration.

The recommendations ranged from NRC basically taking back responsibility for all licensees to assigning responsibility to each of the states, and a number of options in between.

And we talked about the alliance option, which was the working group's recommended option, which to me really reflects a continuation of the evolution of the program of where it is today. It's a program where they would be greater shared resources and greater shared activities with the states.

Move on to the next. The second paper, SECY-02-0074, provided for Commission consideration five pilot projects. The purpose and intent of the pilot projects is to provide a further base of information on how the states and NRC can work together focused on the alliance process, sharing resources, maybe looking to centers of expertise if

the states have a particular area of expertise, and that area of expertise be relied up to help address a rule or guidance area for the nation.

The next paper was an addendum to the pilot projects paper. What that paper did is provided a recommendation. And this in a sense to me was sort of a National Materials Program recommendation. It was a collective recommendation from the Conference of Radiation Control Program Directors, from the OAS Board, the Conference Board, and OAS Board, and the NRC staff.

The thought here was that in moving forward and proceeding, what we should do is use a blending of two of the options that were in the National Materials Program Report. One was the current program option, and the other the alliance option.

And really what's reflected here to me is really the blending in continued evolution of the program where we're looking to see whether working groups, a higher level of state participation in those working groups could help provide the support and infrastructure that's necessary for the Materials Program.

Let's go on to the next one, please. The

Commission considered those three papers, and in August issued guidance to the staff. As you're aware, this is done through what's called a staff requirements memo.

The Commission approved the recommended option of the blending of the current program and the alliance options as we proceeded forward with the pilots. They indicated clearly that future direction on the National Materials Program and any option would be dependent and be guided by the results of the pilot project effort.

They also explicitly identified that we should seek and request comment from a broad spectrum of stakeholders, including licensees and non-agreement states.

Let's move on to the next one, please. What I tried to show here is sort of termed as "Interrelationship of the National Materials Program." But if you look on the left-hand side, what's really reflected when you look at this is that each of our programs, whether it be an Agreement State program or an NRC program, has certain responsibilties that we need to carry out: the basic day-to-day licensing, the inspection, response to incidents, we've got to make we provide adequate staffing, training for that

staff, enforcement investigations.

But, they're really sort of separate activities that we each carry out to cover our areas of responsibility. And they're basically key to the number of licensees that we each have.

On the right-hand side is reflected what I could call "Shared Program Activities." And to me, this is sort of the key to the National Materials Program. Things like rule development, policy development, guidance development, program evaluation, and areas of that nature, there is a shared aspect to that.

And if you look at the box underneath, rather than having two separate boxes, there's one box, and you'll see a dotted line there. I think part of the thinking and part of the evolution of the program is that that dotted line needs to begin to move further to the left.

In other words, given the larger proportion of Agreement State licensees there is need for a greater sharing, if you will, of the regulatory infrastructure work with the agreement states. And that's what reflected here.

And I think today NRC still carries the LIONS' share of that. In the future, we may see the

states start doing more. It may stay as it is, but we may see the states doing more. And that's part of what is being tested as a part of the future work in the program.

DR. VETTER: Excuse me. What do you mean by "program evaluation"?

MR. LOHAUS: Our IMPEP program, what we do is we involve Agreement State representatives both on review teams and on the Management Review Board.

I want to make it very clear though that this is a responsibility that is solely NRC's. They may work with this and help conduct the review, but the final bottom-line determination is made by the Management Review Board. But, it's an NRC determination. It cannot be delegated, if you will, to the states.

Any questions on this? But I think -- what I've tried to do is sort of capture on one slide sort of the spirit of the program. And regardless of how the program infrastructure activities are shared, each of us are going to have to carry out the basic LIONS' responsibilities of the regulatory program: the licensing, inspection, etcetera.

Let's move on to the next slide.

CHAIRMAN CERQUEIRA: Now is some of this

related to budget? I mean just kind of shift it out of the federal budget since the NRC is supposed to generate enough revenues to pay for it. And so, you share it with the agreement states.

Are they going to buy into this?

MR. LOHAUS: This is -- you put your finger on one of the keys here that was sort of the genesis for thinking about this further. And that is, as the number of state licensees increase -- we're talking about 17,00 or so now, with NRC about 4,000 -- NRC was continuing to cover the LIONS' share of the regulatory infrastructure work, the research, the rule development, the guidance development.

And the costs for that were covered through licensee fees. The thought was we ought to look for a more equitable sharing, if you will, proportional to the number of licensees.

There are a number of other factors. There's off fee-based funding that was specifically requested to address international and Agreement State activities that NRC carries out to try and help reduce the fee pressure that's there.

But I think the concept is still there, that there may be some cost sharing. There may be some efficiencies that can be gained. But, there's

also a technical expertise issue. As NRC looses licensees, the states may have the majority of licensees in a particular category.

Well-logging may be a good example. And the expertise in that area may very well reside within a state or few states as opposed to with NRC. And, why shouldn't we use that expertise to address the national picture as opposed to NRC trying to do that.

So, there are a number of different factors in here that we're going to be dealing with and working as we go forward.

CHAIRMAN CERQUEIRA: Jeffrey? I think Jeff's got a question.

MR. LOHAUS: Yes. I'm sorry.

DR. WILLIAMSON: Maybe you're coming to it, but it seemed in some of the notes that we were sent prior to this meeting there was talk about amending the Atomic Energy Act to facilitate this program.

Are you going to comment on what the proposed statutory changes are that you have in mind?

MR. LOHAUS: I had not planned to directly, but if you go back and look at the working group report, there are two areas that they identified for possible consideration.

One was whether the Act should be amended to provide authority to states for licensing, inspecting the regulatory oversight of federal facilities. Regardless of how many agreement states we have today, NRC would still have a residual, if you will, cadre of federal licensees as well as import/export exempt distribution that we would have responsibility for.

I think the working group felt that's an area that could be explored. And if so, it would require a legislative change.

The other area was the fact that NRC has regulatory jurisdiction over byproduct sources and special nuclear materials. The states have a broader focus, including naturally occurring and accelerated-produced materials. And the question was whether NRC should also assert jurisdiction, request legislative change to assume responsibility over that suite of licensees so you have a more comprehensive program, if you will.

DR. WILLIAMSON: I don't see how that would improve your financial standing because what you'd be doing is taking on a larger burden of regulatory infrastructure, but still most of the licensees would be in the agreement states.

MR. LOHAUS: There are a lot of balances that are involved in these types of decisions. And as I said, these were two areas that were identified by the working group in their report. But, there are certainly considerations that would need to be addressed at some time in the future.

CHAIRMAN CERQUEIRA: Dr. Nag?

DR. NAG: Okay. What are the five pilot projects? I mean I think that's helpful to know so we can see where we will be going in the future.

MR. LOHAUS: Sure. The first pilot project is one that's directed at determining whether and how NRC can share with the agreement states the process of setting priorities for work that's done in the materials area.

And here, I think the states believe that with their larger share, with the expertise that they represent, they also should have a greater say in determining what are the priorities, which rulemaking actions are we going to be working on, which guidance areas should we be working on, where are the key technical issues. And that's the focus of the first pilot.

It's to examine whether there's ways within our existing processes to further engage states

and bring them into that process or whether we need to have some additional processes to share with the states the development of those priorities.

The second pilot is directed at an existing program in the states and really relies and utilizes expertise that the states have already demonstrated. And this is to use the Conference of Radiation Control Program Directors Working Group to see if the states can take on the job and administer a national radiography certification program.

There's already been a lot of work that that group's done. And the thought is that could be an area where NRC could shed some work and the states could pick up and carry that responsibility forward.

The third is to examine how and what processes we could use to further engage the states in reviewing events, incidents that occur for generic implications and sort of share and take on some of the responsibility today. Most of that work is done by NRC staff. We review all the events nationally that are in our nuclear materials events database.

The thought here is to examine whether the states can play a greater role here in identifying generic implications and the kind of regulatory action that may be taken or should be taken to address those.

The fourth was directed at seeing whether the states, or a state or a group of states, could take on and develop a set of guidance, the licensing, inspection procedures, etcetera, that would be necessary for a new use of material or a new modality that had not been previously reviewed or approved.

And the last pilot was one that was directed at utilizing an existing working group. In this case, it's the working group that's addressing changes to the Inspection Manual Chapter 2800.

In the basic Materials Inspection Program Manual, there's an existing working group. And the thought was we piggyback and have the benefit and experience of an existing working group to reflect into the pilot programs.

Those are the five pilots. We're in the process of getting charters completed, identifying representatives for the groups. We talked at the agreement states' meeting, I gave everybody similar talk at the agreement states' meeting and we have interest in identifying representatives, getting the groups established, and starting on with the next steps.

DR. NAG: The other question is if funding

for NRC was the major consideration, why National Materials Program was instituted? Did you examine the possibility of taxing the agreement states so that if they are -- you know, if NRC is still providing a lot of fundamental basic input, but not getting reimbursed for that, why not tax the state depending on the number of licensees they have to help fund partially the NRC?

Was that examined?

MR. LOHAUS: The working group certainly talked about that. I think their bottom line was that the level of effort that would be provided by the states in terms of their providing personnel, paying their salaries for participating, that that basically would offset, if you will, the costs. But, that's certainly an issue.

Again, I want to maybe emphasize that cost is not the only consideration. It's one consideration, but there's a lot of other consideration. It's really, you know, how are NRC and the agreements states going to continue to function and operate in the future as NRC's number of licensees continues to decrease.

And certainly, budgeting costs is one. Expertise is another, how we continue to operate.

There are a lot of different factors in there that we're working with. So I don't to just leave the impression solely that it was a cost factor, but that certainly was a major aspect in looking at the fee question.

DR. NAG: The other thing is fundamentally, I think the ACMUI would've been interested in knowing how historically NRC got involved in byproduct material, but not the NARM materials.

And if the risks are the same, if the radionuclides that are produced have the same activity and same half-life and so forth, the risks are going to be similar.

MR. LOHAUS: Yes.

DR. NAG: So why this dichotomy -- how did it come about? And that will help us answer why we are now regulating the two differently and why we should bring it back.

MR. LOHAUS: Very good question, and the states have argued the relative risk part of this for years.

The answer is historical. It really comes out of the genesis for the Atomic Energy Act and the focus of the federal programs at that time. They were

focused on the source materials, the special nuclear materials that were derived from the source materials, and the byproduct materials that were created incident to the use of the special nuclear materials.

The naturally occurring and accelerated-produced materials were not a hard consideration at that time. And it's been a continuing issue within the program that the states have brought up, that NRC does not have as comprehensive a program as the states have when they cover the full suite of materials.

But, it's really a historical reason and it's the genesis of the Atomic Energy Act program. It's where that comes from.

DR. NAG: Yes, but regulation -- we always see that we are trying to go for regulation that is risk-based. The risk is no different than when you're using the same criteria.

MR. LOHAUS: Yes. And again, it's a consideration, where when we do seek state comment, I think they look at this from a risk-based prospective given the totality of their programs. I think those aspects are reflected in their interactions.

CHAIRMAN CERQUEIRA: Neki, you had a question?

MS. HOBSON: Yes. I just wondered how did

you come about deciding that now is the right time to bring everything all under one tent? Have there been incidents for instance?

The states have been regulating these non-NRC materials. Have there been accidents or incidents that would warrant federal intervention? Why are we at this juncture today instead of yesterday or two years from now?

MR. LOHAUS: You mean in terms of asserting jurisdiction over a broader base of materials?

MS. HOBSON: Yes. Right.

MR. LOHAUS: That's a consideration. I don't think there's any hard decision that's been reached at this point in time. But, it is certainly a consideration that the Commission is interested in looking at.

At the same time, the National Materials Program identified this from the standpoint of reducing potential duplication, assigning responsibility in a single organization for materials that have similar risks. Why have --

MS. HOBSON: But you haven't had a rash of incidents that you say, "Oh my goodness. We've got to do something?"

MR. LOHAUS: No, we have not. No. Thank you. I should've focused on that initially.

But, that's correct. We have not. It's more from the totality and universality standpoint.

MS. MCBURNEY: Just to add to what Paul is saying, from the state perspective, part of it is due to looking at occupational exposure and public exposure from a total exposure standpoint rather than splitting off just the byproduct material.

A lot of times in the NRC states when they go in and inspect, they're only looking at that part of it even though they're looking at total occupational exposure; whereas in the states, they look at the total program, the Materials Program, or adding in the x-ray part of it as well.

And in a lot of cases, you're going to have a lot of combined features in medical applications and in industrial applications.

MS. HOBSON: Well, if the states -- and I agree with you. I think the states are really doing an excellent job out there. So if the states are already doing this, looking at the total picture --

MS. MCBURNEY: That's only in the agreement states.

MS. HOBSON: Well, but you have most of

the licensees --

CHAIRMAN CERQUEIRA: There are 32.

MS. HOBSON: -- and it's growing.

MS. MCBURNEY: But I think they were looking at it in the big picture that there needs to be some consistency throughout the regulatory framework on how we regulate all radioactive materials.

CHAIRMAN CERQUEIRA: Jeffrey?

DR. WILLIAMSON: Are you considering also widening the AEA domain to include electronically-produced x-rays that aren't derived from any radioactive materials such as diagnostic radiology, linear accelerators in diagnostic oncology?

MR. LOHAUS: No. The answer is "no".

And again, I want to emphasize that the aspects in terms of jurisdiction were areas that were identified by the working group and are areas of consideration. There's been no decisions reached to move forward along these lines other than to explore potential -- one case is to explore potential legislation dealing with naturally occurring -- excuse me, dealing with accelerator-produced materials where we've developed some proposed legislation.

But some of these other aspects, they're

considerations and there have not been hard decisions reached there.

DR. WILLIAMSON: But a hard decision has been reached to go forward with increasingly, scope to include NARM?

MS. MCBURNEY: Not NARM, ARM.

MR. LOHAUS: ARM. Accelerator-produced material. Yes, yes. The Commission did ask --

DR. WILLIAMSON: Okay. You excluded Radium-226.

MR. LOHAUS: The Commission did ask the Office of the General Counsel to examine some legislation, yes.

CHAIRMAN CERQUEIRA: Dr. Nag?

DR. NAG: Had the working group had any discussion about the role of ACMUI in the National Materials Program?

MR. LOHAUS: The working group requested stakeholder feedback. There was one meeting. But in terms of looking at advisory committees and other aspects, you can see in their consideration and reflection that the use of advisory committees such as ACMUI would continue as a part of the program.

In other words, you need to have the independence, the independent review, the peer review,

and the feedback into the process. That would continue to be a part of the process.

So, I don't think there's really change that was contemplated in that area. It would be a continuation of existing processes and utilization of existing committees and mechanisms. That's not to say that there may be additional mechanisms that might come out of this process in the future as well.

But, I think their thought was primarily focused on how NRC and the states would interact in the existing structures. A lot of that would continue to function such as ACMUI, or ACMW, other advisory committees.

DR. NAG: Would it require any expense, you know, any change in the structure of the ACMUI or would it remain exactly the same?

MR. LOHAUS: I really can't comment on that at this time. I think that's something that as the program goes forward you could look at that item and consider that as an item for consideration, certainly.

I wanted to maybe spend a few minutes and talk about this slide because this has some important aspects on it that really may sort of affect our ability to move forward.

The first item, "Evolving National Materials Program Environment", what I wanted to reflect here were maybe two things. One is the response to 9-11, the response to terrorist activities. There are activities underway here within both NRC and the states, and looking at what kinds of additional security measures do we need to put in place.

That process and those activities need to be taken into consideration, and may very well help shape or affect any National Materials Program structure in the future. So, it's an area of consideration that I sort of wanted to lay out.

Another area that today is really critical, if you looked at the initial work and if you looked at where the states were from a budgetary standpoint at the time the working group engaged, they all had very strong fiscal bases.

And if you look today -- and I have to recognize Texas. Texas did a recent survey. They got very good responses from 23 states I believe. And all those states, with the exception of five, indicated severe fiscal conditions, severe budgetary constraints that they're each dealing with.

That obviously will also have a big impact

relative to the program in moving forward. Because without that base, it's going to limit the ability of states to engage in the process. And that's an uncertainty, so I wanted to sort of highlight those two aspects in terms of an evolving aspect that will have an effect here.

The other is, I've labeled this "Success Measures". If you look at the first pilot project paper, there is about eight or nine success measures that we've identified that would be used to judge and help assess the pilot projects.

I've highlighted a couple of these here, and one is, and we've talked about this, is the ability of NRC to share with the states the establishment of priorities. The second, and we've talked about this also, is the ability of states to assume and carry out greater responsibility for the development of products needed in a National Materials Program, the ability of the states to commitment resources to program.

And the final item is looking to the future. What will the respective roles of the Conference, the OAS, the Organization of Agreement States, and the NRC be in the program? And you can look at a number of different options.

I think there's always going to be a very strong NRC component. But at the same time, the states have demonstrated, are continuing to demonstrate greater ownership, taking on a greater responsibility. And we're going to see that as well in the program.

As I mentioned, the budgetary, the fiscal issue may have some effects here. But as an example, if you look at the agreement states' meeting, today that meeting is truly a meeting of the agreement states. It's planned by the Organization of Agreement States. It's their meeting. NRC is really an invited member to that. They've basically taken on the ownership and responsibility for that meeting.

So, that's one example. It may not appear to be a big example, but in the past the agreement states' meeting was basically set up and run by NRC. And today, it's basically set up and run by the states.

There's very close coordination and integration in terms of the items we cover and the participation in the meeting. There's a high level of senior management participation in the meetings, etcetera. But, it's a change that's occurred that's reflected in the National Materials Program structure.

I'm going to stop at this point, and open this up for discussion. I don't know Ruth, if there's any comments or observations, additional thoughts that you might like to offer as well. Please, I welcome the opportunity.

(No response.)

MR. LOHAUS: Any feedback as well. I'd very much appreciate that. And, I appreciate the comments earlier. They were all very good comments and very good questions.

CHAIRMAN CERQUEIRA: Neki had a question or comment.

MS. HOBSON: Yes. I just kind of -- it's kind of hard for me to grasp how this alliance thing would work.

Would NRC like be the first among equals, or would NRC be the Chairman and the boss of the group, or would it be a pure democracy? Who's going to call the shots on what are the problems we need to solve, where are we going to find the solutions, when is the solution adequate, that kind of thing?

Who's calling the shots?

MR. LOHAUS: Let me answer this in several ways. One, in terms of program performance and

program evaluation, NRC will always have the lead and will always have prime responsibility there. It's a legislative responsibility we have in terms of the oversight and cannot be delegated. So, we will continue to have a strong role there in that program.

In terms of determining priorities, as I mentioned, the states would like to share and participate to a greater extent in that process. And that's one of the pilot areas that we're going to explore.

But as a part of that process, my sense is that the Commission and what we lay out as a part of our strategic plan and of our operating plans and as our budget to support that is really going to reflect the priorities from NRC's standpoint.

At the same time, as I mentioned, if there's states that may have a particular area of expertise, and we identify that there's need for work in a particular area -- and I'll use well-logging because Texas probably has the majority of the well-loggers and has a high degree of expertise there.

And if we need additional guidance in that area, what we may do is we may not identify that as an item that NRC would address, but we may look to Texas. And Texas would pick this up, and either individually

or working with states, identify that.

We're not at that point yet, but that's part of what you can see in the National Materials Program. We still have a ways to go or maybe even a long ways to go on certain parts of this, but this is part of the thinking and part of the evolution that you can see in the program as you look forward.

CHAIRMAN CERQUEIRA: Leon?

MR. MALMUD: Are you requesting our opinion or are we just being informed of the process that's ongoing? I mean that in a constructive way.

MR. LOHAUS: In the spirit of staff requirements memo, we are seeking stakeholder comments. Personally, I would very much appreciate the views of the committee in terms of not only the pilots -- I mean we're just beginning to get the charters formulated -- but in terms of issues or areas that should be considered or things that you see that should be reflected.

I think that individually and collectively as an organization, we'd certainly welcome your feedback.

MR. MALMUD: As a nuclear physician in my training and as a realist in terms of believing part of what I read in the newspaper, number one, the

states are going to be under increasing budgetary constraints as is the federal government.

I'm from a state that's in the Rust Belt, with an aging population and an emigration of its college graduates. It's a state which can ill afford I believe to take on an addition economic burden.

As a provider of services, it means another level of oversight, or a greater intensity on the part of the state in the oversight. And I can't imagine the federal oversight disappearing. It shouldn't disappear.

We're talking about radioactive material. It moves from state to state. It's kind of like shifting the FDA responsibilities for food and drugs into the states. It would make a quagmire of 50 different regulations based upon each state's own myopic view of the world. There are some areas in which the federal government can function much more efficiently. And this, in my opinion, is one of them.

In practicing in the city of Philadelphia, we have city inspections, state inspections, federal inspections. They all contribute to an atmosphere of oversight and concern to the patient, as the primary recipient of their oversight. However, I'm not sure that we need three. The expense of three, though

divided among the three has to exceed the expense of one well run program at the federal level.

So while I am not generally a proponent of central control of everything, I think that with radioactive material given its nature and the fact that it moves across state borders and that we now have a national security issue arising of a magnitude that we didn't have before, I would suspect and I would hope that the states would not have more responsibility in managing this, but that it would rest as it has in the past with the federal government, which is going to make the rules anyway.

That's a personal opinion I have.

CHAIRMAN CERQUEIRA: I think Ralph was going to make a comment, and David.

MR. LIETO: I was going to kind of hold off here a little bit. But, a couple weeks ago I was asked to collect comments from the committee and the intent was to try to create a consensus response to this. But I think because of the timeframe and so forth, that wasn't really too practical to achieve what I think is a full consensus of the committee.

So maybe what I can just do is summarize some of the things that were feed back to me in terms of the documents that were distributed to the

committee previously, which I think probably was your SECY-01-0112, which was the Materials Working Group Report on the National Materials Program.

As I understand it, that this report was basically, was a directive that came out in 1999 I think thereabouts and the report was completed last year. Is that correct?

(No response.)

MR. LIETO: The bottom line was that the National Materials Program, with the stated goals and mission statement and the objectives that were presented in the working group report, has merit and a benefit to medical users.

I think there was support for the four components that were proposed in the working group report. I think you call those options or whatever. But just for the committee's review, these four options were: establish centers of expertise, seek authority to regulate NARM, maintain an information infrastructure, and fourth to create a standing Compatibility Committee.

There was support for that, but there was also a concern that was shared with the agreement states about NRC regulating NARM. And I think the concern from the medical users' perspective involved

the potential for increased regulatory burden, which I think Dr. Malmud expressed just a few moments ago, in an area that the NRC has not been previously involved with.

I think this intrusion is really focused at the use of PET, which is area of greatest potential and growth in nuclear medicine. I think that's where the main comments lie.

There were four major concerns I think that were expressed. One had to do with the regulation of NARM and the increased burden and costs to agreement states, especially those that might not have any significant improvement in safety. This adverse effect would be of greatest concern in the use of positron emitters and diagnostic nuclear medicine.

A second concern that was expressed was that states with strong programs of health and safety might be tied or forced to seek a lower level to create a common denominator throughout the country. I think you've addressed a little bit of that already in your comments and provided some reassurance there that states would still in many areas be allowed to continue their unique functions.

Another concern has to do with the funding of this program from the NRC's perspective. This was

not addressed in the working group report. It was in the information that was supplied.

The funding of NRC activities, especially in the non-reactor area, cannot continue to be funded by the current mechanism of fees supporting NRC activity. I think that if you're going to seek regulatory authority to change areas that need to be addressed by the Atomic Energy Act, I think that the current funding mechanism needs to be changed also.

It's unclear how there would be any cost savings to programs that would have to expand based on a fee-supported program. What we're talking about are those programs, which really don't have much regulatory now in the area of NARM, having to assume those responsibilities.

And then one of the areas of concern was that one of the assumptions for the success of the alliance options was "states develop and maintain a level of technical and regulatory expertise equal to or greater than the NRC."

I think there's some concern that this may not be realized in a third of the states that are non-agreement states, mainly because they do not or cannot achieve this level of expertise. What incentive would there be for them to change to achieve this assumption

for success?

So, those are the comments that I had gotten from the committee as a whole.

MR. LOHAUS: Thank you very much. I very much appreciate those.

CHAIRMAN CERQUEIRA: Would it be helpful -- I mean you got these verbally --

MR. LIETO: I'd be glad to write them out.

MR. LOHAUS: Please. I'd very much appreciate that. Thank you.

Yes?

CHAIRMAN CERQUEIRA: A few other people wanted to make comments then we have one outside person who requested an opportunity.

Ruth?

MS. MCBURNEY: To expand on what Paul said about the changing in the resources on the federal level and the state level, it makes it even more important for us to combine those resources and work together.

For example, on a lot of cases where some of the newer technologies and the sources that are to be evaluated for particularly new technologies, they're probably going to happen in one of the larger agreement states first before NRC sees them.

So rather than having each state have to reinvent the wheel and the NRC have to come up with licensing guidance or review guidance for that source and so forth, right off the bat if we can establish a working group to review that that includes both federal and state people, that will combine the resources a lot better in our shrinking economies.

MR. LOHAUS: Yes?

DR. DIAMOND: Just out of curiosity, have any of these smaller agreement states expressed any interest in relinquishing that status and going back to NRC status?

MR. LOHAUS: In those cases and in this case, it does happen to be at least one small program and then a second that I would characterize as an intermediate-sized program, where they have experienced performance difficulties, principally due to staffing, retention of staff. Those programs were placed on what we call heightened oversight. It's a program where we request a program improvement plan.

The issue of consideration of should we continue the program is certainly a consideration that both of those states have looked at in one way or another. But to date, we're not aware of any formal request, if you will, to NRC to consider taking back

a program.

I think in the cases where it's been examined, the thought is that the program can provide good or better service at lower costs and be more responsive, if you will, to local needs. And that the considerations --

DR. DIAMOND: So there's still a thinking out there that the states can manage these programs in a more cost effective matter as opposed to paying the licensing fees?

MR. LOHAUS: That's correct. And also what these programs have done is to look at seeking legislative relief to increase these.

A couple of examples. One program for example that was on heightened oversight about four years ago took a concerted effort to work with the community and their legislature, and they recently received legislative approval for an increase in their fees.

And another part of this, which other programs have found to be very effective, is the fees are earmarked for that program. So, they go directly into the program. And it has really improved the performance of that program significantly.

So I think the thinking is we need to deal

with it at the state level. We need to seek the kind of relief, whether it be an increase in fees or adequate funding to support the programs. That, to me, has been the bottom line that I've seen as opposed to "Here NRC, you take it back."

CHAIRMAN CERQUEIRA: Okay, Bill Uffelman from the SNM would like to make a comment.

MR. UFFELMAN: I had a question for Lloyd. You enumerated four documents. One of them was the August SRM, and I've checked with my other colleagues from some of the other effected organizations, which obviously are stakeholders in this, and I don't believe any of us have seen that SRM. It has no signed number, so we're kind of shooting in the dark when we go on these website searches.

And Dr. Diamond had commented earlier about how the effected parties find out they are effected. We certainly would like to, if it's available, we would like to be able to look at it.

MR. LOHAUS: It is available. And I may stand to be corrected, but I'm pretty certain we shared this with the agreement states with an all agreement states' letter, which should be on the STP website. But we can double-check that and certainly make sure that you have a copy.

MR. UFFELMAN: The Society of Nuclear Medicine, ACR, ASTRO, et al would certainly like to have a look at it.

MR. LOHAUS: We'll certainly follow up on that.

MR. UFFELMAN: Thank you.

CHAIRMAN CERQUEIRA: Any other questions?

DR. NAG: I have one.

CHAIRMAN CERQUEIRA: Yes.

DR. NAG: Now that the National Security is interested in nuclear terrorism and so forth, and they have a huge budget, is that a source of funding that the National Materials Program can tap into?

MR. LOHAUS: I guess I'll answer it two ways. One is I'm not aware of anything explicit at this time. But I think in terms, if there were to be particular activities that might address increased security, that could be a possible source.

But I would say at this point, the answer is "no". There's been no consideration of that and I don't see anything in the future coming from that particular budget area.

CHAIRMAN CERQUEIRA: Great. Well, Paul, we've got five minutes to go, but Fred and Tom would like to address a couple of the problems that we've

identified this morning before the lunch break. So thank you very much, Paul, for an excellent presentation.

MR. LOHAUS: Thank you very much.

MR. ESSIG: We've been reflecting on some comments that were made earlier this morning, where the committee had in mind certain expectations and our presentations on a couple of issues didn't deliver.

We're mindful of that, and what we want to do is to explore -- right now I'd like to maybe just plant the seed and then we could pick up on it later this afternoon -- explore the ways in which we could interact, maybe myself as the designated federal official, interact more effectively with the committee prior to the committee meeting so that we understand what the expectations are on a given items that's going to be on the agenda.

CHAIRMAN CERQUEIRA: Right.

MR. ESSIG: And so that we have the right person presenting the right material. And so, at this time, I'll just offer that to the committee for consideration.

If we want to engage in the form of a conference call, say a month ahead of the time or some other appropriate interval ahead of the scheduled

meeting date, and then have, if not the entire committee, at least a suitable representative sample of the committee relay to us what the expectations are on the particular agenda items so that we can --

CHAIRMAN CERQUEIRA: I think that would be important. I can tell you in the past the staff, several months ahead of the meeting, actually initiated preliminary agenda to be discussed. It would be presented to me and then we would get it out to the committee, seeking other people's input and to try to get a little bit more clearly defined expectation of the materials to be presented.

I think in part, since we were working so intensively on Part 35 revision, it was kind of a recurring agenda to some extent. Now we've kind of gotten past that, and there are some of these other issues that we've brought up. And, things happen at the last minute like the presentation with the GAO this morning. I didn't know about it until it happened now.

So, we've had sort of a shifting and the designated federal official and -- but I would think certainly starting well in advance of the meeting would be helpful. But other committee members --

DR. NAG: I think that's only addressing

part of the problem. I think the second part of the problem would be the feedback back to us. And I think what's going to be important there is anytime any action material is discussed, it's impossible to read through the entire minutes of the proceedings. But anytime you have any action items those should be given back to us. You know, this is what this was, and this is what was investigated.

We never know what's going on until six months later, and we may or may not go back. So within a certain period, within two weeks or within four weeks of the meeting, the officer should say this was the action item and this was the action statement. So, I think that would be really helpful to close the loop.

CHAIRMAN CERQUEIRA: But see, again, sometimes we have a lot of discussion that's never quite clear to you or to us what is wanted or needed. And what we've tried to do over the last several meetings is actually formulate specific motions that we vote on, and those are action items that we need follow up.

Ideally, we'd like to get the follow up as soon as possible. And once the information is available through the Internet, to be sent out to the

committee. But certainly, if not in that timeframe, at least at the next meeting we should get follow up on those items that were flagged requiring action. So, again, that's something we need to re-institute.

Jeff?

DR. WILLIAMSON: Well, I'm going to bring up one issue here that's a little bit delicate and sensitive to bring up in public.

But, I think it would be useful if you looked over some of the transcripts from the past, say two or three years ago when Barry Siegel and Judith Stitt were Chairmen of this committee. And I think you will see that there's a lot more interactivity, give and take, between the designated federal official and others that he or she designates in the group.

And what it seems to me to have happened over the last couple of years is we essentially conduct our discussion and our efforts to come to a consensus in a vacuum. And sometimes it's like pulling teeth to get a perspective from the Commission staff.

So I think we as a group would appreciate somebody that interacts more intensely with us because it helps us to gain a perspective of the limitation that the agency has by virtue of its charter and

various other commitments to Congress and so on. And we don't necessarily know that.

It's been very helpful to have these very detailed technical dialogues over these issues. And I think the best way you can get a perspective on this is to go back and look at some of the transcripts with an eye towards this kind of interaction back during the time Cathy Haney and Larry Camper were the designated federal officials.

One of my complaints has been that too often we seem to be in too much of a vacuum. And I think it's a very important role that you are taking on.

CHAIRMAN CERQUEIRA: Sally?

MS. SCHWARZ: I think one specific point this particular meeting, as far as the overall input of the training and experience in terms of the work that Dr. Vetter's committee did in writing these regulations and presenting them with no feedback to essentially see any revision of those requirements -- because had we seen the revision, we might have had discussion.

So I think that if can just see, specifically, the return from the staff.

CHAIRMAN CERQUEIRA: And again, there was

no mechanism in place to even bring that up. I mean, when we put together the agenda, I was the one that requested some of that and it was just hard to get the information out. And, even until now, I didn't really fully know the status.

I think, Ralph, you had your hand up, and then David.

MR. LIETO: Did we want to go ahead? Were we going to be taking this up again in the afternoon about this specific issue, or do you just want to go ahead and carry on right from here?

CHAIRMAN CERQUEIRA: In terms of the --

MR. LIETO: Feedback mechanism.

CHAIRMAN CERQUEIRA: Well, it's noon. We will bring it back --

MR. LIETO: Okay.

CHAIRMAN CERQUEIRA: -- for discussion in the afternoon. I think Angela has some time built in at the end. I mean, if the Committee wants to delay lunch, I'm willing to do that, but I think we probably need the break. Is that reasonable?

Why don't we break for lunch and come back at 1:00 o'clock and then we will resume this dialogue in the afternoon session. Thank you.

(Whereupon, the above-entitled matter was

concluded at 12:05 p.m.)

CHAIRMAN CERQUEIRA: All right, so now, we're back from our lunch break and I'd sort of like to, you know, just I think it's sort of understood but we should clearly state that we're not trying to point the finger at anybody, you know. I'm kind of sitting there thinking maybe it's my fault as chairman that we're not getting things done, but rather, I mean, all of us are spending time and effort in the process and for various reasons we're all committed to it and I think it's in everybody's interest to make it as efficient and effective as possible and so that's really our objective for going at some of these various issues.

And we'll come back and discuss some of these things we were talking about just before lunch. And Mr. Essig has put at your desks that actual material that was sent to the Commissioners and it says, you know pre-decisional, not for public disclosure at the bottom, but committee members now have it and we can -- you know, we won't talk directly about this, I guess, unless people have had a chance to look at it.

All right, so the next item on the agenda then is the Health and Human Services data base and I

guess Linda, is she going to present it?

MR. BROWN: Well, we've managed to run Linda into the ground in sending her around the country for the stakeholder meetings so she called in sick today. So, I'm afraid you're stuck with me for most of the rest of the afternoon. I'll try to muck my way through it in my best normal process here.

What we wanted to do today was basically inform you of something that we've been working on for several months now and that it's hopefully nearing completion and that is NRC reporting to the Health and Human Services data base called the Health Integrity and Protection Data Bank and I'll basically go through what that is, what we have to report, and the status of agreement state reporting as well, walking you through these slides.

The next one. What is it? Basically it came about as a result of the Health Insurance Affordability and Accountability Act which is documented up there and I assume that probably many of you are more familiar with this than I am or we are actually, because it effects other activities or effects you in other ways beyond just NRC regulated activities. But the bottom line with this Act, I believe, was that it was important that if a medical

provider or a health care provider or someone involved with health care was found guilty, to use a general term, of a major infraction in one jurisdiction, one state, one locality, that that information would be available to both employers and other health care professionals in other jurisdictions. And so this data base, I believe, is intended to be the way to make that information available to other people where an individual might work.

The data base is confidential in terms of access to the general public. It is not available to the general public but it is available to professionals and institutions that would be interested in the information. Anyone who has a report filed into the data base receives notification of that report and a copy of the information so that they have an opportunity to challenge the accuracy and work out with whoever the reporting body was a hopefully resolution of those concerns. And then as I've indicated, the people with access to the data base are specified there.

How is the NRC involved? The regulations pertaining to this Act are, as I said, Health and Human Services regulations and they're in Title 45 of the Code, Part 61 and those regulations are applicable

to the NRC and agreement states. So we are required by the statute and the implementing regulations to provide reports to the data base. There is also reporting required from health plans as indicated on the slide.

Okay, what will the NRC report? Fundamentally, we report final actions that are publicly available to the extent that they relate to medical practice and health care and it's limited to those actions that are adjudicatable. So if the agency -- if an agency could take an action against an individual and the individual would have no recourse to challenge the validity of it, then that action is not reportable to the data base. Only things that can be challenged are reportable to the data base.

So for NRC purposes the adjudicatable actions that the NRC would take are revocation or suspension of a license, actions to limit the scope of practice and actually the biggest one which didn't make it onto the slide would be escalated enforcement actions. So those are the things that the NRC will be required to report.

The next slide goes over who this rule would be applicable to and it's basically anyone involved in the health care field in a way that

impacts patient safety. So I guess as an example of an exception at a broad scope licensee, a broad scope medical licensee, someone doing surveys in the waste decon area, waste disposal area would not be reportable or a violation associated with that, because that's not health care.

I'm going through this pretty quickly and I'll --

DR. VETTER: Can you give us an example here?

MR. BROWN: Sure. A physician who would be required by the regulations to have a dose or dosage calibrated prior to administration of that dose who failed to do so, if that violation met the criteria for escalated enforcement and the agency took escalated enforcement action against the individual AU or the licensee, that would be reportable to the data base.

DR. VETTER: But a medical event itself wouldn't be?

MR. BROWN: No, only violations.

DR. VETTER: I'm sorry. Okay, well, a medical event ends up being a violation. The inspectors always turn it into one. So if it's a violation, even though it's not escalated enforcement,

it would --

MR. BROWN: No, only escalated enforcement.

DR. WILLIAMSON: I must say, we've had medical events from this Administration reported at Washington University that did not result in violations.

MR. BROWN: Thank you. I didn't think it's worth me arguing the point.

DR. WILLIAMSON: Could you define escalated enforcement and identify that class of violations more exactly that would appear in here?

MR. BROWN: Certainly, yeah, it's severity level 1, 2 and 3 violations are escalated under the enforcement policy. Severity level 4 violations are not. Minor violations and NCVs are not escalated.

DR. WILLIAMSON: NCVs?

MR. BROWN: Non-cited violations.

DR. NAG: Right now, any medical events anyway by NRC?

MR. BROWN: Not into this data base, no.

DR. NAG: No, but I mean, so it's public knowledge.

MR. BROWN: It's publicly available information but it is not centrally maintained or

readily searchable by for instance, an institution looking at a hiring a physician or obtaining service from a radio-pharmacy or someone else.

DR. DIAMOND: Fred, I have a number of questions. Firstly, the health integrity and production data bank, that was established under the statute of 1996 that you enumerated, when did this data bank become active or how long has it been active?

MR. BROWN: The implementing regulation, I believe, is about two years old. I'm not sure how long the data base itself has actually been active, per se. I would -- I'll give you a guesstimate of 12 to 18 months.

DR. DIAMOND: Twelve to 18 months. As I'm thinking through this, I have absolutely no idea whatsoever what the value of this is. As was already just said, this Administration and so forth are publicly available on website and other resources. I just have absolutely what was being considered by our legislators when something like this was passed, what value it has to whom, for what purpose. Does anyone share this sense at all of mine? I'm just -- not that you can do anything about it, of course.

DR. BRINKER: My understanding was that it

was primarily used for situations in which practitioners, et cetera, who cross state lines would not be able to hide problems that existed in another state and that was the up front thing. I don't know how the NRC part got into it but I think it was -- I think it started initially as malpractice -- well, for the government, more likely fraud and they got rolled into one.

MR. UFFELMAN: By way of example, Bill Uffelman, Society of Nuclear Medicine, by way of example, I believe the incident about a year and a half, two years ago the nuc med tech, I think up in the Minnesota walked somebody -- a new tech over the phone. They were on call but they didn't bother going in so they walked somebody else through milking the technetium generator and all of that went well, but then they lied about it to you when they were confronted with it and they were banned, I think, for three years or five years, I forget now which, from working in any nuclear -- you know, anything regulated by the NRC, so I would presume that that incident would have made it to the list.

The recent situation, that I presume, hasn't been resolved in Michigan with the I-131 patient who apparently died, not as a result of I-131,

but then the family was exposed to the extent that if the authorized user and the health physicist involved become the subject of action, then I would presume that incident would be reported. Is that correct?

MR. BROWN: The first example, certainly, we did take escalated enforcement in that action would be reportable. The second event is still working its way through the process.

MR. UFFELMAN: That's what I said.

MR. BROWN: I can't really comment on that but yeah, I mean, I'm sure that's the flavor of Congress' intent and just to follow up, Health and Human Services was the agency responsible for writing, implementing legislation. And when they did it, they made it applicable to all federal agencies which enveloped us, not necessarily because that was, you know, clearly called out in the legislative language anywhere that it was intended to apply to our licensees, but that's where we end up.

DR. NAG: Now that (undiscernible) in my authorized user's name, it would come under my supervision, so that would come under my name and it would be by the name of the authorized user or by institution, who would the final report come?

MR. BROWN: That's a very good question

and I believe the answer is that it's our licensee that we take action against and the reporting will be by the individual against whom action is taken. So in most cases, it would be a licensee that was reported rather than an individual. Now, the exception to that, as Mr. Uffelman identified, there are exceptions where we take enforcement actions against individuals, typically for willful violations but also, I mean, it doesn't have to be willful in that context. It could be careless disregard or gross negligence on the part of an individual. In that case it would be the individual but that's a very rare occurrence that we take action against individuals.

DR. WILLIAMSON: And this Administration wouldn't necessarily appear unless it's tied to, as we said, a severity level 1, 2, or 3 violation which --

MR. BROWN: Correct.

DR. WILLIAMSON: -- I don't know if the majority -- probably the majority of medical events in the Administration is life and death but certainly not all.

MR. BROWN: And the other thing is we're in a new age today, so now there are medical events and I think that we'll see fewer -- I suspect that we'll see fewer enforcement actions out of medical

events than in the past because of the change in the underlying reg so the QMP.

CHAIRMAN CERQUEIRA: Can you give me a feel for the number, say under the old rules over the last year, how many reportable events to this data base would have been documented? Are we talking about 100 or are we talking about 1,000?

MR. BROWN: Well, let me preface my answer by saying that I was most deeply involved with this about six to nine months ago and since then I've been focused on the new Part 35 and Linda is out sick, so I picked up this presentation this morning.

CHAIRMAN CERQUEIRA: Sure.

MR. BROWN: So in that context, I think the answer is in the medical area we're probably at the largest bounds talking in terms of if the agreement states used NRC enforcement criteria, it would probably be 40 cases nationally, that range, but because the agreement states aren't even required to have enforcement programs, I wouldn't -- you know, two-thirds of those may not have involved actions against the facility. In NRC space, maybe a dozen, and that, I think is at the outside.

CHAIRMAN CERQUEIRA: I don't have a good feel, you know, when you tell me severity level 1, 2

or 3 with exhalation. You know, I would not want somebody who gives an extra five milli-curies of technetium to a patient to have their names appear on this, but at the same time, you know, if someone is, you know, totally negligent in verifying pregnancy or other things in administering a dose, that would be appropriate.

MR. BROWN: Yeah, and unfortunately, I didn't bring in the enforcement guidance and your point is well-taken and in enforcement space we do try to be more risk informed with what a violation is. And so in terms of occupational exposure, it would take an over-exposure to reach the level of escalated enforcement and obviously, that's not directly transferrable into the practice of medicine, but procedural issues and minor issues should not reach the level of escalated enforcement unless there is extenuating circumstances, willfulness or --

CHAIRMAN CERQUEIRA: Are you presenting this to committee just for information? Do you want our input? Are we actually going to perhaps see a little bit more detail of what sort of events are reportable to get feedback for severity?

MR. BROWN: The purpose of this presentation was primarily informational for you. I

can certainly take feedback. This is the -- as you sometimes feel that you're handcuffed by the restrictions of the staff on what you can do, and this is a case where the NRC staff feels handcuffed by another federal agency in terms of how we implement this. The approach that we've taken in -- talking out loud here somewhat. The approach that we've taken is in implying -- in applying the regulations from Health and Human Services, we've attempted to limit the burden on our external stakeholders and ourselves in implementing this and I think it would be reasonable for us to share with the committee the current draft management directive and ask for your insights in terms of areas that maybe you can see a way to limit that negative impact and burden but there aren't any decision makers, per se, even in the NRC staff that will be able to address some of the issues because there are things that we are uncomfortable and unhappy with but they're beyond our control.

CHAIRMAN CERQUEIRA: Now, in terms of the committee members is there anyone who has special concerns? I mean, Doug, you feel that the nuclear medicine community is going to be fine with this?

DR. EGGLI: Again, I don't think we have a -- we're probably going to have a whole lot of

choice.

CHAIRMAN CERQUEIRA: Right. Although, again, if the violations have no negative adverse impact, I mean, you know, risk based and if there's minimal risk to the patients or to the users, then I'm not sure that it needs to go to the level of severity where --

DR. EGGLI: It's taking quite a bit to get to the -- it's taking quite a bit to get to the reportable medical event stage these days. It's going to take something close to 50 rem to the target organ to get to a reportable event stage now. So you can -- it's -- and at that point, maybe it's reasonable.

CHAIRMAN CERQUEIRA: Now for the radiation therapy people, are there any concerns?

DR. WILLIAMSON: Well, I think you don't have to have a medical event to appear in this. If you leave your cesium room door unlocked and a terrorist comes by and steals your cesium, my guess is he'll find your institution on this list. So a significant security violation in this climate or any kind of a procedural violation of Part 35 or your license that is classified as Level 3 and a fine is made could end up -- it would be on this list. As long as it involved health care. It might not have

anything to do with a medical event.

MR. BROWN: Well, yeah, actually, I don't believe that's correct in this case because one of the criteria is that the violation itself has to be associated with health care. So a security and control violation, I don't believe meets the criteria that we've established for --

DR. WILLIAMSON: So it has to be something involving the treatment of a particular patient.

MR. BROWN: Or a group of patients.

DR. WILLIAMSON: Or the maintenance of infrastructure necessary to support the treatment.

CHAIRMAN CERQUEIRA: Dr. Nag and then --

DR. NAG: Yeah, and one thing that we have to worry about is a medical event like under dosing which in many times that may not really make any difference to the patient. For example, I might give the patient 4000 and I know -- 4000 centi (phonetic) and other people might give 5000. That in itself is a 20 percent variation. That wasn't made by mistake. It really had no bearing on the patient but it will be a medical event. So on these things, I mean, are these reported or not?

MR. BROWN: Well, I would like to go back to Dr. Williamson's point, which is, just because you

have a medical event does not mean that the agency will take enforcement action.

DR. NAG: Right.

MR. BROWN: If the investigation -- the event follow-up, concluded that there was a violation and that the significance of the violation rose to the level of escalation, then it would be reportable, although, again, there is a right to challenge each individual case.

CHAIRMAN CERQUEIRA: Ralph, before we come back.

DR. WILLIAMSON: Well, as I think back on my history with NRC, I don't think I've personally been involved where we've had a finable offense, but I've been involved long enough to know that sometimes the regulatory and enforcement actions have more to do with protocol and dotting Is and crossing Ts and so on, and really aren't a good marker of the quality of patient care delivered by the institution.

So while I think the new Part 35 and the maybe more how should I say, risk informed, performance based attitude, we hope, of the inspectors will resolve discrepancies between these two goals of regulatory compliance and isolating out bad apples, you know, there still is the potential that, you know,

what NRC might consider a finable offense has nothing to do with the quality of the health care delivered.

So that would be, you know, my concern is that in whatever guidelines you make up, you really consider the purpose this data base is going to be used for which is to -- for others to identify, add practitioners and institutions and so on and be, you know, really careful in articulating your guidelines and try to keep that purpose in mind and not do it mechanically.

CHAIRMAN CERQUEIRA: Dick, you had a comment.

DR. VETTER: Yeah, a question, two questions actually; what efforts have been made to communicate this to licensees and the second one you addressed briefly and I'm not sure I understood it, and that was the accessibility of this information to the public.

MR. BROWN: Okay, where we're at right now is still internally working out the process of reporting and that's not done yet. Once that's done, we'll issue a generic communication. I'm going to go -- later in a couple of the presentations, go through the way we've been doing that for regulatory issues like this but the point is well taken. We shouldn't

surprise anyone with a double whammy here. Here's your escalated enforcement and then by the way, here's the report of Health and Human Services.

That was one half of your question and the second half --

DR. VETTER: Access of the DOEs the public.

MR. BROWN: Yeah, I'm going to have to admit ignorance. The slide basically provides the sum total of my familiarity with the actual statute and the underlying regulation, but it is -- it should be accessible, 45 CFR Part 61, and I can do some follow-up and get back to you. It will be later in terms of what the controls or access to that data base are. I know there is a password protection on the system and you have to be a registered user.

Even for reporting agencies, there's a lot of administrative hurdles to get through to be able to report data in and QA back on that data. So I think it's not inconsequential but I'm not sure who all it's limited to when it says you know, health plans will have access. I'm not sure what that means.

CHAIRMAN CERQUEIRA: Dr. Brinker?

DR. BRINKER: Just a clarification perhaps, did I misunderstand you? If so, I apologize,

but did you state that the agreement states might not have either the investigatory wherewithal, whatever, to do what is necessary to report cases in their jurisdiction?

MR. BROWN: Enforcement is not a mechanism subject to compatibility in our arrangement with agreement states. We require agreement states to do event follow-up and assessment but we do not require states to have a mechanism to take adjudicable actions against licensees. The way the Health and Human Resource regulations are written is only adjudicatable actions are subject to reporting.

Now, I can't imagine that there's an agreement state that doesn't have the capability to revoke a license and I think pretty much universally that would be a reportable event. But in terms of taking escalated action and fining a licensee and having an adjudicated process, some agreement states have that kind of system and others don't.

DR. BRINKER: My point is, isn't that -- isn't it unfair then to practitioners who happen to be in an NRC state to be held to a level that might be -- reportable level, a level in reporting that's different from an agreement state?

MR. BROWN: I guess it's a matter of, you

know, Congress' intent in publicly accessible information both for health providers and for licensing boards. Really what you're saying is for jurisdictions with NRC oversight, there's better information available to decision makers and it's less good information in other jurisdictions.

DR. BRINKER: Well, it's punitive to -- in a way or less punitive to the individuals and license holders to be in an agreement state than it is if you happen to be in an NRC state because not only are you getting reported but this report goes on a data base that's accessible by people that might have your future -- a role in your future.

DR. DIAMOND: My specific concerns along these lines is this; it is certainly possible that a medical event could occur which has my real medical adverse impact, as Dr. Nag was giving an example of, that this information is thought to reach a level of severity that requires reporting by a group of individuals that have no true capacity to evaluate the severity of the event in medical terms, then this makes it to health care plans or makes it to attorneys and the next thing you know, you have a lawsuit, you can't get malpractice insurance, you can't get on health plans. It is a very, very real possibility,

particularly in the context of a medical/legal environment that already is just salivating over every action that we physicians take.

I can certainly see -- and take my own state, the State of Florida, the folks in the state office are very nice people but they know very little about medicine. I do not have confidence that if they received information regarding an event, they could make a reasonable decision regarding the true medical severity of that event and I could certainly see instances where there is a reporting to this entity and this escalates with very untoward ramifications.

CHAIRMAN CERQUEIRA: So I think we all understand the need to do this and you're obligated to do this, but just in terms of the specifics, I think we'd like to see a little bit more clarification both at the NRC level as well as the agreement states on what's going to be reportable. And if it's definitely, you know, a high risk to patients and has a negative medical impact, it should be reported but there can be other things that even though they're not -- they don't endanger patients or the public or the people using the isotopes but could end up on this reporting profile with a lot of adverse consequences to it. So I guess the question is where do we go from

here on this? Do you need more input from us? Does the committee want to see some feedback from the NRC and what they're going to do?

DR. WILLIAMSON: I think it might be good to see the Management Directive that Fred mentioned and give more specific feedback on that at our next meeting.

MR. BROWN: Yeah, we can certainly distribute both a copy of the statute, the Health and Human Services regulations and our Management Directive and any help in finding a more creative and constructive way to satisfy our requirements from the committee would be a great help.

CHAIRMAN CERQUEIRA: And give us some idea again you know, based on your -- the data that you have, what the number of events that would have been sent to this data base and what they consist of so we can get a feel for whether they're medically appropriate or not.

MR. BROWN: Yeah, I guess let me caution, number one, with a change in the regulations, I don't really want to do that, quite honestly. I think that's apples and oranges I think. I think we could get very excited about under the old regulations and the QMP actions that were taken by the NRC and would

be spending energy that's not usefully spent when we've already changed the rule to address a concern.

And I guess the other point I would make is we've introduced now the implication that the data base is only intended to come into effect when there are dead bodies or there's deterministic effect and certainly from an NRC enforcement perspective, we look at the precursors with a reasonable potential for outcome like that. We don't just start when -- you know, when there's an organ loss because of a medical event. So I just request that when you look at what we send out that you think not only about is there always an outcome with a severity Level 3 violation but are we doing a good job at tying escalated enforcement to the types of events with potential for outcomes as well.

DR. WILLIAMSON: So you can send us a list of these events?

MR. BROWN: We can do that.

DR. WILLIAMSON: I think that would be most helpful.

CHAIRMAN CERQUEIRA: That would be -- yeah.

DR. WILLIAMSON: If you could give us like that last 12 events that have been reported to you

that you think would be reportable on this --

CHAIRMAN CERQUEIRA: Under the new regulations. I just still don't -- we've been talking about this, you know, for a half an hour now but I still don't have a feel for what kind of events within the diagnostic area and certainly within the therapeutic. You know, the example that Dr. Nag gave, that's, you know, sort of within the practice of medicine even though it may have some implication on the regulations, and I'm not sure that should be reportable, but we're kind of beyond our time.

You have a few more slides and I know there's probably other questions, but if we're going to stay on time, we should --

MR. BROWN: No, actually, I think we've done a better job covering the topic than what the slides would have done. So that's all I have.

CHAIRMAN CERQUEIRA: Tell Linda she did a good job.

MR. BROWN: I will pass that on.

CHAIRMAN CERQUEIRA: All right, so that brings us to the next item which is the status of implementation of revised rule and Mr. Brown and Young.

MR. BROWN: Actually, what I'd like to do

is probably go out of turn if Tom's ready so I can make notes to myself about the last topic, and when Tom's covered the inspection, then I'll jump in and cover everything else. But if I hear you asking questions of Tom that I know I'm going to cover --

CHAIRMAN CERQUEIRA: So he's going to deal with revised inspection guidance.

MR. BROWN: Yeah.

(Pause)

CHAIRMAN CERQUEIRA: You're using up your time, Tom.

MR. BROWN: Another lesson learned on prior preparation.

MR. YOUNG: Okay, do you have a copy of what I -- okay, good. There's only five slides, four slides actually because my name is on the first one but Dr. Cerqueira, I want to tell you and your committee today about the medical inspection procedures that are being revised so that you'd have an understanding of how they fit with the revised Part 35. And as I recall, as a matter of compatibility, they would not be required in agreement states to implement these same procedures. They can continue to use their own procedures.

The medical inspection program is in

Manual Chapter 2800 in the NRC Inspection Manual and it's publicly available on the NRC Web. What we've done is we've started a pilot program to streamline the administrative procedures that are in Manual Chapter 2800. These medical inspection procedures are being used under those administrative procedures, so we're introducing these inspection procedures as part of a pilot program which was also made available to agreement states. So we've been in this pilot program for about six months.

And if you look at slide 2, you see there just is a quick summary, that we currently have four inspection procedures but we've expanded it to an additional fifth inspection procedure. We're changing the inspection procedure numbers so that we can refer to them in our -- with our inspectors the way they charge our time to a new set of numbers and then we've changed the format to include seven risk informed focus elements which are similar to what was being used with the nuclear medicine inspection procedures for about the past year and a half.

And in slide 3 you see the new inspection procedures numbered. It's 87-130 series and the titles are new titles that fit with revised Part 35. So the first one you see there is for low risk

diagnostic nuclear medicine and then the next one, IP 87131, is for the nuclear medicine therapy where a written directive would be required. Both of these are replacing the existing inspection procedure 87115.

And then the brachytherapy programs have their own inspection procedure just as before and it includes the remote after loader units also and it's a new number, 87132 and then the next procedure, 87133, we've added the medical GSR units to that one. Formerly it was just 87116 for teletherapy and then lastly is the medical broad-scope programs.

And on the next slide, the fourth slide, these are the seven risk informed focus elements that will provide guidance to our inspectors. The way the inspection procedures were revised, each procedure has the same objectives as the current procedures and then the requirements section of the inspection procedure has the seven focus elements, risk informed focus elements and then Section 3 provides the matching guidance for each of these focus elements.

What we did essentially in our revision was to -- there was a lot of redundant information in these procedures and formerly in Sections 2 and 3 for requirements and for guidance, and we've eliminated the redundant information and then reformatted it to

these seven focus elements. So you see in the past, it -- for example, security and control of licensed material, but now we've focused it, concentrated it to one area for the inspectors to use. The same way for shielding.

For number 3 there the comprehensive safety measures would be other types of hazards or events that would promoted or promulgate a radiological condition that would be a problem such as a fire, for example, or an explosion. And then the fourth element is that the licensee should implement a radiation dosimetry program to accurately measure and record radiation doses to workers and members of the public from the licensed operations.

So it's essentially the same information, it's been reduced in size and then it's been reformatted into these seven focus elements and the last slide again, is just a reminder that our inspectors are using a performanced based approach and we have again reinforced that into these inspection procedures that on the last slide, they're to observe and interview, if possible, have the licensee demonstrate a procedure or a radiation safety practice for them and to take measurements along with the licensee or independent of the licensee whichever may

be needed and rather than just looking at records or just looking at a written procedure.

And of course, the second bullet is the inspectors should not interfere with patient care or patient privacy. They should be attuned to patients in the area while they're on site doing the inspection. And then the inspectors should exercise discretion when they're interviewing the licensee staff in the presence of a patient, so that the patient doesn't have to become involved with the inspection.

So those are the revised medical inspection procedures.

CHAIRMAN CERQUEIRA: Dick.

DR. VETTER: Just to reflect on some personal experience relative to the last slide, we just had an inspection last week and the inspector followed this procedure. I don't know if they're supposed to yet or not but he was anticipating if not, and it went extremely well. I mean, I considered it to be a very professional inspection focused on the risk, areas of risk, spent very little time looking at records.

He did look at records, but mostly looking for whether or not we had some performance problems,

not looking whether or not we dotted every I. It was really a very, very well conducted inspection.

MR. YOUNG: That's good to hear because we want them to only just spot check records to see that they exist, you know, for the type of activity that they're observing and that they would be able to not really look at the licensee's procedures unless they see radiation safety practice seems to be lacking in some manner and then they would be asking the licensee for better information about that, perhaps training on that.

CHAIRMAN CERQUEIRA: That was a real plus. I kept waiting for the but, and it didn't come. Now, I think again, I know that the SNM is here and they had a lot of problems before, they felt a lot of the regulations were now being put into the guidance documents and you know, Doug or Ralph, do you have any concerns about what's --

MR. BROWN: I will get to that.

MR. LIETO: I'd like to hear what Fred has to say first before --

CHAIRMAN CERQUEIRA: Okay.

MR. BROWN: Then he can explain to my why I'm wrong.

CHAIRMAN CERQUEIRA: Okay, all right,

Jeff.

DR. WILLIAMSON: Can you give me an idea of what performance would mean in the area of radiation oncology perhaps, with an example, what this performance means, whether you observed that the activities comply with the regulation or the performance end point is not having a medical event? Can you give me a little more of a description maybe through some examples, how the procedure, new procedure for inspection would differ from the old one?

MR. YOUNG: If there were -- if the inspector is on site and they know that there's an HDR procedure scheduled, for example, they might work their inspection schedule so that they could do some observations during that procedure and then they would do some interviews of the staff involved with that and they would just observe to the extent possible how the console is operated and how the lights are working and how the survey instruments are being used and that type of activity is what we would expect.

MR. BROWN: And then discussion with licensee staff about emergency procedures, are you familiar with them, is the equipment staged for source recovery if necessary.

MR. YOUNG: And if there's not a procedure being conducted that day, perhaps at some time convenient to the staff, they could do a walk-through or a demo of that. They wouldn't necessarily have to expose a source, that it would be up to what they want to do.

DR. WILLIAMSON: So the performance end point would be whether they observe -- whether the actual or simulated patient treatment as you observed it, complied with the regulations versus how the documentation complied.

MR. YOUNG: Yes.

DR. WILLIAMSON: So that's the major changes and emphasis on observation as the basis for having citable violations --

MR. YOUNG: Correct.

DR. WILLIAMSON: -- versus the records.

MR. YOUNG: Right, because we realize once we're out there it's a just a snapshot, a view of licensed operations and based on the equipment that we see and the condition of the equipment and the ability of the staff to perform or to answer questions. You know, we understand that some days may be better than others but we should reach a level of assurance of radiation protection while we're on site observing the

operations.

CHAIRMAN CERQUEIRA: Other questions for Tom?

MR. LIETO: Tom, you said that the IP's, the Inspection Procedures were on the website, is that -- do you mean ADAMS or is there some place that's more accessible?

MR. YOUNG: They'll probably be in ADAMS but they are going to be on the NRC website. I could give you the path for it. It's not very clean but or I could e-mail it to you. That would probably be the best.

MR. LIETO: Okay, if you would give that to the whole community that would be appreciated.

MR. YOUNG: Sure.

MR. BROWN: And the other action we can take is to make sure they're linked from the Part 35 page as well, because they're probably in the Inspection Procedure index rather than the Part 35. So we can make a note to fix that as well.

MR. YOUNG: I'll e-mail this to Angela and she can --

CHAIRMAN CERQUEIRA: She can get it out to the committee, that would be appropriate, okay. Sounds good. All right, any other questions for Tom?

If not, we can move onto Mr. Brown.

MR. BROWN: Thanks. I did want to capture the thoughts on the HHS data base and so I apologize for that little break in continuity. The topic that I have is basically the status on implementation. It covers several issues. The first slide talks about -- the second slide talks about the licensing guidance, NUREG 1556, Volume 9 and basically to kind of recap what happened over the last six months, since the last time the committee met and saw a draft of the NUREG. What had previously been available was a March 2002 copy of the NUREG. It largely reflected year-old or 18-month old thinking and content. We distributed that for public comment, had a couple of public meetings requesting comment on it and I'm reasonably confident that provided it to the ACMUI and if we didn't, I'm sure I'll hear, to get comments on it.

And we went through several months process of attempting to incorporate many individual comments on the contents, both of the licensing guidance and some of the model procedures. After doing that in August of this year, we entered the process of making sure that the document really conformed to the higher level objectives that we have. And we did that in what was called a Pink Team of managers and senior

staff.

And the final thing we did was went through what we call a Red Team review -- I'm sorry, wrong one on that slide -- a Red Team review which is the management review to insure that the document is legally enforceable, not that this is a legally enforceable document but that it doesn't overstate the regulations and that it's consistent with senior management perspectives. The next slide, please.

The review team philosophy for the big picture was to, number one, make sure that we were not regulating In guidance space. That was the most critical thing we did. We took the position that the regulations provide for adequate safety where the regulations speak to new requirements in Part 35. And so, anything that was in the guidance document that appeared to require action from applicants or licensees we clearly either deleted it or separated it from the part of the procedure that does provide guidance on required submittals.

There were several other parts that go hand in hand with that. Looking for unnecessary burden in the submittal information from applicants, making sure that the document was understandable. And then, as I indicated, making sure that we listened to

the comments that we got that were specific to things that stayed in the NUREG and through all of that, obviously, we were again focused on safety, but the outcome is that the NUREG that you all have copies of is really divided into two parts.

The first part is what's required in a license application and the information that's required is very limited and it's directly tied to either Part 35 or to the Radiation Protection Program requirements of Part 20. There is not a requirement to provide us a description of information that isn't supported by the underlying regulation. I think the volume and the scope of submittals under this guidance will be significantly less than under previous licensing guidance in the medical area and it actually sets a new standard, I think, across the Part 30 area.

The second thing that we did is we addressed the issue of model procedures. And as you're aware there had been concern that model procedures because de facto requirements either through license conditions that were forced on licensees or through inspector expectations. And we drew a clear line that said model procedures are not requirements, they're simply tools that you can use if you see fit as a licensee. We seriously discussed

deleting them in their entirety from the NUREG and the reason that we didn't do that was public stakeholder comments requesting that we provide these documents to licensees who may find them useful, but the fundamental bottom line is that anyone that uses one of these model procedures does so because they want to and they have all of the freedom to revise that to suit their own situation when they put it into use. It is not something that we will regulate to.

So the next slide, the status, now the NUREG is currently available and we got it up on the website as you can see, just hours before the rule went into effect and it's unfortunate because we had had -- we had hoped to have the NUREG done probably a month sooner than we did. We hope to be able to distribute it at the stakeholder meetings. We hope to be able to get it out to the people at the stakeholder meetings and to this committee well in advance of the time that it took us to finally get it done.

But it is now done and hopefully when you look at the finished product, you won't have the type of concerns that you had with the earlier versions and I'll just give one example, because some of you may be interested in it. In the area of calibration procedures, we deleted calibration procedures, model

procedures for all instruments other than simple survey instruments. So there were lots of public concerns and comments about out model procedures for calibration. Those are addressed. The model procedures are removed from the NUREG.

Let me pause and ask if there are questions about 1556, Volume 9.

MR. LIETO: I'll start. What then is the purpose of the appendices?

MR. BROWN: There's two sets of appendices. The first couple are forms, the form for an application of a license and then a form that can be used to submit the information in the 313 form. The -- all of the appendices after letter H, I believe, are clearly information -- that's I through W, are informational purpose only appendices and a licensee could tear this portion of a NUREG off of the back and throw it away and it would make absolutely no difference. They could write all of the procedures that they wanted to, to address the things in that appendix. That's perfectly fine.

None of those are submitted to us and -- let me be careful. The rule requires submittal of some emergency procedures. Those do have to be submitted. There's a little bit of guidance back

there on ways to do that but it's not like you can just take the NRC procedure and send it in. You know, we wanted to get away from that. The only appendix that has any information in it that is essentially a requirement is Appendix G, which is information needed for transfer of control. And that basically comes right out of a different volume of the 1556 process and if you transfer a license it explains the requirements for that. But everything else is for illustrative purposes other than the forms themselves.

MR. LIETO: Fred, there was a document that was submitted that was a combined review of the previous draft from three of the radiological societies and some of them had some very, I think, severe changes. Can you comment on any of that material and I guess probably in terms of things that were not incorporated into the revision, the final draft.

MR. BROWN: I can comment to the extent that I know we went through -- there were comments that were specific to calibration for the dose calibrators and for the 630 therapeutic treatment device calibrations. And we actually had gone through and incorporated many of those changes and we got to the point that we realized to leave those guidance

documents in 1556 would actually set up our licensees to violate the regulations because the regulations require a calibration to a nationally recognized standard and this document does not meet that requirement. And so we deleted those model procedures in their entirety.

To the best of my knowledge, we did not ignore any substantive comments in the body that remains unless there was a clear regulatory basis to require the submittal of information or to make a commitment. Now, that -- there are -- I'm not sure there's anyone in the room that can help me but there are about 900 individual comments and I've been through them at a high level but I can't quote all 900 of them. Susan?

MS. FRANT: Just to tell you, Ralph, that the -- all the comments and the responses are going to be out in a document that's an appendix. So I'm not sure what -- it's almost ready. It may be posted on the web in the next week or so, maybe, but if you want we'll send you an e-mail when it's posted. But they follow each of the comments and what we did with them.

MR. BROWN: Okay, thank you, Susan.

MS. FRANT: Susan Frant, F-r-a-n-t.

MR. LIETO: A couple of the issues, since

this stuff just came out, you know, within the past week, I've gotten feedback that a couple of the more controversial issues regarding these appendices. The concern is that agreement states especially, are going to take these and keep them as a model guidance for licensees to follow. And there still is in there the issue about the 200 DPM per square centimeter for I-131 which has been something that has been a major problem and really is an unreasonable level.

The patient release examples have errors in them and these were pointed out and the -- in terms of what they're showing and so see, it doesn't -- from what I've been able to just, you know, glance at in the last, you know, day or so, it doesn't seem like those issues which were brought up by those organizations have been -- well, obviously, they've been looked at and they're going to keep them in there. There must have been some reason why they're not going to be changed.

MR. BROWN: I don't mean to interrupt but I can address definitively the contamination control action level issue. The former model procedure basically established expectations on contamination levels inside restricted areas for action and outside restricted areas. The new guidance, if you go through

it, you will see that it provides the same discussion but then it very specifically says that if you want to establish as a licensee different criteria, you are completely free to do so and here are the regulatory requirements you have to meet in doing that.

You have to meet ALARA. Your values have to be ALARA and you have to worry about disposal of the facility long term and beyond that, you are free to do as you see fit with respect to those levels. And that's very specifically added in to address the basic concern of the stakeholder comment. With respect to corrections on the 35.75 release, although I didn't do it, I do know that we did make changes to some of the examples and formulas to address those questions.

Now, we may not have gotten them all and by the look on your face, we haven't and we'll have a continuing battle over that, I'm sure, but the effort was to do that. We went back to the people that had written the original guidance and worked out with them some obvious errors as were pointed out.

MR. LIETO: Because the issue has to do mainly with the patient release issue, deals specifically with when you can ignore internal contamination and using the criteria that's in the

appendix which is basically what was essentially the same as previous, you are not going to be allowed to release patients, okay, based on occupancy factors and so forth in the examples, I think it's above 185 millicuries of I-131. So there's some specific things and this was all written up in the comments that were submitted, so I really think, I guess maybe also this brings up an issue of the concept of a living document and going back and addressing some of these specific issues in terms of the concerns that you know, may still not have been addressed.

MR. BROWN: I think that's a good point. I mean, it may very well be that we make conscious decisions that are in excess of 100 milicuries of 1-131. We didn't think release was appropriate. I mean, I won't swear to that but that is the sort of thing that we can follow up with a living document on.

MR. DIAZ: Okay, other questions? Dick?

DR. VETTER: I know we can't go through this in a lot of detail but I think it was either at the last meeting or the one before we raised the issue of security and the fact that facility diagrams ended up on the ADAMS site. In the guidance here, once again, the licensee or the applicant must provide a facility diagram, room numbers, et cetera. All that

information ends up in the public record. So it seems a bit of a contradiction here where we are supposed to do everything we can to protect and secure radiation sources and yet we are to make available to the public where all of this stuff is.

Is there any thought about allowing licensees to keep that confidential?

MR. BROWN: Redacted. I think Susan Frant would like to --

MS. FRANT: Hi. It seems to be contradictory and I agree with you, there was a decision made by the Commission not by the staff, that this information should remain public. And I think that if the advisory committee believes that it's contradictory to some of the security issues, that would be a good idea to raise that. We also are looking at interim compensatory measures, as you know, which are those things that are the delta between existing security requirements and what we know about potential use by terrorists and others that might be intentional misuse rather than accidental misuse or theft or diversion and as we're reviewing that, it may be that we make a different decision, but right now, based on the fact that this information has always been public, the Commission decided there was no

reason to not continue to make it public.

They have diagrams of waste sites also and spent fuel and other things. The only thing that I know that isn't publicly available any more and used to be is the longitude and latitude of nuclear power plants coordinates. So I think that that's -- okay, so it's been a very contentious issue within the Commission because you have to balance the need for people to know the openness of the information and the process. There are issues on which we make regulatory decisions and the regulatory process has to be transparent to the public.

So you have lots of reasons to have it public and you have to have a reason not to have it public to show where it compromises security and as yet, there hasn't been that kind of information to make it clear. So that's -- I think it's intuitive, you would say, well, why would you send a road map, you know, why leave crumbs, but since it has been public and it's usually posted in the hospital or in the licensee, it's not as if it's a big secret in terms of where the nuclear medicine department is. So that's part of the thinking.

CHAIRMAN CERQUEIRA: David.

DR. DIAMOND: Well, Richard, I'm very glad

you asked the question. I was under the assumption that one would continue to submit this information but this information was not going to be available on the website. So I'm glad you asked the question, I'm glad Susan answered it.

I simply don't understand, for example, why the commissioner would go and remove the latitude and longitude of a nuclear power plant which can be seen from any aircraft of the naked eye 20 miles away whereas we would continue to go and post the locations, security arrangements for a gamma knife stereotactic radiosurgery unit using Cobalt-60 which probably of everything that we're discussing in our purview is the thing that would have the greatest concern as far as a misuse as a radiologic dispersal device, so I'm glad you brought that to our attention, Susan.

I particularly --

MS. FRANT: I didn't bring it up.

DR. DIAMOND: Well, I'm glad Dick brought it up.

CHAIRMAN CERQUEIRA: Okay, are there other comments from Mr. Brown before we move on? So do we need any follow-up either from your perspective or from the committee's perspective on this? You know,

Ralph, you've gone over it in some detail.

MR. LIETO: Well, not so much in terms of the appendices because just -- you know, the document just came out and I'm sure there are going to be more issues, but there were -- I know we're going to be talking about a couple of these a little bit later on in the schedule, but there were also several things that came out of the workshop, stakeholder presentations that I know Fred gave the one in Region 3 and I think Susan also gave a couple of the others, and there were things that were coming out in terms of how the regulations would be followed in terms of some of the specific issues, some regarding radiation safety committees, some regarding calibration of survey meters that would meet the requirements, about licensing of field sources and model numbers and so forth which we're going to talk about a little bit later, dual operation machines.

There were several things that came out that I don't -- some of them, I think, were addressed but I think they were very eye-opening because people didn't realize that this is how the guidance was going to be or the regulations would be interpreted. And, you know, I think that I would be interested to know if there's anything that's going to come out of these

stakeholder meetings in terms of clarification and interpretation of some of these regulations.

MR. BROWN: We're four or five slides ahead of ourselves, but the point is well-taken and I did plan on getting to them. The next slide is diagnostic only guidance. As I'm sure ACMUI is aware coming out of the spring stakeholder meetings. There was a lot of discussion about splitting the guidance for diagnostic off from other uses and the resolution, what we did over the course of the summer or more specifically Society of Nuclear Medicine, did over the summer was to develop a guidance document that's applicable to diagnostic only and they shared that with us and the bottom line is that the NRC in general supports that document.

We think it's valuable to SNM members and to non-members for a fee, but the agency is working with SNM to make the document widely available to everyone that's interested for no fee. And what the document does essentially is to provide a road map to license applications for diagnostic only facilities in a way that is easier to follow.

Now, hand in hand with that, hopefully, we've done the same thing in Volume 9 with a couple of the tools that show applicants for a diagnostic

facility or a 100 or 200 or both, what they have to submit in 15.56 Volume 9 as well and what they don't have to address. But that's the status on the diagnostic only guidance document. We actually hoped to have it widely available now, but the administrative process tripped us up.

The next thing I wanted to just let everyone know and it kind of envelopes what Tom addressed is we did go out and train the regional staff on the new rule and the approach for performance based risk informed inspection. It was one part rule training and another part let's make sure that we're going to implement the rule in the manner that was intended and that we not regress back into the old way of doing business. It was a very -- it was interactive training. It was spirited in some cases and hopefully it was effective. There was certainly a lot of discussion and the proof will be in the pudding.

There was also agreement state participation in those training sessions and hopefully, Dr. Vetter's experience is the proof of the pudding and hopefully others will experience the same. Yes.

MR. MALMUD: I have a question about the

diagnostic only guidance document. I've not seen it and I'm a past president of the Society of Nuclear Medicine. Has any member of this committee seen it? Dr. Eggli?

DR. EGGLI: No.

MR. MALMUD: I'm not oppositional to it, but I just --

CHAIRMAN CERQUEIRA: Mr. Uffelman, comment from the SNM?

MR. UFFELMAN: The guidance document in question went through an extensive internal and external review and was reviewed over here at the NRC and but for the administrative glitch that they talked about, I would have had copies available to hand out to all of you today and you could have seen the document, but we had the Board, the Board of Regents, the Government Relations Committee and a number of other folks in fact, reviewed it.

MR. MALMUD: Has the membership seen it?

MR. UFFELMAN: Many of the members have seen it.

MR. MALMUD: Have members of this committee seen it?

PARTICIPANT: I'm a member of both and I've not seen it.

MR. MALMUD: Now, this is my own organization, so I'm not speaking hostily about it, but I'm speaking about this process. How can this committee see that slide, accept this as an approved document not having seen it. Dr. Eggli, you represent the Society of Nuclear Medicine to this committee. I represent the Administration to this committee. We've not seen the document. So if we aren't to be informed about what's going on, we might as well stay home. If we are to be a part of the process, then we should be reviewing some of this material and I've intentionally chosen something that's from my own specialty and my own organization to point out the deficiency in the process.

MR. UFFELMAN: And to you I apologize. I know it's at your institution because Al Bauer (phonetic), in fact, had a copy.

MR. MALMUD: But Alan Bauer hasn't given me the copy.

MR. UFFELMAN: I'm just telling you where there is one.

CHAIRMAN CERQUEIRA: Hey, Bill, would it be possible for the Society to send the committee copies electronically?

MR. UFFELMAN: I think I can but because

of the way we were doing it with the NRC, it may be easier for me to send you a printed out copy. I would give you the complimentary $40.00 copy that they would have given you for free.

MR. MALMUD: And what does it mean "diagnostic only"? Does that mean that you can't do I-131 therapy?

MR. UFFELMAN: This document relates to diagnostic nuclear medicine only. There's another therapy document that will be forthcoming after but the way -- the way the discussion went relative to the resolution of the issues with Congress this past year was with the focus on diagnostic nuclear medicine. We said we would do a diagnostic only nuclear medicine document in conjunction with the NRC at this time and then we would produce a therapy document.

CHAIRMAN CERQUEIRA: Thank you.

MS. FRANT: Fred, let me make a comment because I think this is not an NRC document. The Commission did not review it. This was a document that was developed by the Society of Nuclear Medicine. They had a review process within their own organization. We looked at it and commented on whether we thought it was complimentary or supplementary or whatever words you want to use, to

Volume 9.

We thought it did not have anything -- and this is what our review was about. It did not have anything that was negative in terms of complying with either the regulations or was contradictory to Volume 9. Volume 9 is the NRC document and that document, I believe, this committee has seen in various stages. So what I guess my point is, is that it's not an NRC document. It is a Society of Nuclear Medicine document and what we are planning on doing is having a licensing agreement whereby something we think is useful and we've done this with other documents by other groups, something we think is useful in order to prevent people who might not be able to either afford the membership in the Society of Nuclear Medicine or by the copy we are effectively having a licensing agreement for unlimited distribution of a Society of Nuclear Medicine document. So that, I think, makes a distinction between something that would be appropriate for us to make sure that ACMUI reviewed, which is Volume 9, and the regulations because you advise the Commission on things that the Commission does. So I can't speak to how it didn't get to you as a member of the Society of Nuclear Medicine, that's why I asked Bill to answer.

MR. MALMUD: I wouldn't expect you to address how it didn't get to me as a member. I intentionally chose something in my own area to point out the relative impotence of this committee in dealing with material. What's the name of the committee? It's the ACMUI. How is it that we don't see something the NRC supports? Where are we in the loop? Should we be in the loop? Should we be --

MS. FRANT: Well, I understand your point. I guess my question would be, do you believe that all the work that the staff does should be reviewed by ACMUI? I don't really want to -- you know, I mean, that is -- there are a lots of things that we do that aren't reviewed by ACMUI.

MR. MALMUD: That relate to the medical use of isotopes?

MS. FRANT: Yes.

MR. MALMUD: Isn't that what this committee is supposed to be doing?

CHAIRMAN CERQUEIRA: I guess that's a broader question in terms of what eventually gets down to the committee level and you know, I serve on several Medicare committees and we've got the same issue. I mean, when they get any kind of, you know, decision making, they set up these panels and what

comes to us is very arbitrary. So you know, maybe we can get to that at the end of the day. I think to try to keep on schedule, we should go on as soon as Ralph has a comment.

MR. LIETO: Well, I have to agree with Dr. Malmud. Even the fact that it's coming out of the Society of Nuclear Medicine, the fact that this -- that the NRC is going to make this available whether you like it or not, it's going to be construed as an endorsement by the NRC. And I think anything that's going out to the general stakeholders as an endorsed means of compliance, I think we ought to have a crack at it, okay.

Maybe everything in it is totally benign and there's not going to be any problems with it but it's just like, you know, the first page of the handouts here, on the slides, there's an issue summary that went out a week ago about new modalities under Part 1000. The first I saw of it was this, yet this has gone out to all the stakeholders and all NRC licensees. And I think we ought to have -- and there is some objections to this and I think what's again, to emphasize, is that when are we going to be part of the loop and why do we have to come back and find out about all this stuff because our societies are going

to ask us, didn't the ACMUI comment on this.

CHAIRMAN CERQUEIRA: Care to comment, Fred?

MR. BROWN: Well, obviously, none of you represent Societies before the Commission. You're providing advice to the NRC staff where requested and we respect that and use it greatly. And everything that we're talking about today, although you may not be 100 percent, hopefully you see the imprint of the advice that you've given us. And you know, I'm not sure that you should wish for some of the things that you seem to be wishing for here today if you hope to continue to practice and have lives outside of this advisory committee.

But you'd have the blood pressure of some of us that work for the NRC, but that would be my observation.

CHAIRMAN CERQUEIRA: Okay, one last comment and then we really should move on. And again, some of these are more administrative things and --

DR. WILLIAMSON: I guess one request for the future, it sounds like there's going to be the possibility of a 35.300 document coming out from the Society of Nuclear Medicine that the NRC may or may not endorse and since that -- since much of 35.300 or

some of 35.300 is done in radiation oncology, I do think it would be prudent for that document to be reviewed by this committee in view of the multi-disciplinary nature of radio pharmaceutical therapy and get a broader perspective than just the Society of Nuclear Medicine before you go ahead and endorse it.

MR. BROWN: I think harking back to Susan's point, it's not an NRC product and as an advisory committee, NRC staff, I don't think we're going to bring it forward unless we reconsider that.

DR. DIAMOND: Wait a second, hold on a second here. So here's going to be a document that de facto will be construed as having an NRC endorsement that will include activities that sometimes extend outside the purview of the one society that is drafting the document; is that correct?

MR. BROWN: Well, to be quite honest, I'm not familiar at all with the document. This is the first time I've heard of it.

DR. DIAMOND: 35, Subpart 300 does include some activities outside the exclusive purview of nuclear medicine. I think it is essential that some individuals or entities outside that particular specialty also have a crack at it before it goes out. It may be perfectly crafted, eloquent language, but if

there's a problem, then we have to go back as a committee and pick up the pieces and it takes three times as long and our blood pressure also goes up.

DR. WILLIAMSON: So we do not have control over what the Society of Nuclear Medicine publishes but we can give you advice as to whether you ought to endorse it or not in its present form.

MR. UFFELMAN: On behalf of the Society of Nuclear Medicine, I can assure you that before the therapy document goes as far as this document has gone you all, in fact, will see the text of that document and your comments will be invited, I mean, as reviewers. I will --

DR. DIAMOND: I appreciate that and I don't anticipate there necessarily being any problems but the point coming from Fred is that it's our discretion whether we choose to share that with you in advance and I ask myself what the heck am I doing here.

CHAIRMAN CERQUEIRA: Could you use the microphone?

MR. UFFELMAN: In their defense, we initially -- we started out to do the guidance document, this -- to do this thing, without the NRC. We were doing it as a service to our members and in

the process of the various -- all the stakeholders' meetings and other things that went on, it became -- there was an opportunity, if you will, to make it more widely available and that's what in fact, the outcome of the licensing agreement is.

MS. FRANT: Okay, let's just back up a little bit which Bill has suggested. There's been no discussion between NRC and the Society of Nuclear Medicine to develop a guidance document for use by NRC licensees. I think the Board of the Society of Nuclear Medicine has asked why there was a diagnostic only document and wasn't there a point at which it would be useful to have something related to therapeutic uses particularly within the Society's practitioner base, and so we haven't even looked at it. We haven't even discussed it and I think if you want to say to us, well, before there's any document that the NRC endorses, we're not endorsing it. We're making it available.

CHAIRMAN CERQUEIRA: But by making it available, though, that is sort of a tacit endorsement and you know, and again I think certainly the nuclear cardiology community had no input into the SNM document on that aspect of it and similarly the radiation oncologists and medical physicists when

you're dealing with, you know, the 300 series, there are some things in there that are not done exclusively by nuclear medicine physicians and --

MS. FRANT: Understood, understood, but I think that not to belabor the point, if we are going to have something that isn't widely reviewed, this document did have a significant review process.

CHAIRMAN CERQUEIRA: But only by one Society. The one thing that's unique about this committee --

MS. FRANT: No, no, I don't so.

MR. UFFELMAN: It went to ACR, it went --

CHAIRMAN CERQUEIRA: To ASNC?

MR. UFFELMAN: To ASTRO, I believe there were ASNC members involved in the review.

CHAIRMAN CERQUEIRA: I'm not so certain.

MS. FRANT: I think that -- I take your point. We'll discuss further what to do and how to do it, but I think that it's not fair to Fred to say to him, "How come you didn't come forward with this", because the process was not an NRC document and I think that maybe we need to --

CHAIRMAN CERQUEIRA: But if it's going to be distributed by the NRC, as Dr. Diamond said, it -- you know, this is the advisory committee and you're

basically --

MS. FRANT: We distribute many documents, ANS, ANSI, many documents that don't review -- that aren't reviewed by any advisory committee to the Commission. ACRS and ACNW do not review documents that are distributed necessarily in support. Even part of the regulations in 50.55(a) there are a lot of documents that are standards and put out by different societies, including EPRI that are not reviewed by ACRS or ACNW. So I think that ACMUI is not being treated as if you're different from the other advisory committees.

CHAIRMAN CERQUEIRA: Well, then speaking not as chairman of the committee but as a nuclear cardiologist who's, you know, sitting on this committee, then it's not a process that I want to be involved in. You know, I think as Dr. Malmud said, if you're going to have the committee, there are certain things -- obviously, we don't want to get every item that comes through, but when clearly it relates to the regulations, we should be involved. Leon?

MR. MALMUD: Perhaps -- may I ask a question? Guidance doesn't mean regulation, does it?

MR. BROWN: That's correct.

MR. MALMUD: And therefore, there are no

rules established by this document.

MR. BROWN: That is correct.

MR. MALMUD: So that my question may have been overkill. This is only guidance, it doesn't establish rules for anyone, is that a fair statement?

DR. DIAMOND: But there's this rules creep.

MR. DIAZ: But some of the states apparently are putting the guidance documents -- right.

MR. MALMUD: So that the non-agreement states would be --

CHAIRMAN CERQUEIRA: It's only like 18 or 17 states. The majority are agreement states.

MR. MALMUD: So I see, so then my question stands as it was. It is a risk.

MR. LIETO: And one other point related to that, even in NRC regions, when they do a license review or come in to look at a licensee, and they inspect procedures, okay, they're going to grab what is an acceptable guidance out there. Okay, so if they're going to compare anything, they're going to compare it to the guidance documents that are out there and even in NRC states, it becomes a template by which they will look at things if they have to review

procedures.

MR. BROWN: I guess to build a constructive point, take building on what Ralph just said and what underlays some of this concern, one of the things that we've dealt with inspectors in implementing this new rule is we don't inspect procedures and we don't expect inspectors to go out and ask for all the records to prove that you were keeping records or ask for your procedures to review them to see if they're adequate because that leads to the use of templates and challenges to the adequacy of procedure when your performance is outstanding.

And so the whole fundamental shift that Tom described is for inspectors to go out and watch real people doing real work and if there isn't any work, then to talk to real people about the real work and come to conclusions about the adequacy of the program based on that, not the procedure. So you know, the importance of some of this informational only procedures, we're doing a paradigm shift with our staff and hopefully as we change, you'll see that change and do a paradigm shift with yourselves with a level of concern about some of these documents.

But I think the more fundamental point that I took from Dr. Diamond's comments is you know,

we need to be careful recognizing and promoting procedures that are not NRC procedures if we haven't had a chance to coordinate with the committee.

CHAIRMAN CERQUEIRA: One last comment and we're falling way behind on the agenda and Ralph may get his day tomorrow if we --

DR. NAG: Just on the therapy on the 300 document guidance, I think that will be more controversy enforced by both nuclear medicine and by radiation therapists and I don't think that you have a guidance document by one society that may or may not be supported by the other. It will be a major point that you'll have conflicts.

CHAIRMAN CERQUEIRA: All right, we've beat Fred enough on this issue. Now, so we've got two topics, the Sealed Source Model Numbers and Practical Issues Associated with Manual Brachytherapy Seed Implant that we're supposed to finish before the 2:45 break. So, let's --

MR. BROWN: And actually, there are important things on Part 35 implementation that go back to Ralph's comments as well that I would like to go over real quick.

CHAIRMAN CERQUEIRA: Why don't you keep going because we actually haven't gone through yours?

MR. BROWN: If we can skip the slides on inspectors and skip the slide on stakeholder workshops and go right to the current action. What we're doing right now goes back to Ralph's point. There were a lot of good things that came out of the stakeholder meetings. There were issues identified that we hadn't fully thought through ourselves and weren't fleshed out by the committee and the staff doing the rule change. And we're in the process of trying to address those. As we address them, we put them up on our external web and I've provided the link to what is the question and answer list which where we address the things that came up. There were questions about RSO qualifications. There were questions about instrument calibration ranges. So that the general things were about maybe a quarter of the way through those questions.

Now, the final slide is that there were several questions that came up where the answer was not this is not a problem. The answer was in fact, this is a problem and we need to address it because it will have a major unanticipated impact on the industry. The first question was the Regulatory Information Summary that's in your packet which addressed 35.1000 modalities and what would be covered

by 35.1000 versus what was covered by 400, 500, 600 types of uses or 300 types of uses.

We issued that regulatory information summary. It covers intervascular brachytherapy which based on the statements and consideration in the rule was previously identified as a 35.1000 application. It also addresses TheraSphere and other Yttrium-90 microsphere treatments and the GliaSlite brain treatment and there are differences in the license community about how to address those types of use and actually I can talk to Ralph outside of the meeting at a break that I think we're actually providing the most flexibility by doing this the way we did it and hopefully I can convince him of that.

The more important one, though, that was a show stopper is that the requirements for manual brachytherapy seed calibration in 35.432 requires seed calibration but they do not require it to be performed by an AMP and yet the record keeping requirement for that calibration required the signature of an AMP and the concern was that that would create the need for all 35.400 licensees to go out and have an AMP do their calibrations. And that was not the intent of the rule, so we are rushing to get a regulatory information summary out, clarifying that an AMP is not

required for manual seed calibration.

A final one and it is an important area, is the Strontium-90 eye applicator calculation of treatment times based on the current calibration of the sources and that is the only requirement in 35.400 types of uses for an AMP. And the question that has come up is what type of qualifications were intended for the AMP who does those calculations and the most significant impact is in Puerto Rico where there are a lot of eye applicators.

CHAIRMAN CERQUEIRA: Apparently 19 out of the 20 that are registered, according to the information. There's one in DC and 19 in Puerto Rico. So we're talking about a fairly limited distribution.

DR. WILLIAMSON: These are licensed, stand-alone eye plant licensees.

CHAIRMAN CERQUEIRA: That's correct.

DR. WILLIAMSON: Many institutions --

CHAIRMAN CERQUEIRA: Have them, that's true.

DR. WILLIAMSON: -- that practice radiation oncology have eye plaque therapy available.

CHAIRMAN CERQUEIRA: That's true.

MR. BROWN: And the basic thing that I wanted to quickly point out here is that the direction

the staff is looking at -- taking is looking for demonstrated ability for that sort of review of an AMP and the principle of having a limited AMP for only that 35.400 it's not even a calibration, it's actually a determination of activity to K and I was hoping to get some feedback from the committee on that concept.

On the one hand, was it intended -- does the committee believe that an AMP qualified under the full qualification process would have to do those activity corrections or is there flexibility for a more performance based demonstrated ability for that stand-alone requirement area of use?

CHAIRMAN CERQUEIRA: Well, that was a closed session.

MR. BROWN: That was discussed this morning.

CHAIRMAN CERQUEIRA: It was discussed this morning.

MR. BROWN: Thank you. Very good, thank you. You're well ahead of me.

DR. NAG: Although that was a closed session, I think the part of it about whether we can have limited authorized medical physicist that's what we discussed here, I think.

CHAIRMAN CERQUEIRA: Jeff, do you care to

--

DR. WILLIAMSON: Well, I think the summary was -- I don't know how much I can say about this morning, but the summary was that -- I think this is fair to say, correct me if I'm wrong, that we felt uncomfortable endorsing a sort of sub-AMP that would have fewer qualifications than the main AMP that I think the group felt that the concept of having a graduate degree in medical physics or a science and the two years of experience, supervised experience in radiation oncology in fact, was intended, you know, as the kind of person that should have oversight of an eye plaque program as well as, you know, in general is the practice with manual brachytherapy as well, although not addressed by the regulations.

I think that in the situation that was presented, you know, we stated that on a case by case basis, exemptions to that requirement could be submitted to this committee and you know, the level of experience for individuals scrutinized but that we weren't comfortable calling that person and AMP but simply saying in the license 35.XXX not withstanding, so and so is authorized to perform Strontium-90. So that came up with what we thought was a very limited exemption and tried to reduce the probability that it

would be taken as a -- how should I say, a precedent.

MR. BROWN: Excellent, thank you.

MR. LIETO: Did you want us to discuss the first item on your slide there about --

MR. BROWN: I didn't really thing it was controversial but I am here to serve.

MR. LIETO: The 1000 emerging technology because it came up earlier this morning about that there was concern about Yttrium-90 microspheres being under 1000 as opposed to be in 300 or do I have the sections mixed up?

DR. VETTER: No, I think the concern was the fact that 1000 requires that anyone who applies the microspheres must qualify under the radiation oncology and that it doesn't qualify under therapeutic nuclear medicine.

MR. BROWN: Let me just, we're going to confuse a lot of people but to jump directly to that, for limited scope licensees, they -- a licensee to use 35.1000 will have to request approval and provide their program and how they want to deal with microspheres and the current guidance suggests that 35.400 provides an adequate program. Now, there's two things to be aware of in that discussion.

Number 1, broad scope licensees are

exempted from the requirements to come to us to describe how they're going to do 35.1000 treatments and so there are current NRC licensees who are using 300 kinds of AU's for the TheraSpheres or the MicroSpheres and that's perfectly acceptable and there's nothing in this approach that prevents that.

The second thing that we've had discussions about internally is that just because it may be correct that generally TheraSpheres look more like brachytherapy than they do unsealed radioactive material, that doesn't mean that a licensee can't have a perfectly good approach and an AU that's a 35.300 AU who could do this very well, and we ought to learn from what broad-scopes have done successfully and shape our approval of specific license requests and/or guidance around that.

DR. VETTER: I guess it's not clear to me from this issued summary that that's the case.

MR. BROWN: And yeah, all the issued summary was to let an applicant come in who was about to begin to use MicroSpheres to make it clear that we do for a specific licensee, expect to see a license request that we can look at how they're going to do it.

DR. WILLIAMSON: Well, I think this

brought up one of the concerns we had as a committee that was raised during our closed session is that we recall being consulted on the TheraSphere issue and what sort of licensing guidance there should be when it was raised maybe 18 months ago, approximately, but we never really got to see the final licensing guidance. So that was a concern about follow-up and now it's a matter of grave concern to several members of the committee that the licensing guidance appears to exclude a discipline, you know, that was heavily involved in the development of clinical testing of this modality and so it's not fair.

And so I think it would be prudent and useful, let's say, to circulate to this committee the licensing guidance for that product and probably the other ones that have been mentioned before this committee and at least give us an opportunity to express our opinions.

MR. BROWN: I think it's a good idea.

CHAIRMAN CERQUEIRA: I think Susan's right, though, our e-mail boxes are going to be overwhelmed but --

MS. FRANT: It's a question of timing because we meet once every six months and if you had a standing subcommittee, we'd be happy to work with

them.

MR. BROWN: I guess, let me go back. If you have a specific request of us to see something, I'm not sure we're saying we're not going to give it to you. Then there's the other issue, the process issue of -- you know of ACMUI --

CHAIRMAN CERQUEIRA: Well, a lot of the things we don't know what to ask for because we don't know all the things that are out there.

DR. WILLIAMSON: I think the 35.1000 is very controversial within the regulated community, who should do what and NRC is caught in the middle of often times unfortunately perhaps for you, in turf wars and such and so I think one useful strategy would be I think whatever licensing guidance is made for one of these new modalities, I think it would be useful to have a standing subcommittee of this committee that could review and give advice, at least, you know, I suspect it would help in the final acceptance of the product to have a lot of these things worked out in advance, you know inter-vascular brachytherapy and some of these applications which are on the boundary between radiation oncology and nuclear medicine are bound to be quite controversial and I think it can only be to the Commission's benefit to seek the advice

of a multi-disciplinary group such as this.

DR. NAG: Can you explain how are you handling radioimmunmotherapy like Zevalin where the radioisotope is bound to antibodies?

MR. BROWN: I wasn't really prepared to specifically address that.

DR. NAG: That's something that will come up and it probably is going to be coming up in licensing.

MR. BROWN: Dr. Donna-Beth Howe is going to grab a microphone.

DR. HOWE: Some of the basic guidance that we use is we look to see how our regulations will -- how a new product will fit into our regulations. And so it may be a new and emerging technology to you but the basic elements for radiation safety may have been well established for the product. And so for the case of Zevalin, it's a radio-pharmaceutical. It's a monocolonal antibody so a monocolonal antibody may be new to the medical community but radio-pharmaceutical and radiation safety programs that go with radio-pharmaceuticals are not and so we looked at our current regulations for therapeutic radio-pharmaceuticals and determined that there was nothing in the monoclonal antibody that was outside of our

regulations for the therapeutic radio-pharmaceuticals and so Zevalin is being covered under 35.300 and even though it is a new technology for you and you may be administering it slightly differently, the radiation safety concerns, we believe are covered.

DR. WILLIAMSON: Well, I think you have to be more than concerned with just radiation safety and technical concerns because the high risk modalities also specify the training and experience necessary for those modalities and it was agreed philosophically along some years ago that as the risk escalated to a certain point, as is the case with therapeutic modalities, clinical experience would be required and so when you have cross-over modalities like this, I think you have to look at what parts the community are you going to include or exclude from use. So it's more complicated, I think than --

DR. HOWE: But I think the new Part 35 with its requirements for the training and experience for the therapeutic authorized users is significantly up'd because of the risk than the old Part 35 and so I think our Zevalin positions would fit very well in the new 35.300.

DR. WILLIAMSON: Well, I think that if the training and experience requirements are repaired as

proposed, there would be a route to include radiation oncologists in 35.300. Who got excluded from practicing radio-pharmaceutical therapy as the regulations are currently published?

DR. DIAMOND: But, Jeff, if I recall correctly when we rewrote 35.300, we did make those modifications. I was hoping to see those today to see if what I wrote was still what I wrote.

DR. WILLIAMSON: They're there.

CHAIRMAN CERQUEIRA: It's there. You just got them late, but --

DR. WILLIAMSON: Anyway, I think it is -- it would all be solved if we had some sort of a standing unit that could look at things like this that come up on and where there's a short-term need for NRC to get feedback more quickly than every six months.

CHAIRMAN CERQUEIRA: With the 1000, this is something that will continue to recur and there are issues related to radiation safety but there's also issues of who's going to be practicing the use and all right, I think we should take a break now and there's a couple of topics that we didn't hit that we'll have to come back to after the break, but let's just take a 10-minute break and be back at 3:00 o'clock. Leon, do you want to make one last --

MR. MALMUD: It's a question again. I have a very simple concrete question. I'd like to think in simple terms.

CHAIRMAN CERQUEIRA: Microphone.

MR. MALMUD: Oh, excuse me. When I go back to Philadelphia, and my colleagues who practice nuclear medicine ask me are they going to be allowed under NRC regulations to use Yttrium-90 therapeutically, what's the answer, yes or no?

MR. BROWN: Broad-scope licensee?

MR. MALMUD: No.

MR. BROWN: Specifically licensee.

MR. MALMUD: They're in community hospitals around Philadelphia and they practice nuclear medicine full time.

MR. BROWN: They'll have to submit a license request -- if they don't already have it on their license, they'll have to submit a license request and make their proposal on why they -- what's the safe way to apply the treatment and there's no foregone conclusion at this point.

CHAIRMAN CERQUEIRA: Then how are you going to make a decision?

MR. BROWN: Well, I think we're going to do it in consultation with the ACMUI.

CHAIRMAN CERQUEIRA: So this committee --

(Laughter)

CHAIRMAN CERQUEIRA: No, no, right but the thing is this is such a common issue that rather than having every application go before the Committee, this is you know, an opportunity to create some rules that would establish that for you.

MR. BROWN: Yeah, I agree and I thought I heard maybe a recommendation that the committee was going to establish a subcommittee to work with NRC staff on the guidance for 1000 applications and the thing with guidance, you know, I guess that I would say is we want to have flexibility and a range of options rather than the only way to do things, and so that -- we're looking at that in the agreement state space and certainly we'd like to do it with the ACMUI and if that's, you know, your recommendation to the staff, then we can respond to that recommendation.

CHAIRMAN CERQUEIRA: Yeah, let's make a motion and so we somehow get it into the minutes.

MR. LIETO: Before you make a recommendation, I guess one thing in follow-up to Dr. Malmud, what was the criteria that made the Yttrium-90 and the MicroSpheres not being Part 300 but in 1000? What was the health and safety issues that determined

just like the monoclonal antibodies why wasn't it 300, why shouldn't it have been -- you know, why did it go in 1000? And I guess that's --

MR. BROWN: The answer again is it involved sealed sources. The MicroSphere is actually a sealed source.

DR. NAG: Then it could be 400, why not being 400?

MR. BROWN: It's not in 400 because you cannot do an inventory of sources as required by 400 for MicroSpheres.

MR. LIETO: A MicroSphere is a sealed source?

DR. NAG: Yes.

MR. BROWN: That's correct.

MR. LIETO: Then why isn't a sulfur colloid?

MS. FRANT: How can you define a MicroSphere as a sealed source?

MR. BROWN: It's in the sealed source -- I mean, you asked me a simple question and I don't know sealed source and devices like other things I don't know but the answer is, it's a sealed source.

CHAIRMAN CERQUEIRA: You know, 1000 was this emerging technologies and so if we had --

MS. FRANT: That's not the title of the sections.

MR. BROWN: Others, other modalities.

CHAIRMAN CERQUEIRA: Okay, so I guess there are no established criteria.

DR. WILLIAMSON: Except that it doesn't fit cleaning in 300 or 600 or 200.

DR. NAG: Similar to the question that Dr. Malmud asked, if I had my community radiation oncologist ask me what is there -- can they use Zevalin or not, would the answer be the same, they have to ask for it and we have to look at it or what?

MR. BROWN: Unless it's a broad-scope licensee.

DR. NAG: No, a community person.

CHAIRMAN CERQUEIRA: So we're getting back to the real role of this committee. This is the playing field for the various turf issues that come up that -- Leon, you had a comment?

MR. MALMUD: It may be -- I mean, this has nothing to do with the NRC. It may be that the manufacturer of the Yttrium MicroSpheres in applying for FDA approval went through the -- not the radio-pharmaceutical approach but went through the instrumentation and technology approach. What do they

call that?

PARTICIPANT: Device.

MR. MALMUD: Device, the device approach. And if they went through devices, then it may have been seen as being a device in much the same way as a tomato is a vegetable rather than a fruit. It's because we say it is, not because it is.

And therefore, the NRC may have responded to that which came from industry in the way that the NRC usually responds to something directly from its source. I'm not attributing any blame to anyone. I just would like to be able to answer the question of my colleagues in a straightforward way so that we can reassure them that their practice of giving I-131 therapy, et cetera, will now be allowed to expand with application to Yttrium-90, MicroSphere, that's all.

CHAIRMAN CERQUEIRA: I don't have a good answer for that, Fred.

MR. BROWN: I think there's one --

CHAIRMAN CERQUEIRA: Yes.

MS. WARBICK: My name is Ann Warbick from MDS Nordion and it's exactly as you said. MDS Nordion represented TheraSphere as an implantable device and so it's a device, not a drug.

MR. BROWN: That's the answer.

MS. WARBICK: So that's the answer to your question.

MR. MALMUD: May I ask, did Nordion intend for nuclear physicians ever to use the drug as a therapeutic agent?

MS. WARBICK: In the early clinical trials in Canada it was used by a nuclear medicine physician in partnership with diagnostic radiology and other medical specialties.

MR. MALMUD: Thank you.

CHAIRMAN CERQUEIRA: All right, one last comment and then we will absolutely break. Jeff?

DR. WILLIAMSON: Shall we make our motion about --

CHAIRMAN CERQUEIRA: Yes, yes, we're going to the motion, yes.

DR. WILLIAMSON: Okay. All right, here's the motion; the ACMUI recommends that the Chairman of the ACMUI form a standing subcommittee to review 35.1000 licensing guidance as it is developed by NRC staff.

PARTICIPANT: Make recommendations on licensing guidance?

CHAIRMAN CERQUEIRA: Licensing guidance, okay. And training and experience would be part of

that. Do we have a second for that?

DR. NAG: Second it.

CHAIRMAN CERQUEIRA: All right, any further discussion? Should we call for a vote? All in favor?

(Aye)

CHAIRMAN CERQUEIRA: Opposed?

(No response)

CHAIRMAN CERQUEIRA: No abstentions? Okay, so Fred, if we could form the committee. Now, do we have -- I mean, we've identified one -- the MicroSpheres obviously belong in that category but are there any other things that are out there?

MR. BROWN: The two that are not IVB, and IVB has been around the table several times --

CHAIRMAN CERQUEIRA: A few times, right.

MR. BROWN: -- is GliaSite, treatment of brain tumors, the MicroSpheres, there's actually two products, and then the question of the Zevalin which actually is coming to you from us, actually.

(A brief recess was taken.)

CHAIRMAN CERQUEIRA: You're back.

MR. BROWN: I enjoyed it so much. No, actually I would like to say, you know several people have said, you know, if you're bleeding put bandages

on and I hark back to Dr. Williamson's comment early on that, you know, there should be an effective and active interchange between staff and the committee and I completely believe that that's true and support it and I think this is productive as long as we're making progress. And so, you know, I come from a school of knocks where this is how business gets done and then you're done with business and you move on.

CHAIRMAN CERQUEIRA: Right, and we could attack the SNM as well as -- you know, as the NRC, so you know no one is without fault here, but --

MR. BROWN: I think the interchange has been very healthy.

CHAIRMAN CERQUEIRA: Good, good. Now, we've covered, I guess -- so we still need to cover Sealed Source Model Numbers as License Conditions.

MR. BROWN: This is an issue that came up with a stakeholder. Ralph probably has some comments on it. I was going to provide the background so the committee would understand where we're at and the potential ways forward. I'll leave it at your discretion, whether you want to rely on the slides or if you'd like me to talk through it very quickly.

CHAIRMAN CERQUEIRA: Well, what's the desire of the committee here? Do you want him to

summarize it or go through the slides?

MR. BROWN: Okay, the very quick summarization is that Part 35 does not require individual sources to be listed on licenses. However, Part 30 does. Part 30 governs over Part 35 unless there's more specific requirement in Part 35. So in the licensing guidance that just came out, licensees will be required to list by manufacturer and model number either all of their sources or if they have multiple sources in a single device, then the device.

This is a change and it's a more burdensome way to do business than had previously been the case and it caused concern in the stakeholder community when we rolled this out. It's -- you know, it is what it is. There are other licensees that deal with this and the last slide talks about some of the ways that other groups of licensee types deal with it. Multiple seeds, for instance, in manual brachytherapy could be registered under a single device so that the licensee, the medical facility would have the device on their license and then you know, manufacturer XYZ could provide multiple seeds for that single device. Therefore, the medical facility wouldn't have to update their license every time a new seed came out.

All that would have to be done would be

the SSDR would have to be updated to reflect the new seed. That's one way this is done. Questions?

DR. WILLIAMSON: That's just not clear to me. Could you -- what device is there? We're talking about prostate implants there really isn't any device. There are the seeds. There are 18 different models of seeds manufactured by approximately a dozen companies.

MR. BROWN: Yeah, and one thing you could do is simply list all those seeds on your license application. That's one way. The other thing is that four instance, if seeds are provided in an applicator, then the applicator could have a device review and the manufacturer, distributor could provide various types of seed in that single applicator as long as they had listed all those seeds on the SSDR. I mean, that is a way to work through this cumbersome process.

DR. WILLIAMSON: So you're thinking a cartridge for example.

MR. DIAZ: Subir?

DR. NAG: Again, I think the same problem that we use loose seeds, I mean, when you're applying, you're applying for Manufacturer Y and tomorrow that same kind of seeds might be from Manufacturer X because of pricing reasons or other reasons and you don't want to change your license for that. I mean,

they're all equivalent seeds.

CHAIRMAN CERQUEIRA: Ralph and then Ruth.

MR. LIETO: Go ahead, Ruth.

MS. McBURNEY: In that case you would probably list all the manufacturers from which you plan to purchase those seeds.

DR. NAG: Tomorrow there will be a new manufacturer with seeds at half the price.

MR. LIETO: I think if I -- a lot of the problems in radiation oncology is that new manufacturers come out with new seeds and so forth and to go through the amendment process, before you can use that is really burdensome. And it really offers no additional health and safety. The intent is, I think as Fred pointed out, was originally that all you had to do was agree to use sources that were listed in the Sealed Source and Device Registry and now even though that's what's in guidance, we have this Part 30 overriding regulation and I'm wondering, one, should there be maybe a petition for rulemaking to change this. I didn't like the look of that. Or could this be handled as opposed to an amendment process, could it be handled via a notification process in that the licensee would notify the region or the licensing agency and say, "We want to use this new source in

Sealed Source Registry", blah, blah, blah, you know, for Part 400 sources.

And that way you don't have this maybe three-month plus delay in getting authorized to use it and so forth.

MR. BROWN: Yeah, there are three proposals there, all -- I mean, and I guess all I can say is it will take rulemaking to change Part 30 or rulemaking to change Part 35 to allow notification specifically for manual brachytherapy seeds or new sources and those are options. And anyone that wants to submit a petition for rulemaking can certainly do so. They get prioritized by staff resources available and I mean, that's basically -- the point that we're at is where on the list of priorities does addressing this problem fall?

You know, and both of those rulemaking changes are -- would have benefits. And I'm sorry, Ralph, the third thing that you mentioned, the last thing was?

MS. McBURNEY: It was to do it by --

MR. BROWN: Notification, that would be a 35.14 change to specifically override 34.32(g)(1).

CHAIRMAN CERQUEIRA: So Fred, help us out here. Again, we made another mistake in the

rulemaking for Part 35 in the sense that we couldn't anticipate all of these things, but we've all agreed that it's not an issue of safely. So, you know, in the rulemaking, like you said, prioritization and there's no short thing to do it. Is there any other means, I mean, between Ruth and the agreement states, counsel and you? Is there a way that we can implement the intent?

MR. BROWN: We've had several discussions on this topic and we --

CHAIRMAN CERQUEIRA: Right, and your best choice for that?

MR. BROWN: We have not found a way around this other than what I have basically on the slide, which is additional burden on the regulated community to work around it and demonstrate that burden to us so that it justifies rulemaking to fix it, but in terms of working around it without a rule change --

CHAIRMAN CERQUEIRA: But can't this committee initiate a rulemaking like we did for the authorized medical physicist and --

MR. BROWN: What you've provided staff is a recommendation that we send to the Commission as a proposal for rulemaking. It's not actually a rulemaking action at this time.

CHAIRMAN CERQUEIRA: So if you've got something that's quick and dirty like this, one little thing, I mean, do you have to go through the whole -- I mean, the Federal Registrar that's easy, but --

DR. NAG: Instead of having a new rulemaking, like it would all -- a source act, all equipment is source so that when it's made by a different manufacturer, yet it's an equivalent source, let it go through.

DR. WILLIAMSON: Why couldn't you say all interstial I-125 seeds listed in the SSDR.

MR. BROWN: The exact words up on the screen are listed, the source by manufacturer and model number.

DR. WILLIAMSON: But they are all listed in the SSDR by source and manufacturer number, right? So why couldn't you refer to that list in your license with just this code word?

CHAIRMAN CERQUEIRA: Yeah. Now did you talk to counsel about doing this?

DR. WILLIAMSON: About doing this?

MR. BROWN: Yes.

CHAIRMAN CERQUEIRA: And what did counsel say?

MR. BROWN: The guidance document is what

the guidance document is and it has counsel review and approval.

DR. WILLIAMSON: The guidance document?

MR. BROWN: 15.56 Volume 9 is where this is called out as a licensing requirement.

DR. WILLIAMSON: Is this a requirement for broad-scope licenses as well as specific scope licenses? And secondly, why is -- why do we have this problem today? How come we didn't have it two years ago? Part 30 has not changed, so why -- surely we weren't required in the past to do business this way. So what has changed that has put this new burden on us?

MR. BROWN: We revised the guidance which brought it to the attention of counsel that we weren't implementing our regulations as written.

PARTICIPANTS: What is the question, broad-scope licensees?

PARTICIPANT: They are required.

MR. BROWN: The interesting thing about broad-scopes, I think you need to look at the example license for broad-scope in the appendix for 15.56, Volume 9 and it appears that we've concluded that Part 33 has specific guidance that overrides 30.32(g)(1) by being more specific on authorizations for Type A

Broad-Scopes because I think if you'll look at the example license, it does not list all the sources individually.

DR. WILLIAMSON: Okay, so you're saying this is not a problem for broad-scope licensees?

MR. BROWN: That's -- the last time I recall looking at the sample license that's how I read it.

DR. WILLIAMSON: Convoluted.

DR. NAG: I would like to make a motion.

CHAIRMAN CERQUEIRA: Please.

DR. NAG: I make a motion that the ACMUI direct the initiation of a rulemaking process to fix it so that sources that are virtually identical or identical sources be covered under one umbrella or you know, one plan. We have to start the rulemaking process to fix this. It is a mistake that was unintentional and we have to fix it as soon as possible.

CHAIRMAN CERQUEIRA: Yeah, I think we should vote on it, and like Fred said, I mean, it's probably not going to get enough of a priority and so the regulated community is just going to have to face the hassle but I don't -- and counsel has already reviewed it and made a decision and once you've done

that, then you're sort of stuck. So do I hear a second on this motion?

PARTICIPANT: Second.

CHAIRMAN CERQUEIRA: Discussion? Yes, do you want to modify it?

DR. WILLIAMSON: A friendly modification that the ACMUI recommends that rulemaking be initiated to modify 35.14 to override 10 CFR 30.32(g)(1) to allow a more generic listing of interstitial seeds and sources.

CHAIRMAN CERQUEIRA: Okay. That's good. Staff has got that and, all right, do I hear a second for the modified motion? Sally, okay.

MS. McBURNEY: I just had question.

CHAIRMAN CERQUEIRA: Discussion?

MS. McBURNEY: We're just talking about for the seeds, not the big sources.

DR. NAG: Equivalent sources, any sources that basically are very similar and there is no essential difference.

DR. WILLIAMSON: Yeah, we are talking about manual brachytherapy sources. I think we're not talking about sources that go in devices like remote after-loaders and teletherapy units that have to be mentioned specifically.

MR. LIETO: But I think the intent is like cesium, iridium, those types of sources.

DR. WILLIAMSON: For manual brachytherapy.

MR. LIETO: Right, manual, irridium wires.

DR. NAG: I mean, the most common one now is 1-125 palladium. Palladium is now being manufactured by more than one company.

DR. WILLIAMSON: To date it's not regulated by NRC, at least at the moment.

DR. NAG: Right.

DR. WILLIAMSON: But it could be depending upon the success of their national materials program.

CHAIRMAN CERQUEIRA: So, Ruth, how do we want it?

MS. McBURNEY: No, I was just clarifying that --

CHAIRMAN CERQUEIRA: Clarifying.

MS. McBURNEY: -- we're only talking about manual brachytherapy, things that are not in a device.

CHAIRMAN CERQUEIRA: Okay, all right, any further discussion? Yes.

DR. VETTER: A question.

CHAIRMAN CERQUEIRA: Yes.

DR. VETTER: Is it even possible for

something in Part 35 to override a requirement in Part 30? So are we proposing something that's even feasible?

MR. BROWN: No, as long as there's more specific regulatory language in one of the subparts of 30, in this case, Part 35, that is fine, you can modify the higher level with a more detailed lower level.

CHAIRMAN CERQUEIRA: Okay, should we call the vote? All in favor?

(Aye)

CHAIRMAN CERQUEIRA: Opposed?

(No response)

CHAIRMAN CERQUEIRA: Abstained?

(No response)

CHAIRMAN CERQUEIRA: Good unanimous. Excellent.

MR. BROWN: One quick thing, just to point out to everyone, at your facilities, this requirement applies at the time of license application. So if you have a license today, as a 35.400 facility and you don't have all these sources listed, that's fine, it won't come into play until you go for another license application process. So just so no one walks out thinking they can't use a source not listed on their

license.

CHAIRMAN CERQUEIRA: All right, what's next, Fred?

MR. BROWN: The next presentation was one of the two remaining, manual brachytherapy issues. This topic actually came up at two of the stakeholder meetings and what I did is I provided a copy of the new rule language 10 CFR 35.40(b)(6) written directives for manual brachytherapy and this didn't really change significantly. The basic structure of the written directive is as it was. Before implantation the AU identifies a treatment site, radionuclide and dose and then -- you don't have it?

CHAIRMAN CERQUEIRA: It was a separate handout that was -- packaging manual brachytherapy.

MR. BROWN: There's two handouts done Friday night at 5:00 o'clock that weren't pre-distributed. Packaging comes after manual brachytherapy issues.

DR. NAG: We got the packaging, we got this one but not the other one.

MR. BROWN: All right. Basically, if you can work off what's on the screen for the sake of time. The second part of the written directive is after implementation, after implantation but before

completion of the procedure, the AU records the radionuclide treatment site, number of sources and then the dose -- total dose or the total source strength and exposure time. And as I said, it's not a big change from what existed before.

What came up at stakeholder meetings, though, were several comments that I thought were significant enough that I wanted advice. I wanted advice from the ACMUI so I'm bringing them to you. One comment which several people made at two different stakeholder meetings was there's an inability to identify exact organ boundaries during implantation. So for instance, on a prostate implant, when that is -- the needle is in the patient's body, when exactly at the finite detail am I in the prostate and when am in the area of the prostate?

The second question that came up that's really related to that is, if you're at a teaching institution and you look at the skill level for someone in their initial treatments, you know, the ability to be in the organ boundary may not be as great as after experience.

The third issue was -- really deals with the when do you record the post-implantation information? Is it while you're still in scrubs in

the room? That would interfere with treatment obviously, and the final comment and I put some questions marks after it because I'm not sure I correctly heard the question and so I'm not stating it as fact but it sounded like someone said that on occasion as needles are withdrawn from the patient, you may have seeds drop out of the needle on withdrawal, so that one is kind of fuzzy.

DR. NAG: Yeah, I think I can explain that.

MR. BROWN: Okay.

DR. NAG: Basically, you have the seeds inside the needle. You put it in the prostate. When you're withdrawing, one of the seeds may not have been dropped into the prostate and as you're withdrawing it, it may drop into the path when you're coming out. So legally you are not within the prostate but basically those are accepted procedures. I mean, they have not problem with that and that can be solved by saying that seeds that were dropped within the organ or that were implanted within the organ but migrated are not considered mis-administration.

We have under Part 35 a provision that seeds implanted into the area but that migrated do not constitute a medical event or mis-administration.

That is acceptable.

DR. WILLIAMSON: It is also possible that it is by clinical intent that not all of the seeds are implanted directly into the prostate but into the peri-prostatic tissue depending upon how the planning target volume or clinical target volume is drawn. Often, especially around the lateral and superior margins of the prostate, they'll add margin full well knowing, you know, that the seeds move and to insure coverage, they'll put some seeds intentionally a few millimeters outside the prostatic capsule.

DR. NAG: And that's only for prostate. In other organs you are not even sure exactly where the tumor was, especially if the tumor has been removed. So you put it in the broad area of where the tumor was. So, you know, if there is not a precise -- you cannot precisely say -- you cannot precisely say I implanted in Organ X, it's Organ X and some area around Organ X. So if an area implanted in the immediate vicinity of that organ that is within that organ and that is not a wrong treatment site.

CHAIRMAN CERQUEIRA: So when do you switch from the practice of medicine and the vagaries of clinical medicine into mis-administration or --

DR. NAG: Because the wording of mis-

administration is the wrong site. And it depends how accurately you call the site, you know, depends on administration. Say you put the injected material into, you know, Organ X. And is the Organ X boundary here or is it one millimeter outside or 10 millimeters outside? So, you know, it's just like saying. Basically I don't think those are -- they're not mis-administration at all.

DR. DIAMOND: Also it's possible to put a seed in the correct site and then the seed to migrate to a different site so occasionally you'll have a seed that you intended to place in the prostate was in the prostate, made it's way into a small vessel and winds up in the lung.

DR. NAG: Right.

DR. DIAMOND: There's no clinical ramifications to that.

MR. BROWN: Right. And that's specifically addressed in the wording for medical event, reporting requirement that migrated seeds are not a problem. If we could skip the next slide and go to the final slide.

CHAIRMAN CERQUEIRA: So it sounds like there is not problem, at least from what the committee is telling you, right?

MR. BROWN: Well, the issue is that there are members of the regulated community who struggle with the words in the regulation and the words which were the slide that we skipped, were was is a treatment site, what's the completion of the procedure and is there an issue with this dropping of seeds. And my basic questions to the ACMUI were if it's -- if some members of the community are quite comfortable with the safety and regulatory issue correct interpretation but others are not, is that indication that some kind of guidance would be appropriate and if some kind of guidance would be appropriate, would you have a recommendation on where that guidance came from either a preface of medicine type guidance or a regulatory type guidance?\

DR. NAG: I think a guidance is appropriate and especially for permanent implant. That is the question I get from many radiation oncologists, you know, when do you call -- you know, when is the implant over, because the implant is continuing for a long time. What is the right organ? You know, I think those can be qualified by a guidance by, you know, intending to implant the organ, plus some margin. Those -- I think those can be just added on in a little more detail and most of the

brachytherapy books will have some idea on how to do the implants.

DR. WILLIAMSON: I think you have to recognize though that there is limited precision and geometric accuracy that the systems, image guidance systems that we use for delivering prostate implants and by extension other sites too, they cannot deliver seeds with one or two millimeter accuracy, so a small number of seeds that lie a few millimeters outside the identified clinical target volume is certainly part of routine practice.

Now, unfortunately if your Office of General Counsel gets hold of this, you know, there could be a problem because even if one seed is outside that boundary there is going to be at least some small bit of tissue right next to the seed that probably is going to get a dose 50 percent in excess of the amount that would have been given had the seed been implanted in that boundary, but the problem is, you know, many, many prostate implants that are absolutely properly done from a clinical perspective would be called medical events and obviously, that is not your intent.

So, you know, you have to take into account the precision of the delivery systems that are available and recognize, you know, that they don't

have an absolute accuracy much better than about five millimeters.

CHAIRMAN CERQUEIRA: So, Neki, do you feel -- what they're saying is, "Trust me, I'm a doctor". Do you feel comfortable with that?

MS. HOBSON: Well, yeah, I do. I think the medical community does a really good job of self-policing. I mean, you guys have all these, you know, boards and committees and you've got a lot of oversight within the medical community.

CHAIRMAN CERQUEIRA: Practice of medicine.

MS. HOBSON: And I think I'm comfortable with that. If there are huge problems that arise, it will come up and the medical community will -- I mean, that's how medical practice changes over time is that someone does it one way and it works better, so everyone follows that lead.

DR. NAG: On the other side of that, if a huge error is made, for example, instead of putting it in the prostate, putting it the rectum which is only two millimeters away, you're going to end up with a mistake, then you end up with a malpractice, so I think we're automatically policing ourselves that we are -- you know, the imprecisement that is there is in an area that would pose it no harm, and in the area

where no harm, that you want to have a position that you don't want to go beyond the target area.

CHAIRMAN CERQUEIRA: So, Fred, do you still have questions?

MR. BROWN: Well, someone made -- I think Jeff made the comment about you know, the legal compliance with the regulations, and the regulations are clear that the treatment site has to be identified and it's the treatment site as defined on the written directive and the treatment site is really an issue of practice of medicine. The NRC doesn't define it.

All I'm still kind of trying to pin down is, is this the sort of issue where someone could add value to help AU's understand how they should write treatment sites for efficacy of the treatment and compliance under the regulations. And if you thought so, as a committee, where you would point that, should you point me to go off and do that or would you like to think about it and come back or --

DR. WILLIAMSON: Well, I think these are really difficult questions. I'll point out another one that occurs. The completion of the procedure is not specified. Now, some NRC personnel that I have talked -- I recently wrote a review article on this for the Journal of Brachytherapy on the interpretation

for medical event for prostate implants, so I discussed this with a couple members of the staff. And you know, there's one view that the end of the procedure is the time you insert the last seed and once you've inserted that last seed, you can no longer write a revision to the written directive.

So here's the problem is that the dose delivered by this implant is not known maybe for as long as a week after the implant, maybe three weeks. It depends on the scanning protocol at the different institutions. Some institutions do a post-treatment CT scan the same day. Others prefer to wait until prostate edema has resolved and do it two weeks later, and maybe a week after that the final treatment plan will be available and it is well-known that the minimum dose, the D-100 dose, can differ by as much as 20 or 30 percent from the minimum dose intended.

The D-90 dose usually doesn't -- you know, differ as much but it can be easily 10 percent and 20 percent would not be out of line. There's literature documenting series of implants from a Memorial showing that the minimum dose which can result from just the perturbation of a single seed by a few millimeters can change as much as 40 percent from the dose intended. So you have a problem that because of the limited

precision of the delivery device, the fact that prostate edema and other factors intervene to change the implant geometry and you're using a different imaging modality to do the final dosimetry compared to the one you used for delivery, you do not have control over what the final dose will be.

So you know, you could call all these mis-administrations or medical events, but again, this is -- you're going to be actually culling out, I think, a large part of the practice if you interpret this too rigidly.

DR. NAG: I think that --

CHAIRMAN CERQUEIRA: Ralph had a comment.

MR. LIETO: Yeah, I think, you know, in defense of Fred, it's -- I think what they're looking for is obviously there are licensees out there that are sensitive and that if there are medical events, they want to know where's the threshold for reporting. And I don't think there's an objection to what both Dr. Williamson and Nag are saying. I think what he would like is let's give them the guidance, if it's a two-week period that you establish as completion of the procedure, then maybe that's what they should have in their procedures and also what they're going to establish as the treatment site. And I think that's

what he's asking for is -- because there's not anything out there to give licensees to say, "Here's your threshold and when you're outside this threshold that's --

DR. WILLIAMSON: I wasn't attempting to criticize Fred. I was just pointing out that if you adopted this sort of narrow, everyday language interpretation of end of the -- or completion of the procedure, there actually will be very large problems, whereas, if you were to say completion of the procedure is completion of radiation, that would obviously allow an enormous time window during which the authorized user could revise the prescription and select the isodose, you know, that he or she thinks best covers the treatment and it may or may not be exactly the same one that was prescribed initially.

So just this sort of simple identification deciding legally when the treatment begins and is over can have enormous implications for how many medical events you're going to have reported to you and their significance or insignificance.

CHAIRMAN CERQUEIRA: David?

DR. DIAMOND: I understand the concerns that you raised. I do not off-hand know of a simple way that as a guidance document these issues can be

clarified with any sense across the board in the therapeutic community as being satisfactory. And therefore, my recommendation would be to go and pursue no further action on this. You're not going to be -- there's no way you're going to be able to make all the different practitioners happy with the different ways that things are done and I think you can really put yourself into a pickle, so I disagree with any process to go ahead with any guidance document on this.

DR. NAG: On the other hand --

CHAIRMAN CERQUEIRA: Ruth, from an agreement states' perspective, how do you handle the agreement states?

MS. McBURNEY: I think that we have some latitude on the procedures when they put treatment site. I mean, as far as completion, I'm not sure. Of course we haven't implemented these particular rules at this time but for the permanent type implants, it would be at the end of the decay.

CHAIRMAN CERQUEIRA: At the end of the decay, yeah.

DR. WILLIAMSON: That would be, I think, what the community is assuming.

MS. McBURNEY: Yeah.

CHAIRMAN CERQUEIRA: Dick, do you have any

feelings on this?

DR. VETTER: I'm not aware of any specific situations where people are having trouble interpreting. Obviously, there are some, but I'm not personally aware of any.

MS. McBURNEY: No, we haven't had that.

DR. VETTER: They understand that the end of the treatment is the end of decay. There's -- you know, seeds do migrate but the regulations cover that. The dropped seeds thing I don't really know what -- I'm not sure I understand whoever used that word. Certainly seeds will follow a needle out but that's the prostate pushing it out. It's not a mistake that the radiation oncologist is making. So I don't know exactly what that third bullet is getting at.

CHAIRMAN CERQUEIRA: So I think the sense of the committee having polled most of the people that are either doing it or are involved in the regulating it, it seems like you've got some comments that, you know, do bring up some issues but I'm not sure that you can come up with the exact language to identify it. Any new comments to make on this?

DR. BRINKER: Just one and this is obviously, from a foreigner who doesn't do this sort of thing but in cardiology, even in intravascular

brachytherapy, there's a litany of literature about target areas, marginal areas, injury areas, et cetera. And it just blows my mind that nowhere in the urologic cancer literature is there -- there must be literature on what would be considered appropriate or usual distribution for treatment sites.

And if there isn't then it would be a short -- I think a short thing to develop a summary paper on what has been published without the specific purpose but gives the kind of information that would be something that people could be referred to. So I actually think it would be a good idea to have -- there must be some understanding of what's right. You're saying that everybody knows it, they just can't write it down.

DR. WILLIAMSON: There are limits, you know, and there's sort of a spectrum of cases ranging from sort of normal to something that's clearly out on the tail as Dr. Nag mentioned. There are cases on record which have been, I believe, pursued as mis-administrations where a large fraction of the seeds were implanted in the bladder base instead of in the prostate and that's a very clear-cut case where, I think regulatory action would be justified.

You know, I actually think some guidance

could be put together --

CHAIRMAN CERQUEIRA: But Fred needs concrete things. Like you said, if it's in the rectum which is close by, it may or may not be a problem. I mean, but how far, what sort of --

DR. WILLIAMSON: I think some rules of thumb could be give and we could probably --

CHAIRMAN CERQUEIRA: There's nothing in the literature --

DR. WILLIAMSON: If I could finish.

CHAIRMAN CERQUEIRA: Get to the point.

DR. WILLIAMSON: All right, yeah, I think that the guidance could be written, I think, with a certain vagueness that's involved and probably a role carved out for a medical expert to make judgments on a case by case basis where it really is marginal and I think, you know, just to emphasize to the inspectors and everybody else in NRC involved with this the limits of the current procedure so that if they see, you know, that some seed is implanted five millimeters away from where the intended position was, they understand that that's a high likelihood in any properly executed prostate implant.

CHAIRMAN CERQUEIRA: But I can see Dr. Brinker coming back, you know, in a few months telling

us that a cardiologist, once he gets it into the coronary, then it's not an issue as to whether he got the right area or not.

DR. WILLIAMSON: What if it moves five millimeters during --

CHAIRMAN CERQUEIRA: They don't leave it in there permanently. Okay, one last comment and --

DR. WILLIAMSON: Then it could move and then it would be a mis-administration, so they actually have the same problem. Whenever you use image localization of an anatomic target volume, you are going to have this problem where you do not have an imaging modality that you can use to actually -- to do some quantitative verification of where the seeds are. The problem doesn't exist because there's no way to evaluate it.

DR. BRINKER: But you could actually say that in scientific terms if you have on a large number of cases done at a reasonably good institution or a number of reasonably good institutions, the distribution away from the central target, retrospectively, you could define what is probably clinically acceptable within one or two standard deviations.

DR. WILLIAMSON: I think one could give

some rough guidelines of what is clearly within the limits of current practice, what are the gray areas and what's some rough rules of thumb of what's clearly outside and would be fair game for being administration, I agree. So you know, I don't quite agree with Dr. Diamond. I actually think so many of these procedures are being done that if we just ignore this issue, it will come back to bite us.

CHAIRMAN CERQUEIRA: Ruth, one last comment and then we have to move on.

MS. McBURNEY: Yeah, I don't think the inspectors are going to be looking at the little narrow details and it would only be if it went to the area of medical event.

CHAIRMAN CERQUEIRA: I don't think this is one area where we can actually make a motion or take a vote on it. I think you've gotten a sense of the discussion from the group. Fred?

MR. BROWN: Yeah, but I think actually it was good to sit on this side of the table for this particular discussion. I guess the one thing that I would offer, though, is if after this conversation, you know, someone comes up with some good ideas or someone is starting down a path that we could communicate after there's a product, then if at the

next committee meeting or between meetings, you communicate with us, that would help me deal with inspectors who are going down a path maybe than --

CHAIRMAN CERQUEIRA: Dick wants to make a comment.

DR. VETTER: One real quick comment, we haven't talked about trainees, the implication that maybe trainees weren't doing as well. But they're actually practicing under direct observation of the preceptor. They're in the same room and the relation with trainees is they have higher fluoroexposure. It has nothing to do with the implant itself. They just take longer and so their fluoroexposure is higher and that's in the literature.

CHAIRMAN CERQUEIRA: We really do need to move. Fred?

MR. BROWN: The final one is Packaging Brachytherapy Seeds. And the first slide, yeah, basically goes over what happens now. The Sealed Source and Device Registry, which is covered in the new rule, you're all familiar with it, what we are requiring vendors and distributors to do is not only have a registration for individual seeds when they produce a new seed or modify their seed, but we're also requiring device reviews if the packaging -- and

packaging in this case could be a Mick applicator, it could be a strand, either an absorbed strand or otherwise. If that packaging could effect the spacing of the seeds at the time of implantation or seed integrity and integrity is usually an issue of temperature or pressure during the loading or encapsulation of the seeds, we're requiring a separate review.

Now, not all jurisdictions are doing that. And so what I was interested in is feedback from the perspective of the committee about whether individual seeds received in bulk and then handled individually represent more or less of a safety problem than for instance strands or pre-loaded, pre-sterilized seeds and also if in the opinion of the committee, the spacing was a significant issue or temperature, pressure mechanical forces on seeds and strands was an issue in your knowledge or opinions.

DR. NAG: A lot of questions in one. If you go one by one, I can give you some idea, but I think it's best if you -- if you are just having different spaces and different length of spaces, I don't think that it is an issue that NRC should go into. In terms of sterilization, we have a different type of sterilization, steam sterilization,

autoclaving for different lengths of times and these are not things for ACMUI to go into. So I think it's best to be handled at -- unless you are making a new device per se and a new device would be when you are sending out the radioactive material back in differently. Otherwise, you know, the seed spacing, we sterilize all the time and that's our normal practice.

DR. WILLIAMSON: Well, I'm very confused exactly what the scope of the question is. I think there are at least three different things, maybe, I am hearing you talk about. One is, you're concerned about the seeds in Vicryl suture, the Model 6720 sold by Amersham (phonetic). As I understood that had a separate FDA clearance. It's sold as a separate product. It has been tested to insure that the seed integrity is not violated by the procedure of annealing the seeds in this Vicryl strand to make it rigid, so I'm not sure why there is a particular issue with that.

The second cluster of issues I'm imagining but perhaps I misunderstand is, are you referring to vendors who supply a service to licensees by pre-packaging the seeds in needles and in cartridges and so on to minimize the need to load these things in

sequence?

MR. BROWN: That's one aspect.

DR. WILLIAMSON: Okay, so you're concerned about whether the process of this vendor performing the activity that the licensee used to perform themselves would be causing a problem. Okay, and so I guess my question would be, if you feel that the individual licensee can take these seeds and put them into a cartridge for use in a Mick loader or some other device, why would you feel uncomfortable having a vendor do that, as long as they're licensed to receive --

CHAIRMAN CERQUEIRA: And they had quality control steps in place.

MR. BROWN: Yeah.

DR. NAG: Especially, the vendor is doing it hundreds and hundreds of times, they will be even better at doing it than ones doing it for the first time.

DR. WILLIAMSON: This is certainly one issue.

CHAIRMAN CERQUEIRA: Ruth and then Ralph.

MS. McBURNEY: I think it depends on whether that original evaluation of those seeds was done with those temperature ranges and chemical

reactions in mind. When you package them all together and there is an issue of impact of temperature or pressure, or chemical reaction, then perhaps it should be re-evaluated under the Sealed Source and Device Registry to take those into account.

DR. WILLIAMSON: I'm surprised. Is the Model 6720 not included in the Device Registry, SSDR as a separate product?

MR. BROWN: I can't speak to all of the products and I didn't really want to speak to any actually.

DR. WILLIAMSON: Yeah, I'm just using it as a prominent example. I'm not trying to pick on them. I think now there may be at least one or two other companies. But I believe it is. I'm sure it had a separate 510(k).

MS. McBURNEY: That is the current practice.

MR. BROWN: Right. The current situation is that we, in many states, require this and the question is, since other states haven't required it, is there a safety basis for our current practice or are we not where we should be and that's what I wanted the feedback on. And one of the interesting points is the assumption of QA.

You know, if an individual licensee is doing this, it's essentially under the supervision of the AU in accordance with the licensing procedure. If a radio-pharmacy is doing it, then it's under the Part 32 QA program, but someone in between, what would your thoughts be on an appropriate level of QA.

DR. WILLIAMSON: Well, I think that's a reasonable question. That if you get a needle loaded by a commercial company with some presumed sequence of spacers and active seeds, what assurance do you have it's loaded properly. I think an institution that really has good quality assurance with audio-radiograph or radiograph those needles to insure that they're in the proper sequence but you know, there is no rule in Part 35 that requires end users to do that kind of a check. I mean, it's part of current practice standards but I don't believe it is addressed -- if a user take seeds and puts them into a needle themselves, I don't know that there's a specific rule which requires a redundant check of that loading sequence.

DR. NAG: No.

DR. WILLIAMSON: I mean, there's general requirements that you deliver to the patient what you say or what is stated in the written directive that

it's delivered properly.

MR. LIETO: I mean, the treatment plan, I think is what Jeff's referring to. I guess my question was, it appears from the slide there that you're asking about changes in the Sealed Source Device Registry and I guess that question, I would say, no, that you don't really -- that that would not be appropriate to require changes in that just simply because you're going to get pre-packaged seeds and spacers and strands. But I would agree that there needs to be documented QC procedures that whoever is preparing these has some means of verifying that they are packaging them in accordance with the authorized user's request or directive.

DR. WILLIAMSON: So I would say, too, that, you know, if a -- when a licensee receives loose seeds and loads them into a cartridge or needle themselves, that is a normal variant of usage and I don't think there's any evidence that that subjects the seed to any kind of corrosive chemical or excessive pressure. You know, as far as I know, I have -- I am unaware that that causes any problems. So if a commercial intermediary, some in between source vendor and the user is hired under the guidance of the licensee to take over some component of routine

source preparation that's within the limits of normal practice and which normally a licensee would do themselves, I'm not sure that that's necessarily an NRC concern. It seems to me it's an acceptable variant of clinical practice.

CHAIRMAN CERQUEIRA: Any other members have any comments other than Jeff?

DR. WILLIAMSON: Well, you wanted some suggestions about calibration, too.

MR. BROWN: Well, actually, yeah.

DR. NAG: The next slide.

MR. BROWN: Yeah, the next slide goes to the issue that's actually come to us from a large calibration lab and that is that in the revised Part 35.400 licensees are required to calibrate the sources unless they rely on the manufacturer's calibration or the results of an AAPM certified lab, and the fundamental problem is that if an intermediate company loads some of these devices, there's absolutely no way to do individual seed calibration after the loading at the facility of use.

So you're left in the position of how do you insure continuity or traceability of the original vendor's calibration to the point of use.

CHAIRMAN CERQUEIRA: Jeff?

DR. WILLIAMSON: Well, the first thing to my knowledge all of the vendors supply NIST-traceable calibrations for all their seeds, so that is not going to disappear, you know, after they're loaded into a cartridge, that cal. So I think the -- unless one had some experimental or novel seed that happened not to have a NIST-traceable calibration, I don't think this issue would arise because the seed does have a NIST-traceable calibration. It comes that way from the original preparer and the certificate would follow it to the how should I say, the package, and would, I presume be included along with the material that the end licensee receives.

CHAIRMAN CERQUEIRA: But once the package is opened and the seeds are manipulated, how do you tie the seeds to the calibration record?

DR. WILLIAMSON: Well, this is a problem that could occur for the licensee, too. You receive a Vicryl suture which is -- along with its certificate and you take it out of the package, and you might have, you know, 10 other stocks of seeds. How do you assure that? The same problem exists at the licensee level as it would at the vendor level. I'm not sure that the problem is complicated particularly by the fact that there's a third party involved. You know,

this is a difficult problem. There are several suggestions that have been made in the literature, how to deal with it.

There are some calibration apparatuses that can be used that maintain a sterile field for putting the Vicryl suture into. Another common practice that licensees often use is to order a separate container from the company of loose seeds that have the same batch number as the seeds that are in their Vicryl suture so that they can check the calibration using that sample of seeds.

Others have developed variance of the calibration procedure that take into account the additional tenuation in the wall of the needle or, you know, the package essentially that the seeds come into. So there are different strategies that can be used for institutions that want to verify the seed strength. And so then they would use something that's analogous to a geometry correction factor used in nuclear medicine when the preparation of the radiopharmaceutical deviates substantially from the NIST standard ampule geometry upon which the dose calibrator settings are based.

I don't know if this is helpful.

MR. BROWN: Well, where we're left with is

deciding whether the rule, you know, as written and implemented, which does require the calibration of the seeds and if the licensee relies on the manufacturers, then the expectation is traceability. The fundamental question for the committee is, does the situation with repackaging represent a compliance issue in the opinion of the committee.

CHAIRMAN CERQUEIRA: Dick?

DR. VETTER: The seeds themselves are traceable to NIST, that's correct, right?

DR. WILLIAMSON: That's correct.

DR. VETTER: So, I mean, an individual seed not the package.

MR. BROWN: No, no, the individual seed is not serialized or --

DR. VETTER: No, I'm sorry, I meant -- I didn't mean each individual one but when you purchase a quantity of seeds they are manufactured in such a way that that -- one of them has been calibrated.

MR. BROWN: Or maybe all of them.

DR. VETTER: Or maybe all of them but that calibration then is traceable to NIST.

MR. BROWN: Yes, and the issue is how do you tie the calibration record to the seeds.

DR. VETTER: Okay, that's keeping the

paperwork straight.

MR. BROWN: Yes.

DR. VETTER: Ultimately the seed ends up in the tissue whether it was surrounded by suture material or not, it ends up in --

MR. BROWN: Right, and the issue here is as a licensee if you have multiple shipments of seeds, it's within your control and ability to segregate the boxes and keep the shipping papers with them and the records. You know, in the regulatory environment when we have intermediary groups, was it the expectation of the committee in giving advice on this new rule, that people doing these loading operations would have to independently perform calibrations that, you know, under the labs, or that they would establish traceability programs in-house under their license that would obviate the need for an individual licensee to deal with this issue after the fact.

DR. WILLIAMSON: I think they should do that latter.

MS. McBURNEY: The second. Yeah, that they need to establish a program for that.

DR. WILLIAMSON: That insures the paperwork doesn't get mixed up.

MR. BROWN: Very good. Thank you very

much.

CHAIRMAN CERQUEIRA: Thank you. I guess the next item is update, recommendations for the Spring 2002 meeting and I guess Angela is going to give us an update. There are minutes in the book from the last meeting and I guess one of the things we should always do is, you know, approve the minutes at the beginning of the meeting, which is kind of standard policy. And Angela, I think, you know, you and I worked on the minutes of the meeting awhile back. We probably should get it out to people once they're finished.

Now, is there a reason that we couldn't do that? Does the NRC prohibit?

MS. WILLIAMSON: I Believe that a copy -- I thought that a copy was forwarded at least to you. If it wasn't then we'll have to --

CHAIRMAN CERQUEIRA: No, I did get -- you know, you send me the version and I kind of made changes and we worked on it, but once that's done, we should get it out to the committee members.

MS. WILLIAMSON: Okay.

DR. DIAMOND: These summary minutes are very well done, very cogent and very useful and it's a shame that this morning was the first time I saw

them.

MS. WILLIAMSON: Okay, well, I can make -- definitely change that procedure and get the minutes forwarded to the committee.

DR. DIAMOND: The summary minutes.

MS. WILLIAMSON: The summary minutes, correct. I won't spend a lot of time on this because we basically all know the outcome of this action, but for the edification of everyone here, I'll quickly go over it. And what happened, I have to go back to the October 29th, 2001 meeting because what happened is at that meeting ACMUI made a recommendation to amend what was at that time the current Part 35 so that existing medical physicists would be granted approval to practice in a modality for which they had the appropriate training and experience. And what happened with that recommendation after NRC staff considered it, NRC staff realized that we needed to hold off on answering that recommendation, actually have the committee revisit the recommendation at the next meeting, the spring 2002 meeting.

Well, as you know, the spring 2002 meeting actually happened in February and this issue was revisited under a topic called Board Certification and under that topic the motion was restated and basically

the motion was stated to say the committee should -- the committee made a recommendation to revise what was then the existing Part 35, revise the training and experience requirements in the existing Part 35 but you did it in -- you basically did it -- pardon me.

What you did was, you agreed to set up a subcommittee to visit this issue in depth and to come up with some specific recommendations to the staff to amend the training and experience requirements. And of course, that subcommittee did meet on June 21 and the ACMUI met in tele-conference meeting that July the 8th to discuss the June 21 recommendation. And what happened is that you formed your recommendations and you forwarded them to the NRC staff and what we did with your recommendations is we posted them to the website. The training and experience recommendations that you made, we did post to the website and of course, you learned at one of the earlier briefings that your training and experience recommendations had been forwarded to the Commission along with an Options Paper that the Commission directed the staff to prepare.

So, I said all that to say this; your training and experience recommendations have been forwarded and will be considered and so that is the

status of that action with regard to that recommendation that you initially made in October and refined and discussed in a subsequent meeting.

Are there any questions? I think we've kind of revisited this to death already earlier.

DR. WILLIAMSON: You're talking about the October 29th, 2001 recommendation on 35.57, the grandfathering clause?

MS. WILLIAMSON: Well, that whole issue was revisited. We didn't actually forward -- we didn't forward you a response to that because we felt that it needed to be addressed further. So, we addressed it -- you actually addressed it again at the February meeting and when you restated the motion and you made the motion a little bit broader at the February meeting and what ended up happening, as you well know, is that a subcommittee was formed.

CHAIRMAN CERQUEIRA: So I think the subcommittee kind of dealt with most of the issues and --

DR. WILLIAMSON: I don't know that we really dealt adequately with the 35.57, the grandfathering clause. I don't think we supplied an interpretation, so actually that is still possibly a problem, which maybe we should carefully consider.

PARTICIPANT: That was not part of the subcommittee's charge.

MS. WILLIAMSON: No, that actually wasn't but that's what ended up happening with it.

DR. WILLIAMSON: So I actually think that the staff should think about 35.57 in relation to the existing regulation that's on the books and the proposed ACMUI subcommittee version and see whether, you know, there is any possible problem in terms of restricting the supply of authorized personages available.

MS. McBURNEY: I think that the new rules will take care of that because the medical physicists will be -- the ones that are on licenses now will be grandfathered in and then the additional training requirements are under the new rules. So I think that that will be covered.

DR. WILLIAMSON: I think it might. Actually, yes, if Board certification remains the primary vehicle for shouldering most of the burden of credentially these individuals, you know, then, there's a reasonable requirement for acquisition of supplementary training should work out, but -- so it wasn't addressed directly is my point.

MR. BROWN: I'm sorry, Ralph brought up

earlier that there was an issue with RSO qualifications in Region 3 and hopefully the grandfathering was primarily an issue with an RSO -- RSO's. And we're dealing with question and answer space with the essential concept that a licensee can have an RSO who is the primary person to run their program in accordance with the provisions for RSO's but that that person may require expertise from other members of the licensee staff for some of the more devices with which they are not familiar. And that's, we believe, covered in the existing rule and we're documenting that in Q and A space and we'll share that with you as soon as we have it, and that may address the concern with grandfathering, the underlying concern about licensees being able to have access to the right resources to meet the rule.

MS. WILLIAMSON: Okay, and then another recommendation that was made at the February meeting, this recommendation is closely related to the previous recommendation in that its purpose was to preserve Board certification as a primary pathway for certifying users. And that -- in that recommendation the ACMUI recommended that the Commission retain the training and experience requirements for uses under Part 35.600 as well as for all categories of

authorized users until such time that a rulemaking initiative could restore Board certifications as a primary pathway.

And you all probably know that in response the Commission did agree with that recommendation and as a result sub-part J is being retained for two years at which time it will expire in 2004, so the new regulation went into effect October 24th of this year. So in two years, October 24, 2002 (sic), sub-part J will be deleted and that's basically it with the recommendations as far as the last meeting.

CHAIRMAN CERQUEIRA: Although I guess one of the things that we had wanted to do was the sub-committee report that is that would deal with the problems that were presently in the current revision. We wanted to put that on a fast track which is why Dr. Vetter's committee really, you know, spent a lot of time to get it done and I asked the question early but maybe Roger could comment. You know, what are the chances that this rule that's before the commissioners now will be implemented in a timely fashion within, you know, 2004?

MR. BROWN: Well, I'm glad you came back to that because what's before the Commission is an options paper to proceed with rulemaking. As we kind

of talked about earlier, you can't just change a rule with a flick of the fingers once you've set it in place.

So if the Commission agrees with proceeding with the rulemaking, we anticipate that that would be completed within two years prior to the expiration of sub-part J and we'd, you know, do everything to make that happen. The bigger issue is in the case of the agreement states, as we discussed earlier, that we would be in the position where the new requirements would be mandated a year after the revised requirements came out and they'd have to do a two-step thing and that -- as you'll see in front of you, that issue is identified but we don't know how to resolve it at this point and it would have to be done in the rulemaking process.

CHAIRMAN CERQUEIRA: But getting back to my question, can we make -- you know, again, I understand rulemaking is more than just the training and experience requirements but the committee, the sub-committee had a pretty detailed description.

MR. BROWN: Right.

CHAIRMAN CERQUEIRA: So once the Commissioners sign off on that, what else is going to really be needed?

MR. BROWN: Legally that process -- that would serve as essentially a proposed new rule that would go out for public comment. We'd have an opportunity to address some of the concerns that were discussed here earlier this morning, get stakeholder comment on it.

CHAIRMAN CERQUEIRA: Just like we did for Part 35. We started that in `98, I think the Federal Registrar Notice, and so here it is October 24th, 2002, so it's four years.

MR. BROWN: It is accelerated because we were -- we would be at the point where we'd have a -- and this isn't my area of expertise, like many of the things I discuss, some might wonder what my area of expertise is, but we have a rulemaking plan now which is something that could take years and years to get to the point. So the effort that you undertook so accelerated the process many years and we have a very -- a product that should be very close to being implementable with few public comments.

CHAIRMAN CERQUEIRA: Dr. Vetter is fairly impatient, you know. He did his end, now, he wants to know why the commissioners aren't jumping on this and what can this committee do to facilitate the process is my question.

MR. ESSIG: I don't know that there's anything in particular that the committee can do to facilitate the process. You've given us your recommendation. It's now at the hands of the Commission.

CHAIRMAN CERQUEIRA: At the commissioner level, right, and their staff people have reviewed it and have favorably given it their blessing. It now goes onto the commissioners.

MR. ESSIG: And they will dictate to the staff then via staff requirements memorandum, what they want us to do because we have outlined three options in there as you've seen if you perused what I gave you earlier. By the way, the EDO did sign that out today, so the copy --

CHAIRMAN CERQUEIRA: EDO is?

MR. ESSIG: Executive Director for Operations.

CHAIRMAN CERQUEIRA: Which means it then goes to the commissioners.

MR. ESSIG: Yes.

CHAIRMAN CERQUEIRA: And they have how many days to act on it?

MR. ESSIG: They have as long as they need.

CHAIRMAN CERQUEIRA: Right, but I think this is the point where Dr. Williamson usually comes in and we need a motion to --

DR. WILLIAMSON: Well, I would like to ask, if the commissioners signed off on it tomorrow, what's the minimum time frame for getting a rulemaking completed? That's really, I think, what the question is.

MS. McBURNEY: Will this one have to go to OMB? I mean, that takes awhile.

CHAIRMAN CERQUEIRA: Mr. --

MR. BROWN: Yeah, I apologize, because you're catching us and we're stuttering over here and we don't have the definitive answers for you. It has been evaluated by the people that are supposed to know and they're comfortable that where we're at now with an answer from the Commission in the next couple of months, we'll be able to move forward and based on all the work that you guys have done, that the comments shouldn't be difficult to address and that we shouldn't have difficulty going through OMB and the other regulatory reviews.

That, you know, we're in the right place to proceed smartly and that's really all that we know.

CHAIRMAN CERQUEIRA: I guess what I'm

asking from staff is some guidance on how we can push this. I mean, the committee is, you know, powerless in many ways but obviously, if we, you know, send a note to the commissioners. When is our next meeting with the commissioners?

MS. WILLIAMSON: Spring.

CHAIRMAN CERQUEIRA: Spring. Okay, so that will be part of the scheduling process, but you know, if we wait till then to put some pressure on them, I don't think that's going to help very much. So nobody is being terribly helpful in how we can move this forward. I mean, you know --

DR. WILLIAMSON: I suppose you, as the chairman --

MR. LIETO: Weekly phone calls by the chairman.

DR. WILLIAMSON: -- could place a call to the --

CHAIRMAN CERQUEIRA: So is that the wish of the committee? Would you like me to --

DR. WILLIAMSON: Yes, I suggest that here's a motion, okay. Okay, the ACMUI recommends that Chairman Cherqueira contact the commissioner chairman to inquire about the status.

CHAIRMAN CERQUEIRA: Good, okay.

DR. WILLIAMSON: And express our concern that it is not proceeding in a timely fashion.

CHAIRMAN CERQUEIRA: Okay, I will take that charge. All right. All right.

MS. WILLIAMSON: And that's all that I have.

CHAIRMAN CERQUEIRA: Okay.

MS. WILLIAMSON: I do have the Staff Requirements Memorandum on the national materials reports.

CHAIRMAN CERQUEIRA: You still have the vacancies.

MS. WILLIAMSON: We did that this morning.

CHAIRMAN CERQUEIRA: But that was a closed session, so we should at least discuss it in public because we do have members of, you know, stakeholders out there and --

MS. WILLIAMSON: Certainly. I should be able to do this by memory. We reappointed five people to the committee. Let's see how good I am.

CHAIRMAN CERQUEIRA: I can read it, I've got the minutes here.

MS. WILLIAMSON: Okay.

CHAIRMAN CERQUEIRA: Diamond, Nag, Schwarz, Williamson and Vetter were reappointed.

MS. WILLIAMSON: Were reappointed for a second term. We do have three vacancies coming up in the relatively near future and they would be Chairman Cerqueira, Ms. Hobson and Ms. McBurney. So my action after this meeting would be to move smartly to start the process to get the anticipated vacancies filled in a timely manner. And one other vacancy that we can foresee in the foreseeable -- well, in the near future would be Mr. Lieto's position as medical physicist and he could be reappointed to the committee.

DR. DIAMOND: Angela, we also have the issue that Dr. Cerqueira is the chairman, so we need to find a new chairman.

MS. WILLIAMSON: Exactly.

CHAIRMAN CERQUEIRA: So I would say that we should -- somebody should make a nomination that we initiate the process for identifying new members to replace Cerqueira, Hobson and McBurney and selecting a new chairman.

DR. WILLIAMSON: So moved.

CHAIRMAN CERQUEIRA: So Jeff makes the nomination, you seconded it. Further discussion on it?

MS. McBURNEY: Who actually appoints the chair? We don't select our own chair, do we? The

Commission --

DR. WILLIAMSON: We could perhaps make a recommendation from the remaining members of the committee. It would probably be logical to have somebody who has served and has some experience, recent experience, on the ACMUI rather than getting somebody cold.

MS. HOBSON: Exactly, I agree. Also just for my own benefit, does the chairman -- is the chairman required to be an MD, a physician or could one of the other highly qualified but not a physician?

MS. WILLIAMSON: I don't know that it's a requirement.

CHAIRMAN CERQUEIRA: I don't think it's required.

MS. WILLIAMSON: I think it's usually the case though, as sort of a past practice.

DR. DIAMOND: I was looking at the bylaws today and I did not see any requirement that the chairman be a physician.

DR. NAG: Now, how as the chairman decided before, I mean, the previous chairman? How was it decided and how --

DR. DIAMOND: Someone left the room for a few minutes and they got dinged.

MS. McBURNEY: He was the only doctor left.

CHAIRMAN CERQUEIRA: You know, again, I think the previous chairman, Dr. Seigel, had some input into it with the committee members. I have to admit, I'm not aware of how the process was --

MR. MALMUD: It was actually Dr. Stitt who was the previous chairman.

CHAIRMAN CERQUEIRA: That's right, it was Judith, yeah. There should be a process. You know, I mean, every society that we're involved in has --

MS. McBURNEY: Maybe while you're on the phone with the --

CHAIRMAN CERQUEIRA: The commissioner, he won't know unfortunately, but I'm sure the staff, like the people that were here for awhile, Larry Camper or Cathy Haney have had the longest experience. I'll look into it and I'll try to -- there has to be some process.

MS. SCHWARZ: Maybe Dr. Seigel could --

CHAIRMAN CERQUEIRA: Could fill us in, yeah.

MS. WILLIAMSON: I actually believe it was recommended in a paper to the Commission by the staff. Now, I don't know how the staff came to the

recommendation frankly. I can always find that out but I do remember seeing paperwork to that effect.

MR. MALMUD: But it's appointed, not elected.

MS. WILLIAMSON: It's appointed, yes.

DR. WILLIAMSON: That's correct, but I think, you know, our group could make a recommendation to the staff if we wanted to, if we felt we had some consensus within this group.

CHAIRMAN CERQUEIRA: But the initial process is to just -- there's the three vacancies. We have to publish it in the Federal Registrar and we have, you know, a period of nominations being submitted and so we should initiate that now. I think our last meeting is the spring of 2004 but, you know, we've had --

DR. NAG: That gives us some time.

CHAIRMAN CERQUEIRA: Right, okay. So we'll do that and we'll try to find out the process by which the chairman is appointed.

The second item, then, I guess is in terms of Mr. Lieto's being reappointed and I don't -- again, what are the -- I mean, he speaks up too much but he's done a fairly good job. And so what's the process by which a reappointment can be initiated. Is that up to

the discretion of the chairman?

MS. McBURNEY: If he wants to be.

DR. NAG: If he wants to be reappointed. If he does, then there's no more questions.

DR. WILLIAMSON: Well, I guess the staff could choose --

MS. WILLIAMSON: The staff could, right --

DR. WILLIAMSON: -- to recommend not to reappoint him, as has happened in some cases.

MS. WILLIAMSON: So basically at the recommendation of the staff, which the Commission usually agrees with.

MR. LIETO: We know the answer to that one.

CHAIRMAN CERQUEIRA: All right, so that takes care of those items, but again, you know, we've kind of made it a priority to avoid vacancies because two years ago we had lots of vacancies and it was very hard for the committee to do business. So we've got 17 months and if we initiate the process, we should get it filled. Okay.

And then the next thing is still -- Angela, you're still there, administrative conclusions.

MS. WILLIAMSON: That's just the routine

discussion about the next agenda items and the next meeting date.

CHAIRMAN CERQUEIRA: So we normally have a meeting in the spring.

MS. WILLIAMSON: April.

CHAIRMAN CERQUEIRA: April.

MS. WILLIAMSON: Right, uh-huh.

CHAIRMAN CERQUEIRA: All right, and that's when we meet with the commissioners.

MS. WILLIAMSON: That can serve as your meeting with the commissioners, yes.

CHAIRMAN CERQUEIRA: And the tone of today's discussion, I think the committee would like to meet with the commissioners and --

DR. WILLIAMSON: Yes, I think so.

CHAIRMAN CERQUEIRA: We what we need to do then, and the issue always comes up of how you get to five commissioners to be in town. So we need to -- if you could check with their staff to see when in April we could possibly convene a meeting and there we need the full day and a half because usually we have a meeting before and are there any national meetings in April?

DR. NAG: There is a Radiation Society meeting at the end of April.

CHAIRMAN CERQUEIRA: If people could just look in their calendars.

DR. NAG: April 26th through 30th.

DR. VETTER: The NCRP meets in April.

DR. BRINKER: Early April is the NCRP.

PARTICIPANT: Is Easter in April?

CHAIRMAN CERQUEIRA: Late March.

DR. DIAMOND: Angela, if you're taking notes, there's a Radiation Oncology meeting February 27th through March the 2nd.

DR. NAG: No, we are looking for April.

DR. DIAMOND: I understand but I'm giving her all the dates I can think of.

CHAIRMAN CERQUEIRA: And there are things like spring breaks that for some of us that's a little bit more --

MS. WILLIAMSON: April is not written in stone. I mean, we could have it a little bit sooner, a little bit later, but normally we hold it in April.

PARTICIPANT: Sounds like mid-April.

CHAIRMAN CERQUEIRA: So Easter is April 20th, so a lot of the school vacations tend to sort of cluster around that. End of April, is the end of April -- that was the one that was bad.

DR. NAG: That is the Radium Society,

although that --

CHAIRMAN CERQUEIRA: But again, we have people representing various constituencies and it would be important, I think, to have them here.

DR. VETTER: The first full week of April is NCRP.

CHAIRMAN CERQUEIRA: The first full week.

DR. VETTER: It isn't all week long but I don't remember the dates. It's that week.

DR. DIAMOND: So what about the second week of April?

CHAIRMAN CERQUEIRA: April 7th, which is a Monday?

DR. DIAMOND: That's the first full week, isn't it?

DR. NAG: That week is open.

DR. VETTER: That's the week of NCRP.

CHAIRMAN CERQUEIRA: Okay.

MS. McBURNEY: So before that?

DR. DIAMOND: What we need is a Monday, Tuesday?

DR. NAG: No, it can be any day of the week, right?

MS. WILLIAMSON: It can be.

DR. DIAMOND: Or Thursday, Friday.

MS. WILLIAMSON: We try not to hold it on Friday, but the flights, it's difficult.

CHAIRMAN CERQUEIRA: So what about -- here again, this is probably not the most efficient use but, you know, once we start sending e-mails to lock in dates, we have to give the commissioners a couple of alternative days to try to get it. So something like April 23rd, 24th is that -- it's the middle of the week.

DR. VETTER: I thought you said that was Easter.

CHAIRMAN CERQUEIRA: Easter is April the 20th, I have, April 20th.

MS. WILLIAMSON: This would be after.

CHAIRMAN CERQUEIRA: So we would try to avoid that Monday and Tuesday, the 23rd, 24th of April?

DR. NAG: Yeah, that's okay.

DR. VETTER: Even the first week in May.

DR. DIAMOND: What about the first week in May?

CHAIRMAN CERQUEIRA: May 5th, 6th, that's a Monday, Tuesday?

MS. McBURNEY: When is the CRCPD meeting?

DR. NAG: Immediately after the ABS.

CHAIRMAN CERQUEIRA: Let's go back to maybe March.

MS. McBURNEY: Late in March, early April around April Fools.

CHAIRMAN CERQUEIRA: How about like March 24th, that's a Monday and the 25th, it's a Tuesday?

DR. EGGLI: A lot of college spring breaks have already started. My son is at Harvard, starts that Monday.

MS. HOBSON: Yeah, but spring breaks bounce all over. There's --

MS. McBURNEY: What about the following week?

CHAIRMAN CERQUEIRA: Then we're into April and April is kind of -- well, can we --

DR. DIAMOND: So let's -- we need two or three different dates, so let's throw a couple out. Let's do that --

MS. McBURNEY: March 30th?

CHAIRMAN CERQUEIRA: No, it was March 24th, 25th.

PARTICIPANT: March 30th and 31?

CHAIRMAN CERQUEIRA: So March --

MS. McBURNEY: I won't be available the 24th and 25th of March, so maybe March 30th, April

1st?

DR. NAG: April Fools Day, yeah.

CHAIRMAN CERQUEIRA: That's March 31st, April 1st. Okay, so let's try those two. So we had April 22nd, 23rd, and then March 31st, April 1st. All right, we'll try those dates to see if we can get the commissioners, and if that doesn't work out, then we'll send out the scheduling calendars again.

DR. DIAMOND: I think the only way we can do it is find when the medical meetings are, get two or three sets of dates, find when the commissioners are available. There's no way we're going to be able to accommodate everybody's schedule. We just can't do it.

CHAIRMAN CERQUEIRA: Yeah, okay.

MS. WILLIAMSON: One other thing, Dr. Cerqueira, as far as everyone's travel and your services vouchers, if you don't mind signing those and just giving them to me, that will really expedite the settlement of those vouchers. You don't have to, it's your choice.

MR. MALMUD: These two pages and just fill them in.

MS. WILLIAMSON: Right, and just give the information to me rather than -- yeah, exactly, then

you don't have to send it through the mail.

DR. NAG: Do you need the hotel receipt or can you use the fax on that because the only other thing would be the hotel receipt that you would not have.

MS. WILLIAMSON: I really should get the original hotel receipt. People here get audited by the IG like to have original hotel receipts, so not faxed, they really -- unless you lose the hotel receipt, they really do prefer that they get an original of the hotel receipt.

CHAIRMAN CERQUEIRA: So if people can sign those and give them to Angela. If you'd leave a signed copy here then you can send her the --

MS. WILLIAMSON: You can just leave -- yes, and I can make copies for you.

MR. DIAZ: Now, Sally had a question.

MS. SCHWARZ: We had discussed the possibility of a committee being formed to review 1000 modalities and I just thought maybe if you wanted to do that before we closed.

CHAIRMAN CERQUEIRA: You know, I think we should. The question is, you know, it's such a broad topic and you'd like to get input from various members of the community, both the stakeholders as well as the

people that don't have an interest in order to -- and you're almost talking about the whole committee in a sense. You know, I guess we could try to break it down but there are going -- when some of these things come up, I mean, you know, having cardiology input is of some value, radiation oncologists in some cases.

DR. WILLIAMSON: Well, there's nothing that stops the subcommittee from inviting additional members for a particular decision that requires their input but I think the suggestion of the committee is that we could have a standing -- some sort of a standing structure to facilitate doing this quickly in between our semi-annual meetings.

MS. SCHWARZ: If there were --

DR. WILLIAMSON: So that was the --

CHAIRMAN CERQUEIRA: Okay, what size should we make the committee?

DR. DIAMOND: Probably get a representative from each discipline that's represented here, so one radiation oncologist, one nuclear medicine, one physicist, one cardiologist and so forth.

MS. HOBSON: That's the whole committee.

CHAIRMAN CERQUEIRA: The only duplicates, I guess, there's two radiation oncologists. We have,

I guess, two medical physicists. So basically it would be everybody with the exception of three people.

DR. NAG: I think you don't need a patient advocate, but you may need a technical thing so Nekita might not be involved.

CHAIRMAN CERQUEIRA: No, but I think she represents a unique constituency that should be there, I mean, really because she doesn't have any ax to grind in terms of you know, turf and I think it's important to have that kind of input. Well, and then as the chairman, I shouldn't be on it, so that leaves Dr. Brinker. So it's a matter of which of the physicists and which of the radiation oncologist we'd leave off.

DR. WILLIAMSON: I'll volunteer.

CHAIRMAN CERQUEIRA: To be on or off?

DR. WILLIAMSON: On it. All right, okay, so Subir wants to be on it then and Ralph, do you have any strong feelings about being on it?

MR. LIETO: Well, no. I mean, I have no problems. It's going to come back to the committee anyhow.

DR. WILLIAMSON: If he wants to be on it, I will happily withdraw.

MR. LIETO: I want to be able to criticize

you, Jeff.

CHAIRMAN CERQUEIRA: All right, so I think we have the committee then. I guess, you know, David and Ralph and I are not on the committee and everybody else is on the committee. I mean, is that --

MR. MALMUD: You don't need two --

CHAIRMAN CERQUEIRA: Yeah, but you're a hospital administrator and you do need that perspective.

DR. WILLIAMSON: Maybe he could cover both.

MS. McBURNEY: True. Most of these items are going to be coming up as devices or something in an agreement state or whatever --

CHAIRMAN CERQUEIRA: Yeah, we definitely need that. All right, well, look let me -- I think we've kind of identified it. The only question is do we need two nuclear medicine. The other thing you don't want is if you have too many -- I feel I've got two people representing the same interest, then potentially there's a conflict there but I think we have the body of the subcommittee.

Let me talk to the staff people and then I'll just send the list out to people unless there's any other issues that come up. All right.

MS. HOBSON: I think both Dr. Malmud and Dr. Eggli, they would serve two different purposes on the committee and I'm sure that they're big enough that they would put aside any parochial interest.

CHAIRMAN CERQUEIRA: Okay, that's probably true. So all right, other issues, any --

DR. DIAMOND: Yes, there were. I don't know at this late juncture in the day we want to go and raise our blood pressure again, but the main focus of this morning's discussions were whether we wanted to have some open and frank exchange of what can be done in the future to improve the function and utility of this advisory committee. Should we take five or 10 minutes to talk about this?

CHAIRMAN CERQUEIRA: Yeah, I think that's -- what do you suggest?

DR. DIAMOND: Well, there are a couple of issues. We talked about some housekeeping things, such as getting the summary minutes out in a timely fashion, getting the staff responses out to the committee members in a timely fashion. So those are very straightforward things. We also spoke about the need to improve communication with the federal designated official as a third point.

Other points really are you know, an open

and frank discussion with response to what our purview is and are we going to be receiving pro-active communications from the staff or are we going to play this game once again where we respond and have to inquire as -- on our own as to what are the important and developing issues. I think it's much better to go and discuss these in a proactive fashion. It saves a lot of heartache and I think it moves much more efficiently.

CHAIRMAN CERQUEIRA: Well, it's a lot of issues. Let's kind of go back then and maybe start with the first point that you made.

DR. DIAMOND: So first is a more timely communication of the summary minutes and of the staff responses. I think that's not a subject of debate.

CHAIRMAN CERQUEIRA: All right, I think one way to do that is once the minutes are finalized and Angela, I think there's agreement that the minutes, once they're finalized, should go out to the committee members and when we open the meeting, we should have the opportunity to review the minutes and let people, you know, make changes or if they have, you know, disagreements with what's said, that should be done up front. So now we can do that. There's no reason that the minutes are not allowed to be

distributed to the committee.

We also identified action items that during the discussions, we -- you know, we basically made a motion and we took a vote on it and we should have a clear -- in the minutes, we should have a clear identification of the motions and that should come out of the transcript. You know, I don't go through the whole transcript, Angela or somebody does and we basically come up with some, you know, nomination and so that should go out to people and it should be brought up at the meeting.

DR. DIAMOND: The next issue is an issue that was formulated really by Dick, which was that we should have standing reports. In other words, to paraphrase Dick, for example, update -- staff update on training and experience, staff update on the National Materials Program, staff update on these other issues. This way the clear onus, the clear burden is on the staff to prepare in advance materials that we can review and discuss instead of us having to go and dig through these issues.

CHAIRMAN CERQUEIRA: Yeah. But who's going to come up with a list of sort of standing recurrent issues that --

DR. VETTER: Yeah, I would suggest that we

actually simply have some broad categories that are standing always on the agenda and maybe some meetings there isn't anything there but we still never remove that from the agenda. An example would be routine trend reports. I think it would be good for this committee to hear from the staff what are the medical events that have occurred across the country and why do we want to know that, to help them. They've probably already got it figured out but at least give them our input as representatives of the user committee, on whether or not there might be some root cause there or we might be able to contribute to the base knowledge on route causes that might be effecting these trends or contributing --

CHAIRMAN CERQUEIRA: Do you mean trends of medical events or reportable events, or what?

DR. VETTER: Medical events is what I'm suggesting. We can come up with -- I'm just saying a broad category of routine trend reports. One example would be medical events. There may be half a dozen others over a period of time we would ask that they update us on and a trend report, you know, one example is if medical events are two next time and 10 the following time meeting and 20 after that there's obviously something going on. Obviously, the staff

would have figured that out by now but the purpose would be for us to have input as members of the user community as to what might be happening out there. That's an example.

So one of those categories that we would always have on the agenda would be routine trend reports, whatever we've all decided are good routine trend reports.

MS. HOBSON: Would the same thing apply to this new national data bank, what would be -- what's been reported.

DR. DIAMOND: Sure, I think that's very important.

MR. LIETO: You could maybe use the category of enforcement actions because isn't that what would trigger that type of reporting to the data base, would be escalated enforcement?

MR. BROWN: In part, not -- it's not the only reporting criteria but that's in part.

CHAIRMAN CERQUEIRA: Now, Tom and Fred, I mean, you kind of get the sense of this. And it sounds like it's a reasonable request from the committee, so --

MR. BROWN: Well, yes. As you ask for more information, the number of people available to do

it and the status of their ability to do it is limited by the hours of budget, so the more you ask for, the less good any of it's going to be is essential rule of thumb to understand.

We do trend analysis. It's a function. It's actually a very important function and it's being revised in its totality right now. I'd love to come in and talk about it at the next meeting and once you're informed of what we do, I mean, you can ask for further updates, but the more updates that we're preparing for you, the less opportunity we're going to be having -- have to --

CHAIRMAN CERQUEIRA: But they're already existing out there as part of the agency, you know, policy. It would just be a matter of sharing the material, right?

MR. BROWN: And some things are and we can explore those. You know, the trend isn't a presentation. It's actually a monthly meeting that goes on to review not just medical events but all --

DR. DIAMOND: Right, we're not asking for a 30-minute presentation. A one-page summary of trends prepared by that particular agency or board would be more than sufficient.

MR. BROWN: That agency or board is two or

three people in my section and one page is something we'll half-way do but that's a level of effort and it detracts from all of the other levels of effort we have.

DR. DIAMOND: Well, gee whiz, I'm spending a lot of effort to come here, too, Fred.

DR. BRINKER: Well, I think before --

DR. DIAMOND: I mean --

DR. BRINKER: One thing, again, as a newcomer, I'm seeing us going not parallel in our -- or not together in our thinking. We're not converging and I think one of the things is our ideation of what we should be doing may be different. I think it is different from what the NRC staff's ideations, what they want and need from us are different than what we think the influence we ought to have and it's further complicated by the fact that you have a bunch of very well-doing, intelligent, hardworking people here that want to contribute and want to be known that they contribute and it's also complicated by the fact that we meet every half a year or something and they do a hell of a lot between the times we meet and they can't -- and I guess they don't know how much of that and how to communicate the ongoing process with us in a way that would be beneficial for us to interact.

But look at today. We are so -- I mean, I feel that I am volume overloaded by all the things that we discussed today and I'm not sure that we had an adequate time to digest all the things Fred was bringing up so that we could give the best -- I mean, we gave the best answers that we could off the tops of our heads in the 10 or 15 minutes that we had to digest the data, but we didn't do the kind of job that might have been done if we had days to think about this and other information access.

So, again, I think one thing that would be valuable to me, I think, is if the NRC staff really had a soul-searching in terms of what they want from us and in order of priority. And we conversely, had a soul-searching and put down what we think we should be doing in order of priority and see where they match.

Now, an awful lot of good has been done already and just as Dr. Vetter's subcommittee was an immense amount of work, and I think that there is this -- we're not connecting. A lot of people here think that they're not appreciated for what they do, that the NRC is not sensitive enough to the desires of the group and I'm sure by the expressions on your faces that much of what we say is, "Oh, boy, what do they

want now and this is going to be a tremendous onus and how can we possibly going to get that done. So to make this work the best, we should be all on the right line working together and we should know what each other's needs are and how best to do them.

CHAIRMAN CERQUEIRA: Those are good points. I think one of the things that would help is, you know, there's a charter for this committee and I have to admit I must have seen it at some point but how many have --

DR. DIAMOND: It's in the back.

CHAIRMAN CERQUEIRA: It's in the back. All right, well, people should look at that and again, just to --

DR. WILLIAMSON: I actually think we should be, you know, fairly careful about how much stuff we request. I think we've made some reasonable requests which is to be -- keep up to date on a routine basis with the 35.1000. That's very important to the community, very controversial. It's very easy to make a misstep but no, I don't know -- I don't have a strong feeling that we should get that involved in tracking trends and so forth and routine information.

I think we've made some specific requests that are reasonable.

MS. HOBSON: But on the other hand when we have worked long and hard on a particular issue and we make a recommendation, it's just sort of like, you know, many times we're just sort of dropped out of the loop and we never hear anything else about it, or else we're surprised by what actually has happened when we do learn about it. So being kept informed is, I think, huge.

CHAIRMAN CERQUEIRA: Leon?

MR. MALMUD: It might be useful because -- it would certainly be useful if we identified those issues that we felt needed follow-up and that at each meeting we identify the items for which we're requesting follow-up at the next meeting and not over-burden the staff here with tracking everything, because their budget is limited and they're going through an ordeal now, as most of government is in trying to anticipate possible needs with respect to bioterrorism, et cetera. So I would suggest that we begin by our assuming the responsibility to identify to you those limited items for which we are requesting follow-up because of the intense involvement of this committee and those issues, that we begin with that and then see how that works. That will give us what we want in terms of the feedback and that will give

the staff an opportunity to see how burdensome this is since you do have limitations on your own staffing within your own organization and all of us working in organizations recognize that reality. So maybe we could begin with those steps. But we certainly have to begin with something because it's wasteful of your time as well as ours to discuss the frustration of the committee rather than the items about which we feel frustrated. So is that acceptable?

CHAIRMAN CERQUEIRA: Those are legitimate points and I think the minutes and the action items again will identify -- and we've tried to limit what we, you know, include, certainly for action items and --

MR. MALMUD: We could get e-mails. If we have a meeting now and the question could be answered next month and the e-mail comes to us indicating this is the response, then it would make -- it should make life a lot more compatible with the committee and the staff and we'll build on that. I don't think we could expect an overnight change. It's difficult to do that overnight, but let's start out with a few steps. Dave, how do you feel about it? A good beginning?

DR. DIAMOND: It's a nice beginning.

MR. MALMUD: And we'll build on it. We'll

build on it as quickly as we can.

CHAIRMAN CERQUEIRA: That's a good approach. Ruth?

MS. McBURNEY: I don't want us to be perceived as trying to micro-manage the staff of the Nuclear Regulatory Commission. That is not our job. Our job is to advise on technical and on issues that deal with regulating the use of byproduct material for medical use. And beyond that, I don't want us to get into the minutiae of the role of the staff of the Nuclear Regulatory Commission.

CHAIRMAN CERQUEIRA: That's a good point and Ralph, did you have a comment?

MR. LIETO: Yeah, I think that, you know, I don't disagree with any of the statements that have been made before. I think having data by which to act on I think is what we're asking for and maybe with the data we realize this isn't an issue we should worry about. Okay, let's not, you know -- you know, maybe like that data base. Maybe the events are so few and far between in comparison that it wouldn't need to be a standing item on committees and so forth.

But I think what we're trying to find right now is that we're sort of like in a vacuum and we want to make some decisions and we want to make

decisions as to do we need to get involved or should we not be involved and that's what we're looking for is the data to make those decisions.

And maybe like Dr. Malmud said is maybe what we should do is come together with our -- you know, what do we think we should be -- or what do we want to be asking for and determine as a group is this really the issues that we want to direct the staff to do.

CHAIRMAN CERQUEIRA: Good points. Leon?

MR. MALMUD: In many ways we have three constituencies. We have the patient first. We have the public second. We have the health care workers third. We seem to be in total agreement as to what is best for the patient. We seem to be in total agreement with respect to minimizing the risks of the public. Where we wind up in a squeeze is when we go back to the community that takes care of the patients, they ask questions of us and they are sometimes startled with the responses and that's not good for the NRC. It's not good for the patient. It's not good for the public and not good for us.

So we need to be able to respond to some questions more definitively than we can presently given the amount of -- given the timeliness of some of

the information given. Is that a fair statement?

CHAIRMAN CERQUEIRA: Yes, I think that's a very fair statement and, you know, again, I think you set the priorities, I think, correctly, in terms of what this committee has focused on. All right, any other comments?

DR. VETTER: If we could get back to the business of the agenda, I find it a little difficult to deal with a call for agenda items that comes just a couple weeks before the meeting and wonder if we couldn't do something about that, try to get them out earlier. And then if, in fact, we are here to serve the NRC, which I think that's what we're here for, perhaps a little stronger leadership from them in terms of what should be on the agenda, what are they looking for.

CHAIRMAN CERQUEIRA: Right, and to get the material out. Some of these items today that you wanted input on, I mean, it was hard for us to see the issue for the first time, to realize how our -- you know, the people we represent, you know, what approaches they take towards it, so whatever you can get out ahead of time, it will give us more time to be familiar with the issues, to seek some input and so that when we're here, rather than just complaining

that we haven't seen this and we think it's important, we could give you very specific information that I think would help solve the issue.

DR. NAG: Well, one quick question, we were talking about nuclear fatalities and ACMUI presented something to the Radiation Oncology Committee about a month ago that was wonderful. We were talking about having that presentation here at the ACMUI and it never happened and we are the ones that are going to be on the line if, you know, questions are asked. And I think in the next meeting, we could have a one day and a half meeting, about an hour or so would be devoted to having a speaker here who knows about all the things that are happening at the national level so that we would be kept informed and we can ask questions and they can ask questions of us.

CHAIRMAN CERQUEIRA: Is that -- again, the presentation this morning that didn't happen I thought was going to address some of those issues and is that something we could reschedule for next time?

MR. ESSIG: We could. The presentation, I think the one you're referring to is by -- was by Lynn Silvious?

CHAIRMAN CERQUEIRA: Yes.

MR. ESSIG: I don't know if that would have scratched the itch because she was going to be talking on something related to security matters, but it was primarily adapted from a presentation she made to the staff on appropriately handling the information that has a certain classification level to it. And so --

CHAIRMAN CERQUEIRA: Yeah, that's --

MR. ESSIG: -- that's security. She would not be the right person for that.

DR. NAG: No, we're are talking about the team and you know, someone from Oak Ridge gave a wonderful presentation to the radiation oncology community and that really helped because there were many things that we didn't know ourselves. You know, what are the immediate things to be taken care of, at what point, you know, do you have to clear the area and so forth. What are the major signals, what are the things you could look for, so basically a medical emergency that would occur.

MR. ESSIG: Yeah, if I could just add, I think what I mentioned this morning about some time prior to the meeting having a conference call where we clarified the agenda items and so that there aren't -- we know exactly what your expectations are in terms of

well, I'd like to hear from the staff on item X. We have an idea what the scope of the item is and what -- any sub-issues associated with that so that we could adequately prepare -- make the right preparations for our presentation and I mean, we don't want to -- as Fred was pointing out, we have a certain amount of budgeted resources for this activity and we certainly don't want to squander them by preparing some material that isn't of value to the committee and doesn't clarify issues.

CHAIRMAN CERQUEIRA: Well, again the value -- it's more of value to you.

MR. ESSIG: Agreed, but it's -- in many respects, it's mutual. Yes, Jeff?

DR. WILLIAMSON: A specific suggestion what we could put on a future agenda would be what Susan Frant was talking about, did she call them provisional or interim security measures? Do you remember, Ralph?

MR. ESSIG: They are interim compensatory measures.

DR. WILLIAMSON: Yes, interim compensatory measures and I understand some will be on the drawing board soon for medical use of radiation. I'm wondering if the ACMUI could be involved in that

discussion and have an opportunity to give our feedback if only in a closed meeting, perhaps, because of the secure nature of it.

MR. ESSIG: It would certainly have to be done in a closed meeting --

DR. WILLIAMSON: And the classified nature of the material but I think it would be -- again, we could offer I think a benefit and service to you in trying to discuss from our perspective difficulties for -- that your proposals might have for continuing with taking care of patients as well as ideas we might have specifically for how to improve security.

MR. ESSIG: Well, in fact, that may be an issue that because of timing, again, maybe if we don't discuss it until next April, the possibility is that that may be too late to provide any reasonable feedback and that's where a subcommittee might be of some value.

DR. WILLIAMSON: Then I think it would be -- it's a very important issue. I would suggest we consider having a small sub-group that could present some advice or feedback on behalf of the entire committee.

CHAIRMAN CERQUEIRA: Would that be helpful to the -- yes. Maybe we could do that? We probably

should break now because some people have flights and things.

MS. HOBSON: Can I just say one more thing?

CHAIRMAN CERQUEIRA: Sure.

MS. HOBSON: And this isn't anything that you can kind of formalize, but you know, I would personally be very appreciative if the NRC staff would just keep us in mind when something is going on and I'll give you a good for instance. I mean, we didn't know to ask about the new nuclear materials program, the National Nuclear Materials Program, until we heard about it accidentally. I mean, we were never brought into that process until it was well down the road and I know a few of us would have probably appreciated at least knowing that that was going on and you know, so that we're not, you know, blind sighted by things that come down the pipe.

CHAIRMAN CERQUEIRA: Yeah, I think the staff has to sort of appreciate our position that we're representing a community that has a lot of questions and many times, you know, they ask us questions about things that we should have some knowledge about and we find out that things have been going on and we don't know them, you know, don't have

enough information. So it would be useful to sort of keep us updated on some of these things because they do impact on the people we represent and sometimes I think we're embarrassed by not having information.

All right, well, I'd like to thank everybody for taking time out of their busy schedules and coming here and I'd like to thank the staff. We've been critical, we're trying to help and if it didn't seem that way, I do apologize, but we are trying to make the process work. Yes, Jeff, last word?

DR. WILLIAMSON: Yes, I'm sorry. Is someone going to follow up on the appointment of a sub-group to deal with the security measures?

MR. BROWN: Let me just say, that issue has a life of its own driven by the Commission in a different office to whom ACMUI is not an issue. And what I would suggest we do is when the process matures to the point that there is something to talk about that we contact Dr. Cerqueira and have him put together a subcommittee because otherwise you're going to be frustrated if you set a time line and it's not based on anything substantive.

MR. ESSIG: Because our office of nuclear security and instant response is the lead and we're

support.

DR. WILLIAMSON: I just wanted to make sure that the ball was in some identified court and the owners of the court take responsibility. I'm hearing you say you'll take responsibility for contacting the ACMUI when the time comes.

MR. ESSIG: At the right time, yes.

CHAIRMAN CERQUEIRA: Thank you.

(Whereupon, at 5:09 p.m. the above entitled matter concluded.)