UNITED STATES NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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OPEN SESSION

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MONDAY,

OCTOBER 22, 2007

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The meeting was convened in Room T2B3, 11545 Rockville Pike, Rockville, Maryland, at 8:30 a.m., Leon Malmud, Chairman, presiding.

ACMUI MEMBERS PRESENT:

DOUGLAS EGGLI, M.D.	Nuclear Medicine Physician
DARRELL FISHER, Ph.D.	Patient's Rights Advocate
DEBBIE GILLEY	State Government Rep.
RALPH LIETO	Medical Physicist
LEON MALMUD, M.D.	Healthcare Administrator
SUBIR NAG, M.D.	Radiation Oncologist
ORHAN SULEIMAN, Ph.D.	FDA Representative
SALLY SCHWARZ	Nuclear Pharmacist
BRUCE THOMADSEN, Ph.D.	Therapy Medical Physicist
WILLIAM VAN DECKER, M.D.	Nuclear Cardiologist
RICHARD VETTER, Ph.D.	Radiation Safety Officer
JAMES WELSH, M.D.	Radiation Oncologist

STAFF PRESENT:

CINDY FLANNERY (alt. DFO)

DONNA-BETH HOWE, Ph.D.

ANGELA McINTOSH

JANET SCHLUETER

ASHLEY TULL

SANDRA WASTLER (DFO)

DUANE WHITE

RON ZELAC, Ph.D.

MOHAMMAD SABA

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

CHAIRMAN MALMUD: I would like to welcome you all back to the open session. And we are now going to move forward, if we may. Next on the agenda is opening statements.

MS. WASTLER: Thank you.

4. OPENING STATEMENTS

MS. WASTLER: As the designated federal officer for this meeting, I am pleased to welcome you to Rockville for the public meeting of the Advisory Committee on the Medical Use of Isotopes.

My name is Sandra Wastler. I'm the Chief of the Medical Safety and Events Assessment Branch. And I have been designated as the federal officer for this Advisory Committee in accordance with 10 CFR 7.11. Present today is the alternate designated federal officer, Cindy Flannery, team leader for the medical radiation safety team.

This is an announced meeting of the Committee. It's being held in accordance with the rules and regulations of the Federal Advisory Committee Act in the Nuclear Regulatory Commission. The meeting was announced in the October 5th, 2007 edition of the Federal Register.

The function of the Committee is to advise

the staff on issues and questions that arise in the medical use of byproduct material. The Committee provides counsel to the staff but does not determine or direct the actual decision of the staff or the Commission. The NRC solicits the views of the Committee and values their opinions.

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

As part of the preparation for this meeting, I have reviewed the agenda for the members and employment interest based upon the general nature of the discussions that we are 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 Committee's decision-making activities.

However, if during the course of our business you determine that you have a 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 individuals seated at the table today: Dr. Leon Malmud, Chair; Ms. Sally Schwarz; Mr. Ralph Lieto; Dr. Subir Nag; Dr. William Van Decker; Dr. Douglas Eggli; Dr. Orhan Suleiman; Dr. James Welsh; Dr. Darrell Fisher; Dr. Bruce Thomadsen; Dr. Richard Vetter.

And I would also like to mention that Ms. Debbie Gilley from the State of Florida is representing the Agreement States since the state government position is currently vacant. Ms. Gilley does not have voting privileges, but she will listen and speak on behalf of the Agreement States. I would like to thank you for acting in this capacity.

Dr. Malmud, Chairperson of ACMUI, will conduct today's meeting. Following a discussion of each agenda item, the Chair at his option may entertain comments or questions from members of the public who are participating today.

Thank you very much. With that, I will turn it over to Janet for opening remarks.

CHAIRMAN MALMUD: Thank you.

MS. SCHLUETER: All right. I will be brief. For those of you who do not know me, I am Janet Schlueter. I am the Director of the Division of Materials Safety and State Agreements in the Office of Federal and State Materials and Environmental

Management Programs.

This is the third meeting that has occurred since I have been in that position. During the two days, you will hear from various members of my staff on issues that are deemed relevant and of interest to the Committee. And we appreciate your interest in all of these matters.

I would also like to say thank you to my staff because they do work very hard to put these meetings on and coordinate with you and provide the information that we're going to go through today and tomorrow.

The other manager that will be present during the meeting for a presentation is my counterpart, Dennis Rathbun. He's the Director of the Division of Intergovernmental Liaison and Rulemaking. So he has all of the rulemaking aspects of the materials program; whereas, I have the materials licensing and inspection and all of the state issues.

I would also like to say welcome to the members of the public, some of you whom we recognize and routinely support our meetings and others may be newcomers, but we encourage your attendance here and participation. And if you choose to speak, you will need to come to the microphone, of course, because it

is transcribed. So we appreciate your contributions to the meeting.

And, with that, I think we will move on to Ashley's presentation of old business.

5. OLD BUSINESS

MS. TULL: Okay. I have one more meeting summary if you want to add it to tab number 5. It's from the fingerprinting teleconference.

Do you want me to go through each motion or just ask if anyone would like to discuss any one in particular? Go through each one.

MS. WASTLER: I think just briefly.

MS. TULL: Okay, I will quickly go through each one. For the first motion, that was to write an IN on Air Kerma Strength. We had presentations on that last time. Actually, we drafted the IN. It's in concurrence. And we are awaiting input from AAPM. So that document is moving along as ACMUI recommended.

MS. WASTLER: This is from the June 12th and 13th meeting?

MS. TULL: Right. This is from our last full meeting.

MS. FLANNERY: I just wanted to add that it will be going to ACMUI for review at some point, just needs to be a little further developed.

MS. TULL: Did that answer your question?

(Laughter.)

MS. TULL: Okay. All right. For the second motion, this is a T&E issue. And for most of those, we are still just compiling them. We still have one more T&E issue to discuss at this meeting. So for all of these T&E motions, it is going to say "NRC is considering it" because we haven't currently taken any action on them.

So the next one has to do with grandfathering individuals. ACMUI recommended grandfathering for previously board-certified individuals. This will be based on the outcome of the Ritenour or the AAPM petition. So that response will be pending until the Petition Review Board makes a decision on that. We do have a presentation on that tomorrow afternoon as well.

For the next motion, NRC staff should reduce the 200-hour radiation safety training requirement to 120 hours for individuals seeking authorization under the alternate pathway in 10 CFR 35.390. We are considering this issue.

For motion 5, NRC staff should not change -- okay. Five, six, seven, eight are all part 35 changes that Dr. Howe presented on. We have accepted

all of the ACMUI recommendations for those. So whatever you told us at the last meeting, we are going to do that.

For the ninth one, this presentation will be later on this afternoon. Dr. Howe will give the remaining item that was tabled from the last meeting. So we should be able to close that out.

For motion ten, NRC staff should allow more than one RSO on a license with the designation of one RSO as the individual in charge. We still have to go to the Office of General Counsel to get an interpretation on this. So that will be assigned to a staff member to do.

For the next couple of motions, these have to do with -- go ahead, Ralph.

MR. LIETO: I just have a question for staff. The issue like in motion ten, where it has to go to the Office of General Counsel, could you give us maybe a time line or a reference on expectations for these? I mean, are these things that will occur by the end of the year? Are we talking next meeting?

MS. WASTLER: By the next meeting, we should be able to provide you with the status of that, yes. Usually what will happen is we will have to write something right up, our position, provide it to

the Office of General Counsel for their review and interpretation of the regulations. And that can take, you know, several weeks sometimes. So we should be able to get back to you by the next meeting for sure, possibly sooner.

But at this point in time I don't have a specific time line drawn out with a due date.

MS. TULL: Okay, so for the next 11 through 14, motion 11 had to do with the 3-case work experience requirement for individuals seeking authorization for yttrium-90 microspheres use. And we did consider this. And I did revise the guidance. And that was published. So for that one, we did use for each type.

For the next one, ACMUI recommend the training and experiences not have to be performed under the supervision of an AU. We did accept ACMUI's recommendation on that. It's included in the revised guidance.

MS. WASTLER: Ashley, could you read the motion number when you go through them --

MS. TULL: Sure. That was 11.

MS. WASTLER: -- just for the record?

MS. TULL: Yes. That was 11A and B. Number 12, motion 12, NRC staff should delete the

attestation requirement for yttrium-90 microspheres users and incorporate a requirement in the second paragraph of the guidance for individuals seeking authorization to provide and retain documentation of the completion of training. We did accept this. And it is published in the new revised guidance on the Web site now.

Thirteen, NRC staff should incorporate the proposed wording for the team approach section of the yttrium-90 microspheres guidance with one exception. The ACMUI recommends the word "oncology" be replaced with "cancer management." We did accept that. It is on the Web site.

Fourteen, "NRC staff should incorporate the proposed wording that notification under 10 CFR 35.14 does not apply to specific medical use licensees." We actually discussed this again at a medical radiation safety team meeting. I don't know if I presented it clearly at the last meeting. So it is going to be in my presentation again tomorrow to discuss further.

So motion 15, "ACMUI tabled the absorbed dose versus activity administered." This will be a big part of the yttrium-90 presentations later on tomorrow.

Motion 16, "NRC staff should revise the current guidance to conclude that the surgical removal of the sentinel lymph node is an independent procedure and should not be regulated by NRC." Again we have to go to Office of General Counsel on this one. So we will get back to you.

The remaining items are action items, not necessarily formal motions. The first one deals with the AAPM petition. We did consult legal counsel to determine the feasibility of discussing the petition in a closed executive session. It will actually be in an open session at the end of tomorrow's meeting.

For action number two, we should "arrange a briefing for ACMUI members regarding the increased controls orders." We did have a teleconference on that. And that is the meeting summary that I just passed out.

Action three, "NRC staff should engage ACMUI in a discussion regarding the review of operational events and data and work towards a goal of minimizing therapeutic medical events if directed by the Commission to do so in the final staff requirements memorandum."

We got the SRM back, and we were not required to do that. So we retained the option to do

it at a later date, but for now that was not an action item.

Action number 4, "NRC staff should provide detailed background information for the current and future presentations on the subject of potential changes for 10 CFR part 35." In your binders, notes pages are printed out for those slides that Dr. Howe will be talking to. So there is background information included in that presentation.

Action 5, "NRC staff should e-mail the ACMUI members a copy of the memo summarizing action items and motions made during the meetings." I believe I have sent all of you the meeting summaries and all of the memos that have come out so far.

Okay? So for the next meeting, that is the fingerprinting. I actually just passed it out and gave you guys my copy.

Yes?

DR. NAG: On action number 3, it says the Commission did not direct for SRM. However, I think it is important enough for the public that we should still try to analyze and see what other ways there are to prevent and so forth like we discussed at the last meeting. And at the last meeting, they said the SRM would be there anyway. And so we didn't take formal

action on that.

Now that there is no SRM, I think we should again provide the analysis. And, again, you know, I had offered last time to help in the radiation oncology part of it.

MS. TULL: Does the Committee agree? Do you want to make a motion?

DR. NAG: I guess I can speak that same motion, a detailed analysis, of the misadministration and ways to minimize, you know, analyze the root causes and find out ways to minimize those from happening.

And, again, we can have a small subcommittee meeting. If someone else wants to help out on the nuclear medicine side, that's fine. I can help out on the radiation oncology side.

CHAIRMAN MALMUD: Thank you.

Subir, would you like to make it just a brief motion, though?

DR. NAG: Yes. I would say that, let's say, the ACMUI along with the NRC staff analyzed the therapeutic medical events and find out the root causes and ways to minimize or ways to prevent them in the future.

CHAIRMAN MALMUD: Is there a second to

that motion?

DR. THOMADSEN: I'll second that.

CHAIRMAN MALMUD: It's been seconded. Is there any discussion of the motion? Mr. Lieto?

MR. LIETO: Two questions. One, this SRM 07-0066, could someone refresh my memory? I am drawing an absolute blank on this.

MS. TULL: AARM report that went up. And that's the SRM in response to that.

MR. LIETO: This is Ralph Lieto.

I am trying to remember what was the content.

MS. TULL: It was not something that dealt directly with the ACMUI. It is something that covered all materials. It was the AARM report, which what is AARM?

MS. WASTLER: Agency action, yes, review meeting. Agency action review meeting.

MS. TULL: Okay. So it covered all materials?

MS. WASTLER: And it covers all materials events.

MS. TULL: We expected the Commission to come back and say, "Do this," and then they didn't.

MS. WASTLER: This was discussed as part

of that. It was a general discussion, as I recall. Again, I try from memory. And sometimes it doesn't work so well anymore.

But in a generic sense, they wanted to look at means to reduce any kind of event to zero. So, in other words, you know, like the plane crash, we want none happening, which is very similar to what the Committee does at each meeting when it goes over the events.

But I think they were thinking in a broader term with the goal of coming up with changes. The Commission was thinking at the time of looking at it from a broader perspective to see if there could be some overall larger changes on how we look at events to achieve that reduction.

So it's not really that much different than what the Committee is doing when Mr. Lieto and Donna-Beth go over the events that have occurred, you know, in the last six months. But it was drawing it more up into the Commission's view, I would say.

My memory stops there. I can gladly pull the SRM, and it didn't come down in the SRM. It came down in a draft that never made it. So I would have to go and find the exact words if you are interested.

CHAIRMAN MALMUD: Are you interested?

MR. LIETO: This is Ralph Lieto.

If it didn't address it, I would say no.

MS. WASTLER: No. It came out --

MR. LIETO: There is nothing there to really look --

MS. WASTLER: There is nothing there to focus on.

CHAIRMAN MALMUD: Okay. Ralph?

MR. LIETO: Regarding the motion, we're having a discussion tomorrow on the medical events. Would it be maybe appropriate to combine maybe this motion after that discussion or does it need to be done independently? I am kind of leaning towards a recommendation that we postpone this motion or action --

DR. NAG: Table it.

MR. LIETO: -- until tomorrow.

DR. NAG: Table it until tomorrow.

MR. LIETO: Tomorrow's discussion. Then we can take the whole thing in the context of the presentation.

CHAIRMAN MALMUD: Thank you.

Dr. Nag, you concur?

DR. NAG: Yes.

CHAIRMAN MALMUD: So it will be tabled

until tomorrow. Thank you.

MS. TULL: Okay. So I'm going to move on to the fingerprinting teleconference. There were two motions made during that meeting. They're on the back of that page that I just handed out. The first one, "Dr. Nag made a motion to support grandfathering for individuals who had previously been determined to be trustworthy and reliable and granted unescorted access."

And the second motion, "Dr. Fisher made a motion that the ACMUI agree to assist the NRC if requested to determine those levels and types of material that could be of such significance to public health and safety to warrant fingerprinting and background checks."

Any comments on that? Dr. Welsh?

DR. WELSH: This is Dr. Welsh.

I have a perhaps naive question about this whole matter. I understand that, on one hand, there are significant costs. On the other hand, there are concerns about security. But I think all of us have had fingerprints taken.

And is there not a means of electronically working with those fingerprints, forwarding them to the agencies that are requesting this now? I see that

the question was raised here and the answer was no.

There is no current method for licensees to send fingerprints directly to the FBI. They must be submitted directly for forwarding to the FBI.

But why not? And can't that be fixed? And would that not solve the problem of the cost that we're all raising?

CHAIRMAN MALMUD: Dr. Vetter?

VICE CHAIRMAN VETTER: The short answer is this is a jurisdictional issue. And licensees are not under the jurisdiction of the FBI. So there has to be a federal connection. And the NRC is able to do that. Licensees can't do that. So we have to do that through the NRC.

CHAIRMAN MALMUD: Thank you, Dr. Vetter.

MS. TULL: On to the next?

CHAIRMAN MALMUD: Dr. Welsh, does that answer your question?

DR. WELSH: Well, it does, but it seems that it raises -- is there not a potential solution that would reduce the concern that we are all expressing about the cost of this to the stakeholders?

CHAIRMAN MALMUD: Dr. Welsh, my understanding is that there is a potential solution, which would be for a uniform single source of

fingerprint files for the federal government. However, there are reasons why that has not happened which are beyond the scope of the --

DR. NAG: NRC.

CHAIRMAN MALMUD: -- the NRC.

MS. SCHLUETER: That is correct. And I would only add that this is one of the many implementation issues that is currently being considered by the NRC and Agreement State working group that I believe you have had some update on in the past.

And there is a set of slides that is in your books and also available to the public in the back of the room but this very item of how do we make the process the most efficient, the least cost-burdensome, working with one set of fingerprints so that individuals aren't re-fingerprinted when they change facilities, for example, moving from one medical institution to another, and whether or not there is a single federal database that would be accessed by the appropriate person.

So they are all very practical, legitimate implementation issues that are currently being considered with not a lot of easy answers at the moment.

DR. WELSH: Thank you.

CHAIRMAN MALMUD: Thank you.

Ashley?

MS. TULL: Okay. The next is the meeting summary from our last teleconference, actually the last two teleconferences. They were both on the same topic, T&E.

So for all of these, there are four motions. And they are all being considered by NRC, really no news or any kind of update to give you on that. We are still going through them.

The last motion, motion 5, was "NRC staff should add increased complexity versus additional benefit as an agenda item for the October ACMUI meeting so the ACMUI may continue the discussion on this topic." That's on the agenda for tomorrow.

CHAIRMAN MALMUD: Thank you.

MS. TULL: That concludes anything I have to say. Any other comments on meeting summaries, memos, old business?

CHAIRMAN MALMUD: Any questions or comments for Ashley Tull?

(No response.)

CHAIRMAN MALMUD: No. Thank you.

MS. TULL: Thanks.

CHAIRMAN MALMUD: We are now moving forward to recent security activities with Ms. Schlueter.

6. RECENT SECURITY ACTIVITIES

MS. SCHLUETER: Okay. We have a set of slides that may come up there that you have in your books, which is titled "Radioactive Materials Security and Licensing."

CHAIRMAN MALMUD: Ms. Schlueter, is it okay that we are ahead of our schedule?

MS. SCHLUETER: Absolutely.

DR. FISHER: Under which tab?

MS. SCHLUETER: Six.

MS. WASTLER: Second set is tab 6.

MS. SCHLUETER: Yes, I believe your first set, correct, is on the increased controls, --

MS. WASTLER: Right.

MS. SCHLUETER: -- which is actually an update from previous discussions, but it also reflects -- it's a set of slides that a member of my staff, Tim Harris, used at the recent annual Organization of Agreement States meeting that some of you may have attended or heard of. And I was not going to focus on those slides.

MS. TULL: More as background.

MS. SCHLUETER: As background, but I would focus on the other set that you have on the radioactive material security and licensing.

Briefly, just as an overview, I am sure you are all aware of the sting operation we like to call it by the Government Accountability Office earlier this year on the NRC and a state. That happened in the May time frame is when we learned about it.

We took certain prompt actions immediately. We had a Senate hearing in July. We were directed by the Commission to submit an action plan on how to address the recommendations of the GAO, the Senate, and our own Inspector General's office. We had a public briefing of the Commission. We received a staff requirements memorandum. And there has been a whole host of activities.

So my purpose in the briefing today is to provide you an overview of what we learned and what we have done since then and where we are at in the process of addressing these recommendations.

We have gone into some detail in our staff paper that we sent to the Commission in September, I believe, yes, September, on our efforts to address the action plan on all of the initiatives that we have

taken since September 11th of 2001.

Obviously we are not doing those independent of our state partners or our federal partners. There are lots of agencies, as you can imagine, that are involved in the security arena, the intelligence arenas.

We have our own dedicated Office of Nuclear Security and Incident Response. And our office, FSME, also plays a role in that. And we are a supporting office. But as far as the agency goes, FSME does not have the lead on security matters. Our Office of Nuclear Security and Incident Response has that lead. So we are a support office.

But in that time, in this time since September of '01, we have taken a lot of efforts to try to quantify and qualify where we as an agency needed to focus our efforts on ensuring that the materials we regulate are used safely and by the appropriate persons and that they are authorized to receive those materials.

And that runs the gamut of activities. We have issued orders. We have imposed requirements through various venues. We have worked with our state partners to try to ensure that we implement them nationwide in a consistent way.

We have been obviously coordinating with DHS and DNDO, DOE with its NNSA organization, as well as others so that there is a very broad spectrum of activities that has occurred during this time frame.

We will go through or I will go through the GAO investigation briefly and the Senate hearing and each one of those recommendations and let you know how we are responding to those.

Also, as the second bullet implies there, we did many different sorts of security assessments of the materials arena as well as the reactor, of course, research test reactors, and other higher-risk activities. It wasn't limited to the materials program.

We have tried to take a graded approach to those activities and tried to use our resources wisely in that regard as to where we were going to focus our security initiatives during that time frame.

We also stood up or began what we called our material security working group, which was composed of representatives of several offices here at the NRC. And we also had Agreement State representation on that security working group.

We had a steering committee for that group as well to try to ensure that whatever recommendations

came out of the working group were fully considered by a broader spectrum of organizations and managers within the NRC as well as, again, coordinating with our other federal partners.

And, as I mentioned just briefly, we had issued orders, which is a tool that the NRC uses sometimes in the absence of rulemaking. It is usually used to impose requirements in a much more prompt manner than the rulemaking process will allow. And we started those with the reactors first and then went on down to other users, categories of users, to impose various security requirements over this time.

As I mentioned, we have used a risk-informed, graded approach. You will notice NRC doesn't use the term "risk-based" because risk is one element of our information, the decision-making. And that's why we refer to it as a "risk-informed decision-making process."

There are always other factors that we consider, including what our federal partners have advised us to do in some cases in coordination with our state partners.

And so we have tried to -- and also the international arena, as I mentioned earlier today, with the International Atomic Energy Agency and others

that we tried to apply a consistent approach, not only in this country but not incompatible with our international partners as well.

As you probably heard, this year the Government Accountability Office did conduct this investigation. And they did form a bogus company. And they set up a company with a p.o. box actually located in Martinsburg, West Virginia. And they used that address to apply to the NRC to receive a license to use portable gauges.

At the same time, they had also tried to obtain an Agreement State license. And that was with the State of Maryland. And the State of Maryland at one point during the process this late winter had said to GAO reps that as part of their pre-licensing procedure, they would need to conduct a pre-licensing site visit. Well, that was enough to turn off the GAO from pursuing their license application with the State of Maryland any further.

But under our pre-licensing guidance procedures, with this type of user and applicant and potential use, we did not require a pre-licensing visit. And so some dialogue ensued between the applicant and the NRC, normal questions and answers, information shared back and forth, and the license was

issued by the NRC but not the State of Maryland.

GAO then took it upon themselves to use commercial off-the-shelf software to manipulate the license document, to alter it, to increase their possession limits beyond what the NRC had allowed them to be authorized to possess.

So they got creative, but I think the point of concern there is, of course, they were able to take a document, a legal document issued by a federal entity. And they were able to use commercial off-the-shelf software and manipulate it so that based on appearances, you would never have any reason to look at this piece of paper and suspect that it was not legitimate.

They then proceeded to contact suppliers, vendors of devices and were placing relatively large orders for gauges. And based on their report two suppliers were ready, willing, and able to sell them devices up to the approximate number of 45, I believe, devices, which, of course, they had done their homework. And they had attempted to purchase a number of devices that were hitting right up against the category 2 level. So they knew no alarms would go off necessarily for obtaining these large number of devices from more than one vendor.

There was another vendor involved that is not really called out much in the report but that, in fact, did become suspicious of a large order and did not agree to sell gauges to them as well.

Once GAO had performed these exercises, they did contact the NRC. We have normal day-to-day working relationships with GAO. And so we have normal contact persons. And they called us up. And they said, "Here is what we have done. Would you like to know more about that?"

And, of course, we said, "Yes." And so we had some conference calls with GAO. And they were very forthcoming, complete in their information to us. We had a lot of questions, of course, to try to understand specifics and motivation and how it was done and a lot of intricacies associated with the licensing process itself. And, of course, we had to immediately take some certain steps. This was at the end of May, early June.

They agreed to terminate the license, which, you know, good first move. They couldn't then use the license any further anywhere else. But we also had to basically cease and desist with our own materials licensing actions that were in house in our regional offices until we could do a sanitary check,

if you will, on anything that we had in house in process.

In part, we were assured that they had not applied for any other sorts of licenses, but it was obviously reason for us to halt all licensing actions until we could revisit our own pre-licensing guidance that we had in place at the time.

So we did that. And we issued some interim guidance to our regional offices that said, while we have pre-licensing guidance in place that requires a pre-licensing site visit for any applicant that is seeking authorization for a category 1 and 2 source, we are now going to cast that net wider. And, in fact, we need to include a higher threshold for applicants to receive this material and consider conducting pre-licensing visits in almost every case.

A good example of not conducting a pre-licensing visit would be a medical institution. And this is readily one that came to mind at the time, an institution that a regional office is familiar with, they have inspected 20 times. You are getting a second gamma knife or you are including another use on your license that you have not previously been authorized but we know the facility, we know the radiation safety officer, we know the users, what have

you. Clearly we would not need to do a pre-licensing visit to determine that that applicant is authentic. So there are some clear examples where we would not, but in most cases, we would.

We also immediately sort of rejuvenated our working group that we had previously established on developing these pre-licensing guidances that we have had in place since just December of '06.

We have rejuvenated that group and the steering committee as well because in light of the GAO findings, we needed to go back and take a look at the guidance that we had issued in December of '06 and say, "Okay. Let's look at it with another pair of glasses on, a different framework, a different perspective" since we had learned of the GAO investigation and determine what changes might need to be made to that pre-licensing guidance considering the GAO recommendations, the Senate findings, and our own IG. And so we have done that.

We also immediately coordinated with DHS and DOE and others to let them know what had occurred just as an awareness issue. It has, I'm sure you have sensed through other venues, gotten a fair amount of attention within the federal family, within the Senate and the House. Even President Bush was briefed almost

immediately. And so whenever that sort of briefing and information flow is happening, there is a lot of attention by FBI, DHS, White House Office of Science and Technology Policy, and many others.

Did you have a comment?

DR. SULEIMAN: Yes. What's a typical gauge? What is the activity?

MS. GILLEY: Nine millicuries of cesium and then americium beryllium source of about 44 millicuries.

MS. SCHLUETER: Category 4 device in this case. Okay? But they knew where, how many they could collect and get up to an aggregate amount and be not subject to additional security requirements.

So we coordinated with the federal partners. It was quite active. There is a high expectation that the NRC would take some actions, and we have.

We also at that time had our Office of Nuclear Security Incident Response prepare a consequence analysis because there were information requests from DHS and others as well if someone were to get a hold of planning devices and to do something elicit with it, then what would be any sort of public safety and health consequence from obtaining the

material.

And we provided through analysis of obviously certain scenario assumptions and distribution of the sources and how that did occur. We're speculating on how that might occur. There was not a public health and safety issue with accumulating this number of devices.

We also immediately -- and we're all talking in the June time frame here still -- did a retrospective examination of the licenses that we had been issuing over the last calendar year to make sure that we went back and we looked again sort of from a different perspective, a different framework, different set of glasses to see.

You know, if we are sitting here issuing that license today, was there anything in the application or the license itself that would make us suspicious? And so we didn't have any reason to believe that anything, any license that we had issued over the period of the preceding year, caused us any concern.

And I would like to mention, too, that when the NRC began to go through some of these efforts and exercises, a lot of our Agreement State partners were proactive and took it upon themselves to do

similar reviews of their own case work because they, too, obviously were concerned with what had transpired and wanted to look for vulnerabilities in their own systems as well.

As you see on this screen, the GAO did make three recommendations to us. They firmly believe that the NRC and the Agreement States should conduct mandatory pre-licensing visits, regardless of what type of authorized use is being applied for and requested, essentially no threshold for knowing the applicant or what have you. That was an issue that they felt pretty strongly about.

The second bullet about periodic oversight of license reviewers, that is more one that's a little bit more difficult to get your arms around in the sense that clearly we train our license reviewers.

They have to have certain training and experience under the supervision of others. They are qualified. They meet internal manual chapter guidance on what it takes to be a license reviewer that works alone.

They are supervised, though. A branch chief or another manager above them would typically sign off on licensing actions, but the gist there was, more or less, is there a need to periodically, perhaps

do more than we do today, go back and ensure that the license reviewers are receiving refresher training, are up to speed, are aware of the latest findings, for example, with the GAO study and what have you? Are we exercising adequate supervision over our license reviewers?

And you will see as I go through these that all of these recommendations are being addressed by either one group or another or both in some cases.

They also were very concerned about their ability to manipulate and alter the license document itself and how would the NRC try to determine or identify methods for reducing the possibility of counterfeiting, how do you do that with a piece of paper that we collectively, the NRC and Agreement States, allow licensees to use routinely by faxing to vendors or manufacturers and distributors to make purchases. That has been a standard practice.

Obviously there are new forms of communication that probably need to take place between licensees that are authorized to purchase devices and when they are making these sorts of purchases through vendors, more communication back to the regulator to authenticate who the potential buyer is, the document itself, are there techniques that could be used in the

paper, in the ink, what have you.

Different states have looked at this issue. And in some states, they have taken some interim steps to try to reduce the possibility of counterfeiting. It does vary, but this is one of the issues that one of our working groups is looking at now trying to come up with a relatively short-term fix to reduce the possibility of counterfeiting.

The Senate -- and maybe if I can think here for a minute their very long title, the Senate committee that was involved here. It will come to me in a minute, the permanent subcommittee on investigations.

They also, of course, were very concerned with the GAO investigation. They called for a hearing, which Commissioner McGaffigan, the late Commissioner McGaffigan, testified at on July 12th.

Again, they focused on slightly other aspects of this and, as you can see by the first bulleted item there, to reevaluate the good faith presumption. What does that mean? Well, we at the NRC and our state partners have always operated from the regulatory philosophy that applicants were coming to the regulator for the purpose of obtaining material for authentic and authorized use for not illicit

reasons, for legitimate purposes, legitimate uses. That has always been our assumption in licensing and through our licensing and inspection programs. We don't make assumptions to the contrary. Why else in more cases than not would people be coming to us to apply for a license to get these materials? So it is sort of fundamental to the way that we do business.

We are not the CIA, the FBI. We are not a security agency. We are here to ensure that when people do receive a license from us that they use these materials in a safe manner and that the public health and safety and environment are protected.

So that has been our philosophy. It is our regulatory approach, but they have called into question whether or not that is the approach that we as regulators who have authority over these materials should be taking. So it is very fundamental to how we do business.

They have also suggested that we regulate category 3, as Mr. Lieto alluded to earlier, more closely. That is not a novel idea. Our Commission itself has also discussed this with the staff. We were charged as long ago as about a year and a half, two years ago to look at the feasibility of creating a regulatory framework where we do, in fact, exercise

more oversight over category 3 materials and perhaps even beyond.

That is an issue that is currently being looked at in the context of our efforts to develop the national source tracking system. So this was not a new idea, but it is one, obviously, of their formal recommendations to us.

And then, lastly, of course, ensuring that only authorized persons get the radioactive material is clearly in everyone's best interest.

Our own Office of the Inspector General has been active in this area and not just recently but over the last two years or so, I would say, in particular. They had previously suggested to the staff that we do set up an independent external panel to identify their vulnerabilities in the materials licensing program.

We felt that based on activities that we had taken and efforts that we had taken over the last few years that we had done what we needed to do in consultation both inside the NRC, with our federal partners, and with the states that we were confident that we had a materials licensing inspection program that considered security aspects, vulnerabilities, and so forth, and we had not to date established any sort

of external group to DHC to take a look at any vulnerabilities in our regulatory process or to even validate what we had done. So they reiterated this recommendation most recently. And we have established an independent external review panel for this purpose.

Question?

(No response.)

MS. SCHLUETER: Okay. So here we are. We are through July. We had the hearing. The Commission then issued a staff requirements memorandum to us in August. And they asked that we submit an action plan to them by September 4th. We did that on that day. We also held a public Commission briefing. And, actually, these slides that I am using today are the slides that we used before the Commission on that day.

The plan, of course, was to be as comprehensive as possible. And, as you can imagine, we just had a few weeks to do that. So we did our best and tried to break down the different GAO, Senate, OIG recommendations or anything else that we had come up with into bins, things that we could do short-term, things that we could do longer-term, put that action plan forward, and then approved it.

And also important to the staff and to the Commission when they wrote back to us in the staff

requirements memorandum was that we closely coordinate with our Agreement State partners since, after all, there are 34 of them and they regulate more than 80 percent of the materials users in this country.

So anything that the NRC does is fine, but from a national perspective not very effective unless we reach these points of alignment with our Agreement State partners.

Okay. So in the action plan, we have these various elements that you see on the screen there. I'll go into each one of them a little bit more with regard to their purpose and scope, but you can see we have this external group. We have the rejuvenation of the pre-licensing working group, which also has a steering committee. We have a newly formed materials program working group and steering committee.

Our efforts on the national source tracking system and the Web-based licensing have been going on for years, but, of course, we are now trying to change the scope of those efforts so that they can address some of the issues identified by GAO and reconsidered by the staff.

We had already been tasked by the Commission and had thought independently of the

Commission the need to look at the general licensing program because there are devices and sources that when you look at it from a risk perspective should probably undergo more scrutiny from the regulator's perspective and be issued perhaps under a specific license, rather than a general license, and also the framework that is used nationally for certain devices that are generally licensed is not uniform as well.

And, again, there is always an Agreement State partnership aspect to the action plan on whatever we do. We have included them in various areas.

Now, to take these individually, the external review panel is really one of the shorter-range issues. We have identified three persons. It's public information that we have an individual from DTRA, the Defense Threat Reduction Agency; we have a former Agreement State program manager; and also, oh, yes -- I'm sorry; thank you, Lynne -- the current Chair of the NRC's Advisory Committee on Nuclear Waste, Mike Ryan. So it's Mike Ryan, Tom Hill from Georgia, and Ben Narute (phonetic) is from DTRA.

So these three persons are now a part of this panel external to the NRC staff that are being

charged with looking at the vulnerabilities of the existing materials licensing program, primarily licensing, but we can't ignore the inspection program as well.

They have 120 days to review the NRC's program. And obviously we have the Agreement State aspect in there with Tom. So Tom can provide a lot of perspective on his experience. And we put him as chair, in part, because he has the materials program perspective, and we would like for these issues to be thought of in context of how the NRC and the Agreement States regulate now.

And, again, they are to review this good faith presumption because this is, as I mentioned, fundamental to how we do business. When it's 120 days, that's 120 days from when we were able to stand up the panel, which was just in October.

And, in part, because it is subject to the Federal Advisory Committee Act, because there are individuals outside of the NRC that are not federal employees, and because they will be collecting information, deliberating on it, discussing among themselves, and then coming back to the agency with recommendations, it subjects them to FACA. So that requires that their meetings primarily are open to the

public.

Obviously there have to be a certain exemptions hit in order to close the sessions. Clearly there would be some security matters that they would be discussing where the sessions would be closed, but they have to be all publicly noticed. And so we just began to issue a Federal Register notice to have the first meeting here in late October.

And so this group is just getting off the ground, but they will have 120 days total to bring back their final recommendation to the Commission. They report directly to our executive director for operations, which, of course, is our highest staff manager outside of the Commission.

So the Commission has put this organization at a very high level. They are also providing periodic reports to the Commission. My staff, we're responsible for providing them information, being a liaison to the panel.

We have to have a designated federal official, of course, under FACA. So that's all under my division, but just to let you know that they are reporting directly to the EDO and to the Commission. So it's a very high-level group.

Pre-licensing working group. As I

mentioned, we have reinvigorated the pre-licensing working group. Now, when we use this term "working group" around here, a lot of times, most of the time, it means that this working group is subject to an internal management directive that we refer to as 5.3, which says that when we have matters of the materials program area, in most cases than not, we have a 5.3 working group, which is co-chaired with the Agreement States. So we have an NRC person and an Agreement State representative co-chairing the working group. And then we have a steering committee as well.

So we reconstituted that this summer. They took a look at the guidance that was issued in December of '06. They took a look at the interim guidance that we put out in the June time frame to our regions. That was NRC to our NRC regions, not the Agreement States necessarily. But this working group is now taking a look at both of those documents as well as soliciting feedback from individual Agreement States as to what perhaps they have been doing over the last ten months or so and to revise or modify the existing pre-licensing guidance to consider the GAO scenario, their recommendations, and what we might do in the future to help reduce this area of vulnerability.

Right now they have come up with a draft. And that draft is out for Agreement State comment, I think a 30-day comment. And they are on schedule to deliver a final product in November. And then that latest version of the pre-licensing guidance would be basically used, but I want to call it kind of interim use, if you will, because we will certainly encourage the Agreement States and our regional offices to use it and then provide feedback back to the working group chairs to improve it based on experience of using it for four or six months or so.

The only other thing I would add on this slide is clearly we have not just people from my staff and the Agreement States, but we also have the regional people participating as well as we almost always have someone from the Office of Nuclear Security and Incident Response as well as the Office of the General Counsel. We always have representatives, both on the working group and the steering committee, that provide very useful input as well.

Now, the one thing I want to mention, too, about this working group is that they are not only charged with looking at the GAO recommendations, the Senate, the IG, but clearly the materials licensing

and inspection program, both through headquarters, where we develop the policy and programs, procedures, and through our regional offices, where they implement it, and the Agreement States, clearly the staff has their own ideas about what we might do in the short term and the long term to reduce these sorts of vulnerabilities.

So they are getting input from many, many different places, one of which will be this external review group. So whatever recommendations are coming out of the external panel, it is very possible that the materials program working group will get a to do list from the external review group as well.

So there is a synergy behind and between all of these efforts, if you will. There is an interface. There is a natural coordination and connection. And so in many cases, one working group will be feeding the other, if you will. But of the three efforts I am describing, the external group, the pre-licensing is much more focused and finite. And this materials program working group is the much broader effort and will be much longer-term than the external or the pre-licensing group.

National source tracking system and Web-based licensing, very challenging areas. You have

heard, I'm sure, in the past about the national source tracking system.

What it is intended to do is to take the interim inventory, which we have been maintaining now for a few years, which are snapshots in time of sources possessed by our licensees of the category 1 and 2 levels, to take that information and to merge it into the national source tracking system. And then that information would be enhanced by also requiring reporting for the transfer of sources between licensees as well.

So it's a somewhat cradle to grave inventory, if you will, not a real-time tracking, as some would perceive or perhaps prefer, but clearly an enhanced inventory of category 1 and 2 sources nationwide, not limited to the NRC. Licensees and Agreement States have been already feeding the interim for several years now, but obviously, as we look at the system now and Web-based licensing, we want to look at it from the perspective of how can we enhance these systems to address some of these authorization issues, authenticating users, limiting purchases to possession limits, trying to assure that people do not have or are trying to purchase and obtain and possess source quantities above what they are authorized to?

So there are other facets to NSTS and WBL that were not a part of the original design, were not the original purpose, but we are having to go back and look at those systems now and see how can we enhance them based on, for example, the situation we had where GAO had a license and began probing and going to various vendors and, in theory, you know, was able to secure an amount of sources that far exceeded what we had authorized them for. But, again, there is that counterfeiting aspect to the process, too, that they took it upon themselves to increase their own possession limits, which we have no knowledge of as well.

Oh, yes?

MR. LIETO: Could I ask a quick question?

MS. SCHLUETER: Absolutely.

MR. LIETO: Category 3.5, now, that's between 2 and 3, correct?

MS. SCHLUETER: No. It's between 3 and 4.

MR. LIETO: I'm sorry. Okay. Right. Okay. Thank you.

MS. SCHLUETER: Yes. It's all --

MR. LIETO: So lower than 3?

MS. SCHLUETER: Yes, that's correct.

MR. LIETO: In activity amounts?

MS. SCHLUETER: Yes.

MR. LIETO: Thank you.

MS. SCHLUETER: General licenses. This is a pretty broad area. In fact, even the Organization of Agreement States and State of Florida -- so Debbie might have to apply duct tape over there or something -- have in the past submitted a petition to the NRC on generally licensed devices. That's in part 31 of our regulations.

It is a framework by which throughout the nation it's been called into question. Have we set the threshold for allowing users to possess certain devices under the generally licensed at the right threshold? Should it be higher? Should more GLs be specifically licensed based on the quantity of material that's in the devices?

There are lots of regulatory issues associated with the GLs. We have known for some time, as well as our Agreement State partners, that it needs attention, it needs addressing. We have formed -- and this is in my sister division. Dennis Rathbun will be here tomorrow. It's under his rulemaking division that we have a working group established to address some of these issues on the GLs. The Commission has given us direction more than once on revisiting the

regulatory framework for these devices.

So it is ongoing. Rulemaking is never, almost never, a short-term fix. The beauty of it is that it is a very deliberative process. It is a very public process. It does take a lot of time and attention. And I think we typically would come out with a product that we all feel pretty competent in.

So we also have to look at the GL arena to see is there something that we should be doing now shorter term and not just waiting for rulemaking in this area to address it from a safety or security perspective. So that is another area that the materials program working group has to look at.

This resource chart, it looks like we received a lot of resources to do this work associated with the GAO investigation. And, in theory, I guess we did, but that, in particular, the FTE, the full-time equivalent, number, is spread across the agency. It's not what my division received.

It's not what the Office of Nuclear Security and Incident Response received. It is what is smeared holistically, if you will, among my division, rulemaking, the regions, Office of Nuclear Security and Incident Response, Office of the General Counsel. Everyone who is involved in materials

licensing program and inspection has a little piece of that.

So yes, we got resources in my division to address the GAO, but what I would also caution against, too, is that that is not all-inclusive or the end-all in the sense that when the external review group makes its recommendations or the materials program working group makes its recommendations, there were a lot of assumptions that went into potentially what they might come up with and what that might cost us as an agency.

And so those were all building blocks into that number, but the reality is that as we move along through this process over the next six months to two years, in particular, we cannot predict necessarily where all of these efforts may lead us and, in fact, may result in additional resource burn and expenditures on our part as well as the Agreement States to actually implement what comes out of those groups.

We feel like that the plan as we developed it is comprehensive and responsive to what GAO learned, to what we have learned since then. As I mentioned, there are short-term, mid-term, and long-term actions, both with the working groups and

the external review panel, but the Commission made it loud and clear in their message to us during the September briefing and since then that, you know, they don't want to see paralysis by analysis. They don't need perfection. They want real-time workable, implementable solutions that are not necessarily rulemaking but things that make sense that are common sense that might in the future need to be tweaked perhaps but that get shorter-term effective results.

And so our groups have all been charged with that goal so that we do try to address some of these vulnerability issues in a shorter time frame than one might expect.

CHAIRMAN MALMUD: Thank you.

MS. SCHLUETER: All right.

CHAIRMAN MALMUD: This was a very thorough presentation and gives us a picture of what evolves from the sting. I guess we could call it a sting.

MS. SCHLUETER: Yes, yes. Probably shouldn't, but that's what we've been calling it.

VICE CHAIRMAN VETTER: Can I ask a question?

CHAIRMAN MALMUD: Certainly.

VICE CHAIRMAN VETTER: Dick Vetter.

You go through all of this exercise. And

you beef things up. What is to prevent a legitimate-appearing group from simply over-ordering, ordering lots of sources, and aggregating them and doing something bad with them?

MS. SCHLUETER: Well, I think that is exactly one area you have hit on that I alluded to and I could be more explicit about. We are looking at near-term fixes where we can have increased coordination and communication with vendors when it comes to people contacting them and wanting to make certain purchases and instead of just relying on that seller and purchaser discussion and communication but having the vendor loop back to the regulator so that we can develop mechanisms to keep a better track on what they are authorized to possess versus what they appear to be attempting to purchase.

Now, that also requires not just, you know, seller and purchaser and regulator, whether it's the NRC, but there has got to be an NRC and Agreement State coordination there because someone can shop around.

There are 34 other regulators out there besides the NRC. So there is a lot of communication that needs to take place to help prevent that.

CHAIRMAN MALMUD: Dr. Welsh?

DR. WELSH: I might want to just add that the true purpose of my little discussion that is scheduled for later this afternoon is an attempt to answer Dr. Vetter's question about what other mechanisms can be imposed to improve authentication and reduce the chances of this happening.

CHAIRMAN MALMUD: Thank you.

Does that complete your -- oh, sorry. Mr. Lieto?

MR. LIETO: I just had a question. Would the increased controls be a part of this? I mean, would this be applied as a part of this program that you're talking about or are we looking at apples and oranges right now?

MS. SCHLUETER: No, you're not. It's not apples and oranges at all. And they are somewhat related. And increased controls have been implemented nationwide for category 1 and 2 sources already, both from the NRC and the Agreement State portion.

The fingerprinting issue that we have discussed at some length is a supplemental tool. It does only pertain to those increased control licensees, you know, those licensees now which are subject to it.

At present, we have not charged the

materials program working group with looking specifically at how we have implemented the increased control program.

CHAIRMAN MALMUD: Thank you.

Dr. Vetter? Excuse me. Dr. Van Decker?

VICE CHAIRMAN VETTER: He's much better looking than I.

(Laughter.)

DR. VAN DECKER: We could debate that all day. Van Decker.

Broad-ranging big stuff in general terms. Can I just ask how communication is going to go with stakeholders at each step of this and also some feedback? Obviously you are going to need to do things from upper levels on down but feedback from stakeholders at the licensee level about how some of this is going, their input to some of this?

MS. SCHLUETER: I think that's critical. It's critical that we include that element in not only the deliberative process but in how we roll these things out, if you will, because I think one thing that, looking back, like on the increased control program that we instituted in '06, I think certain categories of users, like industrial radiography, I think that we could have done more to get to that

community in advance that potentially would have increased the compliance rate because we are having compliance issues in that particular arena.

So I think that is something that is a very relevant point, very important point, that we have to look at very carefully. How can we reach out in advance not only to solicit input but once the direction is taken or decisions made, that we find ways to communicate it before it is fully implemented?

DR. VAN DECKER: Because, you know, I think that I would speak for the table to say that the regulated community is interested in being helpful to this process and sees the importance of this. At the same time obviously, you know, there are the access issues and a bunch of other things.

MS. SCHLUETER: Right.

DR. VAN DECKER: So we will want to be involved in the thing.

MS. SCHLUETER: Point made.

CHAIRMAN MALMUD: Sally?

MS. SCHWARZ: Sally Schwarz.

In terms of the regulated community, as Dr. Van Decker was mentioning, the diagnostic medical group, are there sources that will come under these kind of controls, say, for example, the molybdenum or

the technician generators? Is this a large enough quantity that it will come under increased controls?

MS. SCHLUETER: Well, no, not increased controls. No, it wouldn't, but clearly as part of the materials licensing process, any applicant -- you know, it's all part of our pre-licensing guidance arena as well.

Are we asking the right questions, for example, during the licensing process, regardless of source, type, quantity? Are we asking for the right information? But no, it would not be subject to increased controls.

MS. GILLEY: Increased controls are based on IAEA categories of certain isotopes. And I don't believe the molybdenum is even listed on that group of isotopes because of short half-lives. But that is kind of a different animal than this.

MS. SCHLUETER: Right.

MS. GILLEY: If it could be used in a terrorism activity, is it not secured enough that we need to look at it, even if it wouldn't meet that, or would we need any extra requirements? And I think those are some of the areas that they were exploring, the minimum security we would need for any kind of license.

CHAIRMAN MALMUD: Other questions?

(No response.)

CHAIRMAN MALMUD: If not, we thank you for a very thorough presentation. Oh, I'm sorry.

DR. EGGLI: I have one slightly humorous comment.

CHAIRMAN MALMUD: Dr. Eggli?

MS. SCHLUETER: Good.

DR. EGGLI: I want to thank you for the last slide. Hopefully by the time I rotate off this Committee, I will understand most of the acronyms.

(Laughter.)

DR. EGGLI: Thank you.

MS. TULL: I have a question. We're at lunch. Do we want to break for lunch or do we want to try to do a 30-minute presentation.

MS. WASTLER: Well, I would leave that up to Dr. Malmud. We are scheduled. We are actually ahead of schedule at this point in time.

MS. TULL: We have a 30-minute presentation. That would be by Dr. Welsh. It was going to be right after lunch.

PARTICIPANT: If it didn't take 30 minutes.

MS. TULL: Yes. It's not really, I don't

think, a controversial issue, just kind of a question to pose for discussion.

CHAIRMAN MALMUD: Dr. Welsh, are you prepared to do it now?

DR. WELSH: I can do it now.

CHAIRMAN MALMUD: Then we could do it now and then break for lunch at noon.

MS. TULL: Do you want to speak from there?

DR. WELSH: Yes. This is fine.

7. AU APPROVAL FOR BYPRODUCT MATERIAL

So the question being raised is, should the authorized user be required to sign all letters for byproduct material? And initially this was deemed to be a potential non-issue of such little relevance and importance that maybe not, as somebody told me, worth the air required to voice the words. But I think maybe my opinion is different today after the update from Ms. Schlueter.

So, in way of background, currently there is no NRC guidance regarding the ordering of byproduct material. Radioisotope uses under parts E, F, and H require review, approval, and signature of the AU before administration to the patient, but nothing is said about ordering.

There is a lot of variability -- go to the next slide -- from one institution to the next. And most institutions that I am familiar with and all of them that I have worked at insist that the AU put a signature on the sheet that is going to be faxed to the supplier. This provides some proof that the authorized user is aware that a shipment of byproduct material for medical use that he or she is responsible for will be coming to this institution.

But I have learned that this is far from a universal policy. Several institutions do not have the authorized user sign or acknowledge in any way that a shipment has been ordered. And, in principle, this could lead to some problems.

So let's take a look at the next slide. I looked into this briefly. And in 35.27, "Supervision," it mentions that delegation of tasks, such as ordering isotopes, can be done by non-authorized users. And we all know that most authorized users do not actually place the order.

But this individual must be properly instructed and supervised. And the authorized user is considered the one that is best able to determine what tasks the delegate is capable of performing and what level of supervision is appropriate.

Next slide. The NRC has not gotten directly involved in this matter. And for the purpose of balance between public health and safety and licensee's responsibility for safe use of byproduct material, 35.27 intentionally excludes anything about prescriptive requirements or listing of the tasks that can be delegated.

So, in principle, this could lead to the shipment of radioactive material without the knowledge of the AU. Is this likely to happen? Has this ever happened? Perhaps not.

And it is unlikely to happen in a single department clinical application, such as nuclear medicine taking care of something or radiation oncology ordering something for use in radiation oncology. But it is possible now more than ever given the increasing number of interdisciplinary application: microsphere brachytherapy involving interventional radiology, nuclear medicine, radiation oncology. Somebody might place the order without the authorized user providing a signature on the facts.

Prostate brachytherapy is another example where urology and radiation oncology are attempting to coordinate between the two and there is a possibility that it could, the coordination could, slip, same

thing with radioimmunotherapy involving medical oncology, radiation oncology, nuclear medicine, et cetera.

Next slide. What kind of simple solutions might there be? In a post-9/11 era, where there is appropriately heightened security or concerns about any shipments of byproduct material, perhaps all orders for byproduct materials should have the signature of the authorized user on it. Whether this is a must is open for discussion.

Initially, as I said, this was brought up simply to point out variations from one institution to another. And most people that I spoke to felt that it was a non-issue, but I think in light of the GAO investigation and the identification of some vulnerabilities, maybe this issue should be discussed a little bit more thoroughly.

For me personally, this whole matter came into greater focus recently because a cesium-137 source was stolen in Wisconsin from an industrial site only 10 miles from the hospital and still missing, incidentally, as far as I know. But I was pulled into that very deeply.

And questions came about within our own institution, the local hospital I work at, about what

kind of weaknesses might this hospital have in terms of losing material.

And that is where somebody asked the question about whether or not an individual from the hospital could call in an order on my behalf, fax in a bogus or excessive order, and have it delivered to the hospital, pick it up, and then disappear.

And apparently with this system right now, the answer is potentially yes. And although this would never be a concern for mass destruction, certainly quantities that could call mass disruption might be easily accessed because of this.

The Senate staff recommendation was one of the many that was mentioned was to ensure that only authorized persons gets radioactive material. This might be one step in that direction.

If suppliers required an authorized user signature or other means of verifying authentication on all faxed orders, it might represent a small step in the right direction as well as being good medical practice, which was the purpose of me bringing it up in the first place. But now I see it has potentially broader implications.

CHAIRMAN MALMUD: Well, that is now open for discussion. Dr. Eggli?

DR. EGGLI: I guess I would ask Dr. Welsh how far down the food chain would he go in this kind of authorized user signing? The implication is part 300 uses from your slides. Would you go all the way to part 200 uses? Two hundred uses orders are placed actually by telephone several times a day. Would you have an authorized user sign for part 200 or would there be some risk threshold?

I know the source you are talking about, cesium source, would be a part 400 brachytherapy source if it were a medical source. Do you include 300 with unsealed sources, like radioiodine? Do you drift all the way down into diagnostic technetium-labeled compounds and part 200 uses? Where would you draw the line for the kind of AU written authorization that you would like to see happen?

DR. WELSH: I don't know that I had any particular cutoff in mind, but perhaps a simple answer might be anything that requires a written directive.

CHAIRMAN MALMUD: I think that Dr. Nag was next.

DR. NAG: Yes. I think in principle, what Dr. Welsh has suggested is very good. However, a concern we have is what is the difficulty in having that signature? For example, in many places, the plan

is almost automatic that for a certain case, you have 100 millicuries or 100 whatever ordered. And, therefore, you don't need a signature.

Now, to acquire a signature would mean finding that person. So I think part of the deliberation should be that yes, in principle, it is very good, but what additional burdens would it entail on the institutions?

CHAIRMAN MALMUD: Dr. Thomadsen?

DR. THOMADSEN: I would like to point out another major medical facility in Wisconsin that Dr. Welsh probably is familiar with orders all of its radioactive materials without any authorized user's signature whatsoever.

I would suggest that possibly the answer to the question that Dr. Welsh poses as far as could the material be obtained would lie not so much in requiring the signature on the order of the authorized user but tighter security on the receiving and distribution end of the medical facility.

CHAIRMAN MALMUD: Dr. Welsh, do you wish to respond to that comment?

DR. WELSH: Well, my response to Dr. Nag's important point is that I personally don't think that it would be too burdensome for the individual who is

placing the order, maybe via telephone, and promising that the facts will be coming shortly to find the authorized user and say, "Please provide the authentication that is necessary" sometime before that shipment gets here. So I don't think that it would be too much of a burden on the physician authorized users.

As far as the receipt of shipment and security in that regard, this is certainly not going to solve that problem by having a signature there. But if it could set off a possible chain reaction of increased security measures, it might be worthwhile such that the producers of radioactive material before they ship anything out require some form of authentication and maybe another form and maybe another form of authentication before that actually leaves their facility and maybe the same thing on the receiving end.

CHAIRMAN MALMUD: Dr. Zelac, do you wish to make a comment?

DR. ZELAC: Ronald Zelac, NRC staff.

Dr. Welsh has just gotten to the point that I was going to make. Yes, we are all interested in preventing illicit transfer and use of materials. And in my experience, typically the responsibility has

been on the part of the supplier to know that it is an authentic shipment, authentic order. And that typically has either involved the order being placed by particular people that were known to the supplier or perhaps in some cases some paper transfer but typically telephone orders from known individuals. And before an order would be accepted and filled by a supplier for a facility, the person placing the order would have to be in some way authenticated.

This is the way it has been in the past. And it seems to have worked relatively effectively.

CHAIRMAN MALMUD: Thank you, Dr. Zelac.

Dr. Vetter?

VICE CHAIRMAN VETTER: Yes. Dick Vetter.

There may be a number of different ways to answer the concern that Dr. Welsh brought up, but I would caution that requiring the authorized user to sign is micromanagement. I think there we are dictating how programs answer the concern, and there are many ways to do that.

As Dr. Thomadsen suggested, larger academic medical centers, the radiation safety office or purchasing or whomever is placing the order actually might be a little suspicious if they saw an authorized user's signature on the order form because

they're pretty busy taking care of patients. And the procedures are set up in such a way that it is very clear that a nuclear pharmacist or a physicist or someone of that sort who might be intimately involved in the final plan for that patient would be the person to actually order the material.

I would caution that we not venture into the area of micromanaging how programs answer this question.

CHAIRMAN MALMUD: Thank you, Dr. Vetter.

Dr. Nag?

DR. NAG: Yes. I think the important part is not whether the order is authorized because if you are worried about lost shipment and so forth, it is the person of what happens to that radioactive material once it has left the supplier. That means, where did it come in? And then who received that? That is where the loss is likely to happen and not whether someone ordered another 100 millicuries more.

CHAIRMAN MALMUD: Thank you.

Dr. Welsh, it has been my experience that the control lies in the institution as we receive the material. It is delivered to us by the radiopharmacy and speaking of nuclear medicine. And it has to be received into the hot lab, which is controlled, locked

and controlled, by the technologists who work for us.

Larger therapeutic doses are all in response to written directives. And they do initiate with a physician. The diagnostic doses are not handled in the same fashion, but they are received in the same fashion.

So that I am not certain that having a written request for the radiopharmaceuticals would add any greater degree of security because it would mean that the weakest point would still be the receipt of the material, which is currently tightly controlled. It is a theoretical concern, but I don't know that it is a real one in handling radioisotopes for diagnosis and therapy.

I cannot speak to the procedures that are employed in radiation oncology, but Dr. Zelac just did, having had years of experience with them.

I see Dr. Suleiman.

DR. SULEIMAN: I think, obviously, this is a very complex issue. And I think it would probably depend. One facility's experience or safeguards may not work in another.

So I have a knee-jerk reaction that just coming up with another regulation or guidance that says everybody has to do this, but at the same time,

we have to make sure that there is responsibility, whether it is legal or whatever.

And so I would think each facility has to assume that responsibility because once something happens, I am sure somewhere somebody who -- I have never heard this person, but somebody argued unsuccessfully to make sure all cockpit doors were locked. This is pre-9/11. And so that was a scenario that just was very, very unlikely.

I am very convinced that even diagnostic levels, I mean, of radioactive materials, can be used in a very creative way with people who understood these materials and made a conscientious effort to subvert the system.

And so even if you have got qualified authorized users, you almost need a system of double surety. I mean, even the Air Force screwed up on that recently.

But you almost need one system to guarantee against one individual being able to manipulate the system. And we are not talking about a natural accident. We are talking about somebody who has sufficient knowledge.

And so I don't know. I will be frank. I don't know what solution, you know, will solve that

problem, but I don't think we can ignore it and argue that this isn't going to work and that is not going to work because as we argue or debate it, somebody, you know, may decide that they can subvert the system.

CHAIRMAN MALMUD: Thank you, Dr. Suleiman.

With regard to the analogy to the locking of the cockpit doors, the cockpit doors already are locked in that the hot labs are locked. And the hot labs are the ones who receive the radioactive material or it is received by the radiation safety officer.

But I may be incorrect in that. I would ask Dr. Zelac for his comments since he has had experience with both radiation oncology receipts and nuclear medicine receipts.

DR. ZELAC: In my experience, the point that Dr. Nag brought up is a very relevant one. The ordering is one thing, but it is the receipt of the material and what happens to it once it is received that is really critical.

I certainly know of circumstances where orders were placed by individuals who shouldn't have placed orders, companies sent materials that they shouldn't have placed based on the person who made the order, but the safeguard in the system was where the material got delivered to the institution.

Once it got to the place where it was intended to go, you know, the recipient, the standard recipient location, at that point a determination would be made that there was something awry, something incorrect, something that needed correction.

CHAIRMAN MALMUD: Thank you, Dr. Zelac.

I think we have two comments. First, Dr. Nag, do you want to?

DR. NAG: Yes. One, other than the safety problem, this may address another issue, which is the fact that, let's say, in a prostate implant program, the urologist, radiation oncologist, [and] physicist, that team that does the process and, for whatever reason, the radiation oncologist may not know, the order may be done by the urologist, but, again, I think that in a safety area, that before that amount is inserted into the patient, it is still under the radiation oncologist's directive whether to write that directive or not. So even they may or may not help very much.

CHAIRMAN MALMUD: Thank you. I think --

DR. WELSH: Why don't I respond to Dr. Nag's point before proceeding?

CHAIRMAN MALMUD: Please.

DR. WELSH: The reason, part of the

reason, why this was all brought up was that an individual radiation oncologist authorized user informed me that at his institution, an order for yttrium 90 microspheres was placed by interventional radiology. And it was placed, and there was expectation that the authorized user would be there to supervise this proceedure, and that authorized user was planning on being out that day.

And after the news came in that on Tuesday, there's a yttrium 90 microsphere brachytherapy procedure at 1:00 o'clock just so you know -- but he didn't know. He was planning on being out of town, actually.

This whole thing changed his schedule, and it identified a weakness in the system at his institution. And it was requested that maybe we bring this up for discussion so that it wouldn't happen at other facilities.

And as far as I know, it doesn't, but perhaps it happens routinely. I don't know. With the system as it is presently, it is possible that this happens more often than I thought. And that was the initial reason for bringing this up.

After putting this on the agenda, the point about ordering byproduct material for terrorist

purposes became a secondary reason for bringing it up.

It was pointed out that at a facility I am familiar with, a radiation physicist is not board-certified, is not a citizen of the United States, and is trusted, implicitly and explicitly.

But is it possible that this individual could order two or three times the amount of iodine-131 for a particular case without me or the authorized user knowing about it and then the material showing up and then disappearing forever? The answer is yes, this could happen quite easily with the system currently in place. So that is part of the reason why I brought it up, partially to answer Dr. Nag's point.

CHAIRMAN MALMUD: Thank you.

There were several more comments? Sally?

MS. SCHWARZ: Dr. Malmud, I was just thinking in terms of, I mean, I think the places that you were speaking about may need ordering and receiving policies established but not necessarily that the authorized user needs to be the individual ordering these or even signing for them.

I mean, certainly I am at a broad scope license. And the Radiation Safety Office places all orders other than what comes out of the orders from the nuclear pharmacy, and they are received at

radiation safety.

And, again, as Dr. Zelac was saying, the receipt and inventory essentially of what's -- I mean, once it's received and entered into inventory, then again it's checks and balances, I think, but that you account for what you have ordered and that it's actually physically still there. But I don't know that the authorized user's necessarily signature would improve the safety of the operation.

CHAIRMAN MALMUD: Thank you.

Mr. Lieto?

MR. LIETO: Yes. I had two points I wanted to raise. Regarding the ordering of radiopharmaceuticals that require written directive, I am going to have to ask my colleagues on the subcommittee, Drs. Eggli and Vetter and Sally.

I thought one of the recommendations of our subcommittee was that in order to order radioactive materials requiring a written directive, that the written directive had to be in hand at the time or immediately available.

So I would like to maybe reference that as one of the issues addressing Dr. Welsh's concern. The other point is that I think there is a concern about how just general orders going to a vendor are done

because very often -- and I have had this occur -- if a person identifies themselves from being from the licensee and it is a trustworthy and reliable person, they can order various isotopes in amounts from a vendor, and they will get shipped.

I know of one situation where an institution was not getting generators. And although they were authorized for 100 and 200s, a nuclear medicine supervisor wanted to have more technetium on hand and instituted an order for generator shipments.

So I think that one of the things that I think might be done is maybe a reemphasis with licensees that the ordering, either through a designee for radioactive materials, especially for maybe -- like the broad scopes probably have a very firm situation set up, but I think maybe in other situations, maybe what needs to be done is a reemphasis that licensees look at their ordering procedures to assure who is designated for making these orders with vendors.

CHAIRMAN MALMUD: Thank you.

May we go back to the incident that you referred to, Dr. Welsh? This was where a non-authorized individual, a physician who is not authorized to handle a radioactive material, placed

the order in anticipation of your being available without checking with you? Is that what happened?

DR. WELSH: It wasn't me specifically, but interventional radiology at that particular institution pretty much runs the show as far as microsphere brachytherapy.

They had planned on doing the procedure on a certain date. And they expected that the radiation oncologist would be available and have time to come up and perform this procedure, but they did not ask or inform the radiation oncologist. They went ahead and placed the order. Only after the fact did they learn that he was on vacation that day.

CHAIRMAN MALMUD: But within the practice standards of that institution, I would assume that person was not authorized or empowered to place such an order. I wouldn't use the word "authorized." Empowered to place that order.

DR. WELSH: That person was empowered to place the order.

CHAIRMAN MALMUD: He was empowered to place the order, even though he was not licensed to handle radiopharmaceuticals?

DR. NAG: Well, I mean, I think that can easily happen because in many institutions --

remember, this is before 390. Now, microspheres, 390 users can be authorized users, but before it was only the 490 group of users. At that point the radiation oncologist had to be the one ordering it.

However, if the interventional radiologist is the one who is injecting it. And they only need the radiation oncologist to be there for signing the prescription basically. They are not the one injecting.

I am determining we are going to give -- they are basically running the whole show. And so they are needing the radiation oncologist there or the nuclear medicine person that basically asks for the signature because they could do it.

I mean, even though the urologist -- if they are the one doing the needle insertion, I want to do the patient on such and such a date and you're putting a needle, theoretically when they're putting the seeds except for the requirement of the NRC that the authorized user's signature be there for the first -- theoretically it would do it.

However, my feeling is that we do not need a regulation to stop that kind of an internal miscommunication. I think it is more of an institutional communication issue than an overall

radiation safety issue. And the NRC should not get into internal communication issues.

CHAIRMAN MALMUD: And that's the point that I was trying to drive at in asking Dr. Welsh the question because it would seem to me that the institution's own practice standards would prevent that dose, if delivered, from being administered without the collaboration of these two individuals if that is what is required.

But I think next someone had -- Dr. Thomadsen?

DR. THOMADSEN: I think that the situation actually is already taken care of when you point out that the orders have to be by the authorized user or that person's designee and that if the authorized user hasn't designated these people to place the order and if the authorized user wants to have them designated to place the order, they have to have a protocol in mind which the authorized user would trust them to follow.

CHAIRMAN MALMUD: Dr. Eggli?

DR. EGGLI: We have a very well-defined process for internally listing who has the authority to order radiopharmaceuticals from our vendors. As our staff changes, those lists get updated with

regularity.

However, I don't think there is anything in the process that either requires us to or even urges us to share those lists directly with the vendor.

If one of my technologists calls a supplier of radiopharmaceuticals and identifies themselves as from Hershey Medical Center, I am not sure the vendor has any way of verifying that individual's name against a list of people authorized by the institution to place the order for radiopharmaceuticals.

Now, maybe in part 400 uses, that is tighter, which is why I asked Dr. Welsh the question earlier, at what level he would trigger his threshold. But certainly it is in the daily ordering of unit doses for part 200 uses. We have an authorized list, but the question is, how does the vendor know who is on that list?

CHAIRMAN MALMUD: If I may, I still think that the issue that Dr. Welsh correctly raises is a scope of practice issue within the institution or the organization, rather than an NRC issue.

Now, I may be incorrect, but it seems to me that if the practice standards at the institution

mentioned were that these two individuals must be collaborative in the performance of that therapy and one of the individuals has taken it upon himself to move ahead singly, that he really is in violation of his own institution's standard of care and that is the issue, rather than the NRC issue.

That is my view of it, but I may be incorrect. What was your perception?

DR. WELSH: I believe that what actually happened was the nurse coordinator for the program, who was given the authority by the AU when the program was initially set up to place orders for yttrium-90 microspheres, worked with the interventional radiologist and the other members of the team with the exception of the radiation oncologist to set the date of the procedure.

She went ahead and placed the order and after this was placed and the shipment was going to be received realized the error and said, "Oh, I must inform the authorized user," who when it comes down to it is the only one that really is allowed to allow this procedure to proceed.

The procedure would have been impossible to take place had the material shown up on Tuesday, the patient shown up on Tuesday, but the radiation

oncologist not been in the building on Tuesday. And he happened to be the only one who participates in the yttrium-90 microspheres at his institution.

CHAIRMAN MALMUD: Therefore, the procedure could not go forward in the absence of that individual?

DR. WELSH: That's correct.

CHAIRMAN MALMUD: Therefore, the patient was not placed at risk, but the expense of the delivery of the material is the issue. And that really from my perception administratively has to do more with the standard of care within the hospital and the hospital's privileging process than with the NRC in dealing with the clinical issue.

Now, I would appreciate someone else's opinion about that. Dr. Zelac?

DR. ZELAC: I think it's important to point out that a licensee is required to generate and to have available and, of course, to use procedures relating to radiation protection, which certainly should include the ordering, receipt, and delivery of materials for use.

That's not to say that these procedures have to be submitted for review in advance, but they have to be there. In other words, there has be a plan

at a licensee's facility for handling these matters. And it is expected that the licensee would develop such a plan and follow such a plan.

If there were variances that became apparent, either to the licensee or to an inspector, then the procedures would come out and variances from the conduct of those procedures would become apparent and some method or mechanism would have to be put in place for rectifying this problem.

So what I am basically saying is that NRC's involvement is to the extent of having an ability to enter into this internal matter when necessary to effect correction as required.

CHAIRMAN MALMUD: Thank you. Dr. Fisher?

DR. FISHER: Darrell Fisher.

I know the time is short, but I will make a very short comment. To follow on with what Dr. Zelac said, I believe that it is the quality assurance process associated with the order that checks for the signature on the written directive that compares the order against the treatment plan generated by the medical physicist and reviews the order to make sure it's accurate. And with an effective quality assurance system in place, mistakes like this can be avoided.

CHAIRMAN MALMUD: And my point is that the mistake didn't occur in terms of the patient. The mistake was an administrative one which created an unnecessary expense and delay. But the patient was not harmed.

The system did kick in. But I think that it is a quality assurance issue within the department and not requiring of NRC's intervention except as Dr. Zelac has indicated.

I think you had a comment, Dr. Nag?

DR. NAG: Yes. Should we have a vote on this issue? We have had discussion on both sides.

CHAIRMAN MALMUD: A vote.

DR. NAG: We can have a vote.

CHAIRMAN MALMUD: All right.

DR. NAG: Then we can see.

CHAIRMAN MALMUD: Someone make a motion.

DR. NAG: I think the one who brought it up, Jim, you should make the motion.

DR. WELSH: So the question is, should the authorized user be required to place a signature on all faxed orders for radioactive material?

CHAIRMAN MALMUD: Is there a second to the motion?

DR. WELSH: I posed it as a question.

DR. NAG: No. It should be made as a motion. I mean, not should but that authorized user should. That's the way the motion has to be made.

DR. WELSH: That the authorized user should be required to place his or her signature on orders for radioactive material before the supplier can legally ship that material to the institution.

CHAIRMAN MALMUD: Is there a second to that motion?

DR. EGGLI: So that a record will be made of the feelings of the Committee, I will second the motion.

CHAIRMAN MALMUD: All right. The motion is seconded. Is there discussion of the motion?

(No response.)

CHAIRMAN MALMUD: I will just make a comment as a practicing nuclear physician. It is impractical for that to occur in that the physician may be in the institution on Mondays, Wednesdays, and Fridays. The order may need to go out on a Tuesday.

He may be the authorized user or she, in which case the order couldn't go out for the delivery on Wednesday, when the physician would be there, because the physician wasn't able to sign it on Tuesday.

I think there are some impracticalities. And, for that reason, I would discourage the motion. Anybody? Any other comments?

MR. LIETO: This is Ralph Lieto.

Just a point of clarification. This would be diagnostic as well as written directive orders?

CHAIRMAN MALMUD: You said isotopes.

DR. WELSH: I would like to amend that to include only materials requiring written directive.

CHAIRMAN MALMUD: Materials required in written directive. That's a different motion.

Dr. Vetter?

VICE CHAIRMAN VETTER: I would still speak against it because in some programs, it still becomes an issue of practicality. For example -- this is just one example -- some institutions use liquid radioiodine.

There is no order placed, basically. I mean, there is a written directive. The technologist goes to the nuclear pharmacy, gets the material, administers it to the patient.

There is no order. I mean, it is taken out of stock. And the differences among programs are so great that I think you have to have program-specific procedures, as outlined by Dr. Zelac,

that would prevent someone from ordering material who shouldn't.

CHAIRMAN MALMUD: Any further discussion of the motion? Ms. Schwarz?

MS. SCHWARZ: Sally Schwarz.

I think that the bottom line is that the authorized user must sign the written directive. And certainly what we are concerned about is the safety of the patient and the administration of appropriate material to the patient.

But in terms of placing the order, I don't think that the authorized user is a required person to be signing the order to the vendor to receive the material.

I think certainly procedures need to be in place that allow the appropriate team members to be present for various procedures. But the signature of the authorized user I don't think will be required, shall be required.

CHAIRMAN MALMUD: Further discussion? Dr. Eggli?

DR. EGGLI: And again, to come back to the point that Ralph Lieto made a little while ago and the recommendation that our subcommittee made on reduction of events is that the person ordering should have in

hand the written directive prior to ordering it. And, therefore, the authorized user would be aware.

And, again, I seconded this motion so that we could have a record of the discussion and the outcome of the vote, but I would agree that my inclination would be to vote against it.

CHAIRMAN MALMUD: And Dr. Suleiman?

DR. SULEIMAN: I also would not support the motion because I think it is micromanagement. The issue hasn't been clearly defined. I think your solution would be appropriate for your facility.

And I don't think it's a patient/public health issue. I think it is a security issue and these are two very different ones. So some sort of requirement that each facility has to have sufficient safeguards to know what they have and who has got access to it would be more beneficial.

But I think right now we have had our discussion.

CHAIRMAN MALMUD: If I may, then, make a comment? It appears before we take the vote that the spirit of the Committee is that we join you in your concern with regard to that issue and believe that the issue can be dealt with institutionally, rather than at the level of the NRC.

And, with that, may we call the motion? The motion is called. All in favor?

(Whereupon, there was a show of hands.)

CHAIRMAN MALMUD: All opposed?

(Whereupon, there was a show of hands.)

CHAIRMAN MALMUD: And abstentions?

(Whereupon, there was a show of hands.)

CHAIRMAN MALMUD: Two abstentions. Thank you.

And, if we may, I would make a motion for lunch.

(Laughter.)

(Whereupon, there was a chorus of "Second.")

CHAIRMAN MALMUD: What time shall we return?

MS. WASTLER: 1:20.

CHAIRMAN MALMUD: 1:20. Thank you.

(Whereupon, a luncheon recess was taken at 12:22 p.m.)

CHAIRMAN MALMUD: We're going to begin the afternoon session with Mr. White's presentation on NARM. And this will update the Committee on the NARM Transition Plan, Rule, and Guidance. Mr. White.

MR. WHITE: Good afternoon. I just wanted to give an update on the status of the NARM Transition. I'll provide an update on NRC's effort to

implement the requirements of Section 651(e) of the Energy Policy Act 2005 for certain naturally-occurring accelerator produced radioactive material. The topic that I'll discuss is NRC's final regulations, associated guidance in support of the regulations, and the transition plan to facilitate orderly transition of this regulatory authority.

We did receive -- while the rule has been published, and we do now have an effective date of November 30th, 2007, and the final regulations are responsive to stakeholder's comments and incorporate the model state standards.

As part of the publication of the rule, as I mentioned before, the staff worked on three new, or revisions to the NUREG Guidance. We have Volume 21, which was on program-specific items about possession license for radioactive material, producing radioactive material using an accelerator. That guidance is being finalized, and should be ready by the effective date of the rule. We also have Volume 13, which was on the commercial radiopharmacy licenses, and that also should be very close to the effective date of the rule on November 30th.

Volume 9 on the medical use of licensees, we're thinking that guidance will be done in December

to January, it will be completed, but it's going through its final stages now. And we'll still be working on a few other guidances to revise that accordingly to NARM rule.

As you know, on August 31st the Commission issued a waiver to allow states and individuals to continue their activities involving NARM. Once the waiver is terminated, all persons that possess the new materials in NRC jurisdiction must be in compliance with NRC regulations, and will need to apply for a license amendment within six days, six months, sorry, or apply for a new license within 12 months from -

PARTICIPANT: You heard the collective gasp.

(Laughter.)

CHAIRMAN MALMUD: They're listening.

MR. WHITE: -- the waiver termination. We issued -- we had a transition plan that gives a general plan of how we're going to implement this new NARM rule, and so that was published on October 19th, which was Friday, so that's out now for -- it came out in the Federal Register, so that's out on our NARM tool box, which you probably are familiar with on the home page of the website.

Currently, these are the states that are

going to be -- their waiver is going to be terminated first. And along with these states, we also have federal agencies. And the NRC Chairman is working, or is currently in the process of signing letters for the 34 Agreement States. These are the 34 Agreement States, sorry about that. These are the 34 Agreement States, and the Chairman is signing the letters. We received comment from all the governors saying that they are in compliance with these regulations, and so the Chairman is signing those, and will be effective on the effective date of the rule.

These are the states that are the first states the waiver will be terminated, and plus the federal government agencies. We have two more phases, second and third phase. Right now we're looking at the second phase to be probably between the summer and fall 2008, and the third phase would be spring and summer of 2008. At this time, we do not have the specific states that will be affected, but we will give notice within six months before the termination.

For the Transition Plan, NRC, also an authority for NARM, exempt distribution licenses upon waiver termination. NRC will assume authority of all Sealed Source and Device Evaluations, and registrations for NARM in Agreement States with the

authority, which was authority as part of their agreement with NRC, and for non-Agreement States upon their waiver termination.

We just sent out a new RIS updating, giving the status of this update, and we also published, or will be publishing, like I mentioned before, Federal Register notices for when the other phases will come into play. And we did publish the Transition Plan. And all of our information currently is on the NARM tool box, which can be found at this address. Right now, it's in the Key Topics on the home page of the NRC website.

If you have any questions, I'd be happy to answer those.

MS. SCHWARZ: The next two sets of states, second and third transition phases, is it reasonable to think that the last phase will be those states that are currently non-Agreement States, becoming Agreement States will be in the third phase, and those others will be in the second?

MR. WHITE: I think it would probably depend on when we expect the agreements to come. Like there's a good chance, I believe, that Pennsylvania might make it for the second phase, Virginia might make it third phase. But yes, it would be closer to

when we would finish their application.

MS. SCHWARZ: And the other Agreement States.

MS. SCHLUETER: If I could supplement that, that's an important point. Yes, Pennsylvania isn't a good example, because they're coming down the home stretch, and we think they'll have an agreement in place probably in the March-April time frame, but with Virginia and New Jersey, their goal, and ours, too, is to see the agreement in place, if that's the ultimate decision, before or coincident with the August `09 date, because that's the last date that we can grant any waivers. And we wouldn't want to see those licensees in those non-Agreement States going agreement to come under NRC's jurisdiction, then go back to the Agreement State within a few months period of time. That whiplash effect, we've referred to, so we want to avoid that. So that is one of the reasons that we will push out those states as late as we can to terminate the waiver, but it would be -- the waiver would be terminated when the agreement goes into effect. So it's possible that Virginia or New Jersey, if they an agreement go into effect sometime in `09, prior to August, they would be treated individually, so that the waiver would be terminated when the

agreement is signed and in effect.

CHAIRMAN MALMUD: Other questions for Mr. White? Mr. Lieto?

MR. LIETO: Yes. Mr. White, there was the news release I guess just late last week about the Transition Plan, and there was a statement that was made, and I just don't know if this is accurate or not, that the NRC expects 400 new licenses in non-Agreement States just from NARM. Is that correct?

MR. WHITE: Yes.

MS. SCHLUETER: Yes, that's what we've estimated.

MR. LIETO: In just the non-Agreement States. Okay.

MS. SCHLUETER: Right. Well, in our 16 non-Agreement States, there are NARM users that have previously been licensed by the non-Agreement State. But now that it's coming under our jurisdiction, they have to then apply for an amendment to their existing NRC license, or a new license.

MR. LIETO: Okay. I guess that's kind of my question. I'm trying to clarify it. Amendments would be one thing, but what it means is that they're new entities, so these are 400 entities that are not currently with NRC licenses.

MR. WHITE: Correct.

MR. LIETO: Okay. Thank you.

CHAIRMAN MALMUD: Other questions for Mr. White? If not, thank you very much for the update, and information. At which point, we will move on to the next item on the agenda. Dr. Howe will provide information on the new Leksell Gamma Knife. There is a handout for that.

MS. TULL: I just gave an additional handout. I put it on top of your binders, the actual revised guidance for the Perfexion.

CHAIRMAN MALMUD: Tab 9, and the handout.

DR. HOWE: Okay. The Elekta Perfexion is, essentially, the latest version of the Elekta Gamma Knife, and I want to give an introduction on how we decide whether something is a new technology, and goes into the emerging technology section in 35.1000, versus staying in the regular regulations. And I think it's important for you to understand that NRC has a policy that we cannot regulate by exemption, and so in 2002, Sub-Part K was added to Part 35 to codify how we license activities that are not in the regulation for medical use. It gives us procedures on how to apply for it, and provide certain exemptions. And that's so that -- we've codified the fact that we

can regulate things that are not currently listed in Part 35.

Our Policy Statement in 2002 was that if a use required an exemption from the new 2002 regulations, that would put it into 35.1000, so when we get something that we think may be new, we take a really close look at it. In this case, we have a device. We look at how it functions, we look at how it's used, we look at who can use it, what it's being used for, we talk extensively to the manufacturer, and go out and get as much information as we can. Then we sit down and we go through 10 CFR Part 35, and we start at Section A, and we go to the end, and we see if, in fact, this new device will fit into our current existing regulation.

The Perfexion is a Gamma Knife, so what we're looking for, primarily, are things that are -- regulations that are related to Gamma Knives use, and as we went through the regulations, we found that many of the gamma stereotactic radiosurgery specific regulations in 10 CFR Subpart H applied to the Perfexion; but because you had substantial redesign and re-engineering, there were components that were required to be tested in the regulation that no longer existed on this device. Therefore, we would have to

grant a number of exemptions in order to license this under Subpart H. That throws the device into Subpart K, which is the other medical uses.

The other point is that when we have a use or a device, such as the Perfexion, we don't develop guidance until we have a specific request from a limited specific licensee to use this new device or technology. And, in that case, we respond by TAR response, Technical Assistance Request to the Region, so the device or the use may be out there for a number of years. Generally, these things will come through the broad scope licensees, and the broad scope licensees can do their own authorization. They're granted an exemption with 35.1000 uses. And they develop experience with the device or the use, and then it ends up moving into mainstream limited specific.

What happened with the Gamma Knife is that the Gamma Knives are not issued under the broad scope licenses, and so our new users that were coming in for the Perfexion were all limited specific licensees. They were -- generally, they're big medical centers, but the Gamma Knife was listed on its own limited specific license, and so we had requests for using the new Perfexion.

This puts us in a situation in which we have to respond in a quick and timely manner to the licensing request. We have to develop the guidance, we have to make it available to the licensee, and then proceed with issuing the device.

To make this system as functional as possible, what we do is, once we have the device that's been developed in response to a Technical Assistance Request, we put that guidance up on the website. It is a draft-type of guidance. We make a disclaimer on our medical tool kit that 35.1000 guidance is always open for comments from stakeholders, and we will respond to those comments. So the differences between putting guidance for a device, such as the Perfexion, on the website is that we can do it fairly quickly. We do it in response to a Technical Assistance Request. The Technical Assistance Request response has been, in this case, vetted through our regions, and through our Office of the General Counsel, and also has had a great deal of input in collecting information from the manufacturer so that we can tailor it. And we do it in response to a licensing application, so we already have how the licensee believes the device should be regulated, and the commitments that they should make. So these

things are not done in a vacuum, but are done quickly, and we're putting them on the website. If you were going through rule making, we would be here for the next two to three years working on specific language.

This gives us a chance to put something out there, get use, have many people use it, come back with comments. And, eventually, if we have enough use of the device, and we have the resources, we can then move it into rule making, but rule making is an expensive proposition. And in some cases, these devices may never go into rule making because there just isn't enough demand for it. So that's kind of an overview of how we go to where we are. So in this case, we had substantially redesigned and re-engineered components that are no longer part of the device, and those components are requested to be tested in 10 CFR.

What are its major features? Well, there a number of manual movements that are now automated and computer-driven. The fact that they're computer-driven doesn't necessarily put it into 1000, but in this case, it certainly helps.

The biggest thing was the sources are no longer stationary, so we now have moving sources. The Gamma Knife's claim to fame when it was first

developed was that its sources did not move, so you did not have changes in mode or movement, and you had exact precision.

One of our biggest changes is there are no collimator helmets. The Perfexion now functions by moving the sources over top of precision collimator settings, so that you can now, because the sources are now set up in eight different sections, you can set each section to a different collimator size, and you can really tailor that particular radiation exposure or setting into something that's not spherical. With the old collimator helmets, you had to go on a certain diameter. Now you can go to beam shapes that are no longer spherical, and you can manipulate it much quicker. In the old Gamma Knife, if you wanted to change collimator size, you had to take the helmet -- you had to pull the patient out, take the helmet off, put a new helmet in, and then align the patient again.

In the very first Gamma Knife units, you had something called trunions, and the trunions essentially set the axis so that you could position the head properly. There was an immediate type of Gamma Knife that went to an automatic positioning system, which was computer-driven, that could move the

head without having to pull the person out of the Gamma Knife, and adjust the trunions.

And in the Perfexion, what you have is that the patient is positioned on the bed, and you do not move the patient's head, you move the entire bed, very small movements, up, down, left, right, in and out, so that you can hit the focal point where it's supposed to be on the tumor treatment. I like to think of it as moving the aircraft carrier to put the person in the right place, so you have a different situation here.

We looked at, and I guess one thing is, how do we decide what has to be in the guidance, and how do we decide on the format that we use? To some extent, we use how to fill out the 3.13. The guidance will address those issues that need to be addressed specifically for the Gamma Knife. There are many things that we don't include in the guidance, like the licensee's name, their location, those things, because we get that information anyway. So we do, to some extent, follow the format and the sequence of events in our NUREG Guide.

The first thing you have to do is identify what the use is, what the materials are. One of the first things you identify is, also, the authorized

users, and eventually get into the radiation safety program, so most of our guidance is focusing on the radiation safety program. And as we walk through the regulations, we'll pick up things as they appear in the regulations. So the first thing is 35.40, which is a written directive. It's a Gamma Knife, it requires a written directive.

The information that's required currently for Gamma Knives is that you have the target coordinate setting. Well, when we looked at the Perfexion, we said well, the shape of the beam is equally as important, and so we've added that you provide the sector positions, in addition to the target coordinate settings in the written directive, so that the administration is given in accordance with what the physician describes. We also check with the manufacturer to see if these sector settings and positionings could be printed out automatically through their treatment planning system, and the answer was yes, so they can print this information out, and they can collect it one place, and it shouldn't be a hardship for the licensee.

One of the major areas that you have for the regulation of a Gamma Knife is in the spot-checks and the full calibration. And this is where we ran

into our exemptions. It doesn't have helmets, it doesn't have relative helmet factors, it doesn't have helmet microswitches, hydraulic backups, trunions, trunion centricity. It does have other components that meet the effective purposes of all of these components, so when we looked at the requirements for 35.635 and 645, we found that we would have to grant a lot of exemptions, and that's why it's in 35.1000.

But we also looked, and we said, many of the things that are in these sections also apply to the Perfexion, so because it's in 1000, the licensee is not required to meet the requirements in 600. So an application that comes in generally has to state that they will do certain things. If it was a 600 use, it would automatically be tied into the 600 uses, so what we say in the guidance is, the applicant can simply its application by saying we will meet the criteria in, and then list the different sections of the regulation that pertain to the Gamma Knife.

It gets a little tricky, because they have to make a commitment, because many times those sections say in accordance with 35.6 whatever. We will do such and such. Well, you're not required to follow 35.600 whatever. So you have to say we will commit to following it. And so when you get to the

information requirements, you'll say we have a commitment in the guidance that says we will provide the information that is described in record keeping section such and such.

So that's basically how we got to where we got to. And we looked at these tests that no longer exist, and looked for their function. One was to make sure that the patient docking system functioned correctly, another was to make sure that the center of the stereotactic frame could be at the radiological focal point. The other was to know the size of the radiation focal point, and to test the precision of the treatment site, and placing it at the focal point. So those are the functional-type things we were looking at.

CHAIRMAN MALMUD: Question for you.

DR. HOWE: Ralph.

MR. LIETO: Just, I'm not sure if I understand your point. These are tests, on this slide, these are tests that are not applicable to the Perfexion, that are listed in 35.600. Is that correct?

DR. HOWE: 35.600 has helmets, helmet-relative factors, microswitches, trunions. What were the purposes of those tests? These were kind of the

purposes of those tests in global terms, and you can't perform something on a trunion if it doesn't have it, but what in the Perfexion will essentially do these things? And so that's how we developed guidance. How can you test to make sure the patient docking system is functioning correctly? How do you test to make sure the mechanics are in the right place, so that's what that set was.

We also looked at training and experience. We have a new device, it's very similar to the Gamma Knife, but it has a number of components that are different, and it really is used differently, because you can adjust the shape of the beam, you have a lot more complexity, and a lot more computer-driven things, so we looked to see who can be an authorized user, an authorized medical physicists and a radiation safety officer. And our first approach was, we really are in device one. When we started to develop our guidance, there was only one device that had been set up in the U.S., and that was out in California.

We talked to California to find out what they were doing to determine their authorized user statuses. And so we recognized that it's not an established unit. We have to do something to get people on board initially. So we, essentially,

divided all three of these groups into two basic categories. The first category is if you already had experience with a Gamma Knife, you were listed as an authorized user for Gamma Knife, you were listed as an AMP for Gamma Knife, you were an RSO at a facility that had a Gamma Knife.

For those individuals, we focused on one part of the training and experience criteria. Training and experience criteria is basically in three parts, you're board certified, the alternate - and if you're board certified, you have to have training in the device. If you are coming through the alternate pathway, you still have to have training in the specific device. And we decided there were really three things going on, board certified, alternate pathway, and this additional training. And everybody needed this additional training. So if you were an experienced individual, we said you could be a Perfexion AU, AMP, RSO, if you had the additional training.

Generally, if you're coming through the board certification pathway, or the alternate pathway, you have to have a preceptor statement. We decided that, one, there are no preceptors, because the device is day one. So if you are already working with a

Gamma Knife, you need the additional training, but there is no preceptor statement. Okay.

Now what if you're brand new, you never used a Gamma Knife, you haven't been a medical physicist for a Gamma Knife, and you haven't been a radiation safety officer? We believe the preceptor statement is important, and should be required. But we're also faced with the concept, we don't have any preceptors, so what we did was we put a time period, and I think it's July 1st, 2009, and we said that if you don't have Gamma Knife experience, you have to either come through the board certification pathway, the alternate pathway, you have to have specific training in the Perfexion, but you don't have to have a preceptor statement.

This was done to give done to give enough time for Perfexions to be installed, and for a large enough group of authorized users, medical physicists, and RSOs to be out there to perform as preceptors. We also put it in the future, with the idea that the ACMUI is not too pleased with preceptor statements. It is in the guidance document on the website. It can be changed between now and July 1st, 2009. So if the Agency goes in a different direction, doesn't require preceptor statements, we can modify the guidance. So

we feel like we're in a pretty flexible situation, we're allowing for people to use the Perfexion, and we're not holding them back because of preceptor statements, and we have time to make decisions.

Okay. So that's, essentially, what we did with -- so all of our individuals have to meet this alternate training. What is the alternate training? At the bottom of the slide you'll see the radiation safety officer's, device operations. AU is trained in device operation safety procedures in clinical use, the medical physicist has clinical use and operation or treatment planning system, the RSO is just radiation safety, regulatory issues, and emergency procedures, so we use the same training criteria. And we said everybody needs that.

We also said that if you're an existing AU, AMP, or RSO, when you get this additional training, the training should also focus on the differences between the device you're used to using, and the Perfexion, so that you start out knowing how to change how you're thinking about approaching treatments, or medical physics for this device. And we talked to the manufacturer, and it appeared like that was a reasonable expectation.

And this is the part about the

attestation. We, essentially, just require that there be documentation that the person has successfully completed the training on the Perfexion prior to July 1st, 2009, and then after July, on or after July 1st, 2009, there also be a written attestation.

We looked at spot checks and full calibration. We allow people to commit to meeting the requirements, with the exception of those things that are not there. They can commit to performing tests on the location of the radiation focal point, respective table position, location and function of sectors, patient bed, docking service, frame adapter, source exposure. And we had the light on the wall. It used to be the light had to be on the console, no longer on the console, so we put it on the wall. We got feedback from of our licensees that said we don't want to put it on the wall, we want to put it on the ceiling. We don't think that's a big issue, no problem, acceptable.

And we've gotten other feedback from licensees that we're going to be looking at to modify the guidance. One is this light location. We don't care whether it's on the wall or the ceiling. It could be on the floor, for all we care. It's just not on the console because the manufacturer doesn't put it

there.

There's also emergency timer circuits, and so we're trying to work through with the manufacturer. There seem to be three different timer circuits, two may be visible, or it may be the same one is visible in two different places, so we're trying to get a better understanding for that.

One of the things we added in the written procedure, was that we've had a lot of -- we've had a number of medical events with Gamma Knives before because of the head frame, moving, because of the pins sliding, and so we've asked that when they're developing their internal procedures, that they have a procedure for when a patient moves, and checking on the patient between when they change the gamma angle, because that's the only time they go in and readjust the patient, and, also, at the end of the procedure so that they know nothing has moved.

We're not saying that you have to stop the procedure if a patient moves, but they should have procedures that highlight the fact that that could be a potential problem, and they can make an evaluation.

Another aspect of this device is that it's pretty well automated, and so with the exception of manually having to go in and change the gamma angles,

you could run a patient through many individual treatment points shots without ever going into the room, and so it's pretty automated, and it takes a lot of that direct personal contact that you had with the older units out. And so we're just trying to make people aware of those kinds of things.

I think that is the end of my presentation.

CHAIRMAN MALMUD: Thank you, Dr. Howe. I think Dr. Nag has a question to ask.

DR. NAG: Yes. It will be more than one question. There are a number of concerns that have been raised by the radiation oncology community, and I would like to summarize some of them, and you may have additional ones from people you know.

Now, obviously, different equipment are somewhat different. Let's say in brachytherapy, we have 35.400 brachytherapy, there are so many not only different equipment, but even different radioisotopes. You have permanent implant, removable implant, everything still regulated under 35.400. Even under 35.600, you have Gamma Knife, and then, yes, this might be slightly different from the Gamma Knife that we have been used to, but you're also regulating high dose rate brachytherapy under the same 600, which is

entirely different. And I would submit that the HDR is far more different in a Gamma Knife, than the Perfexion is to the old Gamma Knife. And, therefore, I see no reason, even though there are differences that you have mentioned, to now bring this up and regulate under a separate category of 1000. That's a broad statement.

Secondly, even if you were to do this, why do we have an ACMUI? Were any of the ACMUI members who represent radiation oncology, were they involved, were they asked their opinion? Otherwise, why are we here? Why are you not making use of our resources, even if we don't know it, we would have asked our colleagues. So that's the second point that I wish to make, is that ACMUI members need to be involved in this decision making process.

DR. HOWE: Dr. Nag, I'd like to just add one quick thing, and that is that when we were developing the guidance, we did have a number of questions, and we did go to Dr. Diamond.

DR. NAG: Okay.

DR. HOWE: And we got input from Dr. Diamond. We had originally -- California had requested -- has required their people to have so many clinical cases, and we were thinking of following that

model, and so we did go to Dr. Diamond, and we said you are our Gamma Knife expert. We've got the Perfexion. What is your opinion on that? So we backed off on the number of clinical cases, and we just put -- essentially, mimicked the wording in 690(c), so we did get some input.

One of the things that you have to understand is, we really are developing the guidance in a very quick path, and so we have to get things out so we can license these things. It is now open. It's not a final document. If the ACMUI would like to discuss it and give input, then we're open to suggestions, because it is a living document, and that's the whole purpose of the website.

DR. NAG: I would like to submit that you can very well regulate this new equipment, the Perfexion, by still keeping it under 600, and making some of the modification required still under 600. The advantage to the NRC is that then you don't need to rewrite a whole separate section. Most of the regulations would apply. The places where they are different, you can always make those, that for the Perfexion, do A, B, C, D, quite simple, even the training and T&E can still be under 690, and say plus, you get vendor training or vendor or authorized user

training from someone who has Perfexion. And then you don't even need the date of 2009, because it could be by anyone who already has 690 training, and then if he never used a Perfexion, would go to either a vendor or authorized user, because even if you say up to 2009 only by authorized user, there will be only a small number of these authorized users. So I would say you can still keep it under vendor or authorized user, that way you have only one statement. So I would like to make a motion, and have discussion on that.

DR. HOWE: Dr. Nag, I need to point out that we can't regulate through exemption. And in order to put the Perfexion into 600, we would have to make probably four, five, six statements, notwithstanding the requirements in 35.635, you may do such and such instead of such and such. And we would have like about six of those, and we would have to -- and that's what our NRC policy is, that we can't regulate by exemption. And that's what 1000 was put there for, was so that when we have something that requires an exemption, it goes into 1000. And then we don't start from zero.

DR. NAG: The 1000 was for a brand new - entirely different thing, because now you are going to have modification of almost all equipment, because of

various reasons, improvements, to get away from trademark issues, to get away from patent issues, people are going to use the same type of technology modified a little bit, and then you will now -- if you start a plan that every new modification you are going to do under 1000, you are going to be having a lot of new technology that will be done under 1000.

I think here there's still a lot of similarity with some differences that you can -- if you want, you can still put under 600, and say 600 point whatever, 35.600 is for the old style, and 35.680 for the new style, or something like that.

MS. WASTLER: What I would point out, if I may, is that basically, that's what we're doing. I mean, when -- to modify 600, it's a rule making.

DR. NAG: Yes.

MS. WASTLER: All right. This is a new device. We're learning how we use it, what the ins, outs, issues that might be involved from a regulatory perspective, so what 1000 allows us to do is say okay, this appears to be very similar to 600. However, there are some differences, so if you read the guidance, basically what we're saying is, you can, basically, applicant submits information required by -- confirming all of Section 600, 605, 610; in other

words, it just says provide us the information you normally do for these sections of 600, because they're no different. And then focuses the write-up on where there are the differences, and where there should be additional information. So it allows us to take something new, where we do -- if we -- and get it into -- under regulations quickly, allows us to use it. All right? And then as we move through time, we may find out, all right, there really are no real differences. All right? And then we'll go back, and we'll modify 600, and pull in the Gamma Knife to the regulations. But right now, this allows us to use existing regulation, highlight those where we feel that there are differences, provide some guidance in that arena, and, basically, see how it plays out as it develops as a modality.

DR. HOWE: And, Dr. Nag, you may be recommending that we go in and modify 35.600, and we modify 35.600 so that -

DR. NAG: On guidance.

DR. HOWE: Well -

DR. NAG: Guidance for Perfexion under 35.600.

DR. HOWE: You can't modify guidance for Perfexion under 600 without a rule change to 600,

because there are requirements in 600 that the Perfexion cannot meet, so there are exemptions to it. But we can modify 600 to talk in terms of what performance-oriented goals that are not tied to specific device components that get out-moded.

Now the HDR is written in much more of a performance mode, and so it doesn't make any difference whether you're a nucletron HDR, or a Varian HDR. All of those can be covered, but to do what you want to do for 600 for the Perfexion, we need rule making change. And one reason we put it in 1000, so that we get that experience, so when do the rule making change, and you could recommend right now that put it into 600, and we could add that to a user-need memo, and it would go through the process. But it may take years to use it, to do that, as its fastest. In the meantime, we're gaining and licensing are gaining experience, and we're not in the way.

DR. NAG: Allow me to be a little skeptical. Once something goes under 1000, it's almost like a one way course, it never gets back to a normal one. I mean, we've seen that for the intravascular brachytherapy, where everything was very, very different, but it never moves out. I mean, when do you think that the 690, I mean 600 for Gamma

Knife, and the 1000 for the Perfexion are quite similar, when do you think it will ever move out? I don't think it will ever move out. It will take a long, long time before it ever moves out. I'm very skeptical about the time sequence that NRC can adhere to move something out.

DR. HOWE: And, Dr. Nag, you have a good point there. And I think the intravascular brachytherapy was in 1000, and we had talked to the ACMUI about moving it out of 1000, because it seemed like it was maturing enough that it was ready to come out of 1000. And at the same time that we made that decision, the drug code stats came in, and so the pressure -- and then we ended up with two of the companies go out, the third company sold its business and looked like it was getting out all together, so it didn't look like we had any more intravascular brachytherapy left, so it was why pursue intravascular brachytherapy if there are no users?

Now we still have a company now, one of the devices is still in use. It's being used in very limited number of locations, but there is the possibility, and we do have it on our user-need memo to try to bring intravascular brachytherapy into the regulations.

CHAIRMAN MALMUD: Dr. Welsh.

DR. WELSH: This is Dr. Welsh here. I just want to reiterate some of the points that Dr. Nag brought up, and if I understand you correctly, Dr. Howe, it sounds like the placement of this Perfexion into 1000 is sort of a temporary holding site until 600 could be appropriately modified so that it could accommodate the Perfexion, where it logically appears to belong. Is that a fair assessment?

DR. HOWE: I think that's a fair assessment, and I think it probably will -- it could happen faster for the Perfexion, because we know that's an up and coming device, and it will be here for a while. And we could change 600 into more performance-based things that are not component focused. If you -- I mean, if anybody wants to make a motion, we could add it to our user-need memo. In the process, we will be gaining additional experience.

DR. WELSH: So if your response to Dr. Nag's skepticism is that this would move out of 1000, into 600 faster than the vascular brachytherapy did, is that what I'm hearing today?

DR. HOWE: I think so, because the intravascular brachytherapy we were actually moving towards that, and then the whole industry dropped

away.

CHAIRMAN MALMUD: I think Dr. Fisher was next.

DR. FISHER: Thank you. Darrell Fisher. I enjoyed your presentation, Dr. Howe. I've been looking forward to this for quite a while. I was hoping to hear it at the last meeting. I think it's refreshing, from my viewpoint, at least, to see the NRC move quickly to support the implementation and licensing of new technology, albeit doing so within a somewhat rigid and inflexible framework for Part 35, you're able to do this, and find reasonable ways to justify it. And I think it's extremely important to the user community that a federal agency is so accommodating, and accepts new technology in this way. I just think it's a good policy that the agency has taken, so I would slightly disagree with colleague, Dr. Nag, on that point.

CHAIRMAN MALMUD: Thank you, Dr. Fisher. Is there another comment? Yes? Debbie Gilley.

MS. GILLEY: Debbie Gilley. It's my understanding that the sources are exchanged in these devices somewhere between every five to seven and a half years. If we look at this requirement of a written attestation, and my experience with Elekta is

that they will not, when it comes up for source exchange, they're going to try very hard to push for the latest and greatest to be out there. And if we look at the attestation letter running into July 1st, 2009, and the fact that there are a very limited number of authorized medical physicists and authorized radiation oncologists that have the skills and abilities, in my state it's one medical physicist per Gamma Knife, I believe we may have some problem meeting that attestation requirement in July of `09.

DR. HOWE: And that's one reason we put it out. We put it out there at that point because, one, there are two Perfexion training sites that are going to be coming up, one is in Ohio, and one is going to be in Pittsburgh. And it's going to take them some months to get approved by Elekta to provide the training, and so at that point, we'll at least have two training facilities in the U.S. that medical physicists can go to, and authorized users can go to, and get some training.

And we also put it out that far so that we can find out what the situation is, as we get closer to the date. And if we're still having trouble in providing space, it can be readjusted.

MS. GILLEY: And there is not a

compatibility issue for the Agreement States being in guidance, its recommendations?

DR. HOWE: It is in guidance. It is not in the regulations.

DR. SULEIMAN: How many units are out there?

DR. HOWE: Right now, I think we have about five, possibly six. Two of them are up and functional, the others are probably - well, maybe three are up and functional now, and the others are pretty close.

DR. SULEIMAN: Why don't you look at them when they're at a certain amount? In other words, it sounds like this is very, very, very early on the curve.

DR. HOWE: Well, we have to license things from day one, if they're limited-specific. And so we have to look at it really early on. Generally, something that's in a new technology is going to come through our broad scope licensees, and so it will have time to develop and there will be users that have used it, that move from broad to limited-specific, so we aren't -- in most cases, we're not sitting at the first device in. This one we are.

CHAIRMAN MALMUD: Dr. Nag.

DR. NAG: Separate from what I had expressed before, but since this is a very complicated equipment, the manufacturer or the vendor will have to be giving training to the user. In that case, why not just leave it as training by -- needs T&E for 690 plus training by vendor or authorized user. Why does it have to be an authorized user giving training even up to 2009? Because the vendor is probably going to be able to give very good training, anyway. So is there any problem just leaving it as authorized user or vendor?

DR. HOWE: Okay. We have the vendor in it, and we have the authorized user in it, so that there's flexibility when the site - I think right now the sites can send three people to the Elekta training, and so when they come back, they can train their colleagues at their facility. So are you asking that we take out the authorized user?

DR. NAG: No. What I'm saying is right now you are saying that after 2009, the training has to be by -- the attestation has to be by the authorized user, not vendor or authorized user. I'm saying leave authorized user or vendor, even after 2009.

DR. HOWE: Well, we parallel our

regulations, and the attestation, the only person that can attest right now on any of these training experiences, is an authorized individual. So only an AU can attest for an AU, only an AMP can attest for an AMP, only an RSO can attest for an RSO, only a pharmacist AMP can attest for an authorized -- so the attestation, to follow our regulations, has to be the authorized user. The training does not have to be by the AU, because we've already described that the preceptor does not have to provide the training, they just have to verify, so the training can be by the vendor, but the attestation is an AU.

DR. NAG: What I'm suggesting is that we leave only the training by the vendor or authorized user. Just leave it at that, given the others where we are not requiring separate attestation because of problems. Even like the microsphere, we are having, that they must have either 390, 490 users with training from either the vendor or the authorized user. And we could leave it at that, even for -- I'm trying to see how we can minimize the burden on the number of authorized users who are available.

DR. HOWE: Dr. Nag, one reason we have it out at 2009 is that we do know that the ACMUI is very vocal about not having attestations, and this gives us

a chance to see if we are going into rule making, to do anything about the attestations, and if we are, that date in the future can be pushed out further, or it can eliminated all together. It is guidance space, it's not affecting anybody right now, it's a place saver.

CHAIRMAN MALMUD: Thank you. Let's see, Dr. Welsh.

DR. WELSH: Dr. Howe, I would agree with Dr. Nag in this particular setting, because although there are five now, and we're anticipating that by mid-2009, there may be many others, in many ways this Perfexion is attempting to emulate what is already now becoming fairly routine in SBRT, Stereotactic Body Radiation Therapy, and already being delivered through devices like the Cyber Knife, Tomotherapy, other IMRT technologies. Therefore, I am presently somewhat pessimistic that there will be dozens and dozens of sites that have Perfexions that, I, after 2009, for example, could get training as an authorized user from. I suspect that in mid-2009, the only option that might be available to the majority of the radiation oncology community will still be exclusively through the vendor training. And, therefore, I would support Dr. Nag's inclusion of the term "or".

CHAIRMAN MALMUD: Dr. Nag.

DR. NAG: Yes. The other thing the NRC has to be cognizant of, and I have mentioned this in the past, is that brachytherapy and radioactive material externally, and radioactive material stereotactic radiosurgery is somewhat complementary, and competitive with the electrical counterpart, with this external beam teletherapy, now you're having electronic brachytherapy, and you have stereotactic radiosurgery. So they are competitive, comparable, and complementary.

Now if, on the one hand, you make the regulation so burdensome, what will happen to people that are now -- you always try to compare what loops you need to go through to do something. If you have more hurdles, people tend to back away, and I think -- I'm trying to think that what the overall benefit, how it will be still efficient, it will still be regulated well, it will still have public safety, and have reasonable access. And so based on all of these thoughts, I would like to make a motion that we keep Perfexion Gamma Knife in 35.600, and we can have a discussion on that.

CHAIRMAN MALMUD: Dr. Nag has made a motion that the instrument be kept as a 600. Is

anyone willing to second that motion?

MR. LIETO: I'll second it.

CHAIRMAN MALMUD: Mr. Lieto seconds the motion. And now discussion? Dr. Suleiman.

DR. SULEIMAN: I was thinking along the same lines. I know there's lots of flexibility in regulatory authority, even though it sometimes seems like it's very rigid. Why don't you consider maybe, when a new technology like this hits the streets, I mean, one option is to throw it into 1000, but I hear Dr. Nag's concerns that once it goes into 1000, it may never get out of 1000.

Why not classify it, call it some sort of an interim classification for a two-year period of time, where a threshold, in terms of five, or ten, or some number based on workload, where you just don't regulate it in terms of coming up with classical regulations, where you allow the vendors really providing the proper training, where you allow a population of users to develop, who have some expertise. And only when you reach a critical number of users, and experience, then you can benefit from their expertise, along with the vendor, and then, at that point after two years, you can say our interim classification, we're going to reconsider it. Now

we're going to decide to permanently classify it. It will either be in 600, or some other category. But then you don't make the mistakes that you're going to make right now by trying to come up with a final building, when you haven't really designed what the plan is. So I think the problems, the user problems, some of the technology problems, just like the first generation of anything, are going to -- you can't anticipate them. If you could, it would be a perfect world, so I would support the motion, for lack of a better alternative. I would consider it a temporary sort of thing for maybe a year or two. In other words, the NRC should see what flexibility they have in this kind of, what I call a temporary classification.

CHAIRMAN MALMUD: You're seconding the motion to keep it in 600?

DR. NAG: That has been seconded, already.

DR. SULEIMAN: No, no.

CHAIRMAN MALMUD: Oh, that's been seconded.

DR. SULEIMAN: I was discussing it. And I'm suggesting that maybe this classification not be permanent. But that's not in the motion. Let's discuss it, and then if you want to reclassify the

motion later, that's fine.

CHAIRMAN MALMUD: All right. Other discussion? Dr. Vetter.

DR. VETTER: Dick Vetter. I wonder if, in a nutshell, Dr. Nag, you could give us the disadvantages of having the Gamma Knife classified in 1000?

DR. NAG: Yes. When you make -- when you put it in a separate classification, then you have to sort of import rules from different things. When you are importing something, then the problem -- it's possible that you may not be importing all the different things that need to go in. And rather than say oh, we didn't do this, we didn't do that, if you keep it under the same category, you can modify and say all of the things will automatically follow, including training and experience.

And the other thing, as well, for the Perfexion, you need in addition training in Perfexion. So you only have to add one or two words. Whereas, if you put the whole thing under a different classification, you have to take almost everything, and reclassify it, and put every - not only training and experience, but all the other categories have to be pulled in, as well. And the two are so similar,

other than a few differences, that it's probably better that it remains in 600.

For example, if a new isotope is made, and we are doing removable brachytherapy, if I were to say well, now, the Cesium-131; by the way, Cesium-131 is very different from Iodine-125, and Palladium-103 in terms of the way their half-life, and so on. But in terms of the usage, they have many commonalities. If that was put under 35.1000, you would have to take every rule in 35.400 and put it under that 1000.

Rather than going through that extensive thing, I would say keep it under the same category and just point out what the differences are, and just look at the differences, and say under this category, these are the differences.

CHAIRMAN MALMUD: Dr. Vetter.

DR. VETTER: A question for Dr. Howe. If it were left under 600, then you're saying that the problem with that is that the Perfexion unit doesn't have certain features that the old unit has. Why can't the inspector simply say, well, if there's no trunion switch, there's nothing to inspect?

MS. WASTLER: I think what Donna-Beth was trying to say in her slides is that the reason, the basis for doing the checks have to be achieved with

the new unit, as well. And that's what the -- and we -- it's a function of the way the regulations get set up. We can't put something in guidance space that's different from what's in the regulations.

For example, if we would write guidance, say we modified NUREG 1556 that currently governs Gamma Knives, and say all right, we've got the Perfexion. It's got these differences. We can't do that. Our lawyers will not allow us to do that, because we're regulating through guidance. That's a no-no. That will not be approved. So, all right, your options are, all right, but the regulations are very specific. And you're not allowed the flexibility either to just say it doesn't have it, no problem. I mean, it's bureaucratic, I understand that, but that's the nature of the way the regulations are.

If it says you're supposed to do these checks, that's what we have to do. Our ability to be flexible was 1000. It allows us to take something that we know is 90 percent 600, put it in 1000, grab that 90 percent, and provide the changes. That's how they allowed us to deal with the flexibility, and the problem that you're talking about, it should be very straightforward. It doesn't have a helmet, and you can't do a test for the helmet, but it's the

underlying concept. Just because it doesn't have a helmet, doesn't mean I have to test for -- with the new design, aspects of it that test doing the test for the helmet got me the information for. In other words, there's underlying reasons that I did the test in the first place, and that's where you're trying to get to. And, so, from our perspective, that 1000 allowed us to capture all the things in 600. And it allows us the flexibility to move within the regulatory framework that has been set up, that we need to follow. So, I mean, going ahead and saying we want to put it in 600, well, there's a variety of things. I mean, if you wanted it in 600, all right, that would require a rule change, so we wouldn't have the flexibility, it would be a concept, we wouldn't have any place to do the new things. We can't just automatically throw it into 600. That's a rule change. That's going to take a couple of years, so here's a modality that won't get implemented for at least two years, and, I mean, there's a lot of unsatisfying, I'm sure, from your perspective, problems with it, but it was a mechanism to give us the flexibility to achieve exactly what you want, not providing more or less than is required, but just focusing on those few changes. I don't know if I

clarified it, or muddied the waters. I'm not sure.

CHAIRMAN MALMUD: Dr. Thomadsen.

DR. THOMADSEN: Are there examples of devices or practices that have gone into 1000 and eventually gone out and into another section?

CHAIRMAN MALMUD: No.

DR. NAG: Not yet. That's what I'm worried about.

DR. HOWE: In 2000, we added Part 1000 to essentially codify what we've been doing all along. We have gliasite, we had intravascular brachytherapy. We were very close at putting intravascular brachytherapy into the regulations, and then the entire market fell out. We had the gliasite, we haven't had any pressure to move the gliasite out. We've had the microspheres. That's probably the next most mature group out there. And then we've got -

MS. GILLEY: Seed localization.

DR. HOWE: Seed localization. But we don't have any licensees with seed localization right now. Most of the licensees were up in Canada.

DR. NAG: What was that?

DR. HOWE: Seed localization. It's a -

DR. THOMADSEN: I think we both thought you were saying sea.

DR. HOWE: No. Seed. It's a permanent implant remote after-loader.

MS. GILLEY: Temporary implant using permanent seeds.

DR. HOWE: Yes. So we haven't had anything that has gotten enough use or been close enough to something already existing to move it out of 1000. The Perfexion may be a good candidate for it, because that seems to be a pretty stable type of market.

CHAIRMAN MALMUD: May I -

DR. THOMADSEN: Just a follow-up.

CHAIRMAN MALMUD: All right.

DR. THOMADSEN: On something like the gliasite, what is it that determines when you would move that out?

DR. HOWE: First of all, I think we would have to have someone from the outside saying it's time, or we know we have a lot of them out there, and we aren't having any trouble, and it's time to move things into the other side. We'd have to come up with probably a whole new place in the regulation for that one.

CHAIRMAN MALMUD: May I summarize, and make a suggestion? Dr. Howe's presentation suggested

that things would move faster if this were put into 1000. We understand the concerns about the possibility that something moving into 1000 won't move out quickly. Could your motion, or your recommendation, excuse me, Dr. Howe, simply be altered to put a time limit, call it an interim, to state that it's interim in 1000, and put a reasonable time limit on it, at which point it must be revisited. Let's say this is workload, or the number of -- something, must be revisited. Follow-through with your suggestion, because your suggestion, very clearly from your first statement, was that this is the way to move it along faster. And then just say that this is an interim move into 1000, which requires re-evaluation with regard to its remaining 1000 or moving to 600 within a fixed time period, 24 months. Is that reasonable?

MS. WASTLER: We have no problem, as we said, this is interim guidance. It's listed that way. We take comments at all times, so we can take it upon ourselves to revisit it at any point in time. But the fact -- we could set a date, but there's a variety of factors that will play into that.

CHAIRMAN MALMUD: We understand that.

MS. WASTLER: It's going to be number of units.

CHAIRMAN MALMUD: We understand that there are a number of factors, but you understand the concerns of some of the members of the Committee, that nothing, thus far, has moved out of 1000. And, therefore, there's anxiety about doing this, so if we insert a few words, "interim", and "this must be revisited by" whoever, is it ACMUI or NRC?

DR. NAG: Both.

CHAIRMAN MALMUD: ACMUI and NRC with 24 months, or sooner, depending upon the circumstances. Circumstances may mean the instrument may be pulled off the market, under worst case scenario, or this may bloom into the therapy of tomorrow very quickly.

MS. WASTLER: That would be viable.

CHAIRMAN MALMUD: So what about that, as a means of moving ahead with your suggestion, which was to move it ahead quickly, this would be more efficient. But insert those words, and require us or our successors to be forced to revisit it in 24 months.

DR. NAG: I have -

DR. HOWE: I think that's a policy -

CHAIRMAN MALMUD: I beg your pardon?

DR. HOWE: I think that's a policy decision, and as -

CHAIRMAN MALMUD: It's a legal -

DR. HOWE: -- as a policy decision, could be implemented fairly quickly. As long as we're not doing rule making to put it in, when we revisit, I think we can do that.

CHAIRMAN MALMUD: Dr. Nag?

DR. NAG: Yes. We have a motion on the table that has been seconded.

CHAIRMAN MALMUD: Yes.

DR. NAG: And this is part of the discussion, and we'll have to have a vote on it. But I can suggest one other way, and that would be that to bring -- if this goes to 1000, to bring it to 600 will require some rule making in 600, anyway. Am I right?

DR. HOWE: That's exactly right.

DR. NAG: I would be willing to withdraw my motion if we can say that we start the modification of 600, whatever rule making modification it requires in 600, we start working on that, and this can be kept in 1000 until such time 600 is modified to allow Perfexion to move into that, because otherwise, what will happen is after three or four years, we'll say, yes, we have learned about it, but then we can't move it because 600 -

CHAIRMAN MALMUD: Dr. Nag. Okay. Dr.

Howe, how does that sound?

DR. HOWE: Actually, my interpretation of DR. Nag's original motion to put it into 600 would have required rule making, and would, essentially, be saying to us that we need to develop part of our user-need memo to the rule making group to move it into 600.

CHAIRMAN MALMUD: So you're basically -- you agree.

DR. HOWE: So I'm agreeing.

CHAIRMAN MALMUD: All right. Dr. Nag?

MS. SCHLUETER: But we need to be clear that my sister division responsible for the rule making would need to prioritize the request that we would send to them for this rule making. And given their workload, it would not be a high priority.

DR. HOWE: No, but if it goes in now, it -

MR. LIETO: This is Ralph. It would remain in -- this is Ralph Lieto. In other words, it would remain in 1000 until who knows when.

DR. HOWE: But at least it would be part of the user-need memo.

CHAIRMAN MALMUD: Ralph, you're next.

MR. LIETO: Thank you. I think that,

first of all, I want to support what Dr. Nag has recommended about this going into 600. What is being recommended is essentially rule making by guidance, anyhow. What you're setting up in terms of the guidance document is what the regions are going to implement as regulatory license conditions in order to get these materials, or this device. So, in essence, it's not something that's going to be changing a lot, because what's going to happen is that they're going to be, as a license condition, stuck with these conditions, as indicated, anyhow, in order to get the device.

One of the things that I think Dr. Vetter alluded to, I don't understand if you do not have a component to test, the problem that the licensee would have with compliance if it doesn't exist. What you're alluding to is that because they couldn't test for it, because it doesn't exist, that they're going to be in violation of the rules, or that it wouldn't apply. So I don't -

MS. WASTLER: No, what I was trying -- I was trying to get to Donna-Beth's slide. Where was it? Where she listed the purpose of the tests. For the Perfexion, I mean, and if I'm reading it right, Donna-Beth, correct me if I'm wrong, but the purpose

of the test, and this was slide, I think it's 6.

DR. HOWE: Six.

MS. WASTLER: Was assess whether the patient docking system functions correctly, to place mechanical, center stereotactic frame at the radiation focal point, et cetera. Those were the purposes of the helmet test, the relative helmet factors, helmet microswitches and the like. All right? Those don't exist in the Perfexion Elekta. Okay.

The question is, if they don't exist, what does someone test, what test do they run to assure that these -- whether you assess the docking station system's function correctly? It's not a matter of if you don't have them there, you can just ignore them. The question is, how do you assess what the tests were supposed to be getting at. You don't have another set of tests. You need to specify something. If you don't test -- if there's no helmet, you don't test it. You put something else in its place.

MR. LIETO: Can I finish?

MS. WASTLER: Sure. I'm sorry.

MR. LIETO: What I was going to state is just like you do for HDRs. You don't put -- you don't have the prescriptive nature of the test in regulation. You have it in guidance that certain

performance of certain issues need to be evaluated in guidance space. You could do the very same thing with this device. Okay?

Putting it in 600, and saying in light of the fact in guidance that you don't have these components, you must develop tests, and not be prescriptive about the tests, just say you must develop tests and measurements, and frequencies to evaluate these aspects in order -- as a condition of use. And you could have those out in guidance space, and that's your living document. It still would meet the point that Dr. Nag has said about the fact that this is simply a stereotactic device that's out there.

I'd like to get on my soapbox, if I may, Mr. Chair, in that I think this is a classic example of where the ACMUI is making recommendations based on its expertise, which was never sought to begin with, and there's obviously this Grand Canyon between the ACMUI and NRC staff. I don't think it's going to get changed. Okay? And I think it's very unfortunate, because Dr. Fisher said that he saw this as a very readily, quick response of NRC staff to this new technology. What Dr. Nag is proposing is actually another step past that. Okay?

We're taking the current regulations,

using them to our advantage for a change in model, really, of a device. To me, this is no different than CT going from step and shoot to helical. I mean, it's a change in technology, but it's still that type of a modality. All right? And I just really think that we can do this within the framework of the Part 600 regulations.

CHAIRMAN MALMUD: Dr. Thomadsen.

DR. THOMADSEN: Sort of looking at it from the other side, I would be hesitant to have the NRC start making Part 600 rules for this, lest the rules get set in stone that are quite inappropriate, such as the early rules for HDR. I would much prefer that there be some experience and feedback on the rules before they get made permanent.

CHAIRMAN MALMUD: Dr. Thomadsen, you're speaking in favor of Donna-Beth's recommendation?

DR. THOMADSEN: I'm speaking against the motion, that they start making Part 600 -- is that the current motion, that they start 600 right now?

CHAIRMAN MALMUD: Yes.

DR. THOMADSEN: Yes. I'm speaking against that. I think it's premature.

CHAIRMAN MALMUD: Thank you. Dr. Suleiman.

DR. SULEIMAN: All right. Again, although

the motion on the floor is to adopt it under 600, my opinion is that if Part 600 rules were less prescriptive, and allowed for more flexibility, you would have been able to put this into 600 in the first place, and clarify the details that you want as guidance. I think that would be a much more effective regulatory strategy, to back-off, be less prescriptive so that you allow these new technologies to evolve so that you don't have this yttrium-90 in 1000, and decide where you want to put it later, so you don't have what's obviously a 300, I mean a 600, in 1000. So if you were going to change 600, I'd change a bunch of other things, and make them actually less prescriptive, and get more prescriptive in the guidance.

This may be a strategic thought, but you won't -- technology is going to continue to evolve and change a whole lot faster than it is right now. And if you don't start thinking about that now, if not us now, sometime, somewhere in the future maybe somebody is going to come up with the idea, and say this is not a bad idea. Let's think about this. But I think less prescriptive would be better.

MS. WASTLER: I guess the only comment I would have to make is that in the 2005 rule making,

and in 2000, there was a lot of back and forth between Agreement States and the medical community. They're looking at this as, I believe Dr. Welsh said, from two different sides of the animal. And a lot of times they have resulted in more prescription than, for example, that you would support here. So yes, if 600 was less prescriptive, and more performance-based, there's always the possibility, and it makes our ability to include new devices, for example, like this one, in under 600. But because it's not -- so there's a variety of -- I can't say I disagree with you, but there's other sides to the issue, as well.

CHAIRMAN MALMUD: Dr. Eggli, then a member of the public. Dr. Eggli.

DR. EGGLI: I'd like to pull my poke on Nebraska farm boy routine here, and ask for an explanation. It appears that what I hear is, we can't regulate by guidance in Part 600, but it is perfectly acceptable to regulate by guidance in Part 1000.

MS. WASTLER: That's the way it was -

DR. EGGLI: And I'm confused why that should be, if we can't regulate by guidance, we can't regulate by guidance.

DR. HOWE: No, in 1000, 1000 is written in such a way that you can develop guidance. And if you

look at our guidance, it always says it represents an acceptable means of complying with the regulations. You can provide something else. It says the NRC says these people are approved, but you could provide us with something else, and we would evaluate it, and make a determination. So 1000 let's us use license conditions to bring in new technologies that don't fit within our regulation. That's not the same as regulating by guidance. It is in the regulations that we can license it.

DR. EGGLI: I think that we're -- that's a fairly fine semantic point. I personally can't see the difference.

DR. HOWE: Okay.

DR. EGGLI: It seems to me, you can regulate by guidance in 1000, but not in 600. And guidance is guidance, and in one case you're regulating by guidance, in the other case you're not.

CHAIRMAN MALMUD: We have a member of the public who wishes to speak. Would you please introduce yourself?

MS. FAIROBENT: Thank you, Dr. Malmud. Lynne Fairobent with AAPM. I just want to bring up, and I hate to also go back in time, but in the Statements of Consideration to the 2002 Final Rule,

Issue 2 is "What process will be used to establish regulatory requirements and evaluate applications for emerging technologies?" And within that comment, there's discussion about a model was suggested for establishing the requirements for emerging technologies under the suggested model.

Anyhow, the model that was referenced was a model which when Gamma Knife initially came into being in the 1980s, NRC reached out to the appropriate technical and professional societies for helping to look at what the regulations were. And in NRC's response, it says, "We intend to evaluate each technology on a case-by-case basis, and to work with the ACMUI, the medical community, the public, and the developers of the new technology, as appropriate, to determine the specific risks associated with the technology, and any additional regulatory requirements for the medical use of the technology."

In our reaching out to our members who are users of this new Gamma Knife system, to my knowledge, there has been no outreach to the medical community, at-large, for input on this guidance before or while it was being developed initially, in the same manner as which I don't believe the outreach was done to ACMUI.

We would certainly like to make the offer to NRC that we would be happy to convene a panel of experts on this technology to look at whether or not the differences that NRC is seeing is as significant as it appears from the discussion today. There is a different of opinion on, and to work with NRC to come to some reasonable guidance on this.

In addition, in the same Statements of Consideration, there is a time frame suggested for when Part 1000 elements should be withdrawn from Part 1000, and put into the regulatory framework.

CHAIRMAN MALMUD: Thank you. All right. Dr. Welsh.

DR. WELSH: I have two very brief questions. One is in relationship to Dr. Suleiman's point about the, perhaps, overly restrictive nature of 600. If Elekta modified the Gamma Knife ever so slightly that it no longer fit under the exact wording that's in 600, and they called it Gamma Knife II, or Gamma Knife 2007, that would mean that it would have to move out to 1000. And that's, essentially, what we have here with the Perfexion, it's Gamma Knife II, it's Gamma Knife 2007. And it clearly belongs in 600. So I do support the concept that it move into 600, unless so doing today would slow it down in terms of

acquisition by institutions and facilities that would like to use it, and the clinical use and availability to patients. Would a move from the proposed 1000 to the correct 600 categorization slow it down?

DR. HOWE: I don't think so, because it would stay in 1000 until it moves to 600. And to move it to 600 would require rule making. And the rule making I envision is going to more performance-based, versus prescriptive-type requirements. And that could take a while, because as Janet has indicated, it depends on resources and priorities in the rule making group. And we have a lot of flexibility while it's in 1000, as it gets moved into the final rule making, so it's available. If we have problems with the guidance, we can correct those quickly, and we will have a better document going in.

CHAIRMAN MALMUD: Mr. Lieto.

MR. LIETO: I would like to throw out maybe a suggestion. My suggestion would be, would it be of interest that the motion be withdrawn pending a sub-committee of the ACMUI, that would include the vendor, maybe some people from the regulated community, which, obviously, I think we have several of them in the Agreement States, and coming back, looking at this guidance document, and making

recommendations based on the input of both vendor users, potential users, and the ACMUI on the 600 versus 1000 argument.

CHAIRMAN MALMUD: Any discussion of Mr. Lieto's point? Dr. Nag? I'm sorry, I didn't see your hand.

DR. SULEIMAN: The only point I'd have is that since the motion on the floor is still on the 600, we can't do that. You couldn't put under 600 right now, the way 600 reads, so the motion is really impossible to fulfill.

DR. NAG: Except I can modify my motion. Can I be allowed to modify my motion?

CHAIRMAN MALMUD: Absolutely.

DR. NAG: Okay. I move that the regulation of Perfexion be moved to 35.1000, importing the applicable rules from 35.600, such that until such time that 35.600 is modified to be more performance-based, and modified such that it will allow regulation of Perfexion in 35.600. So what I'm trying to do is force the NRC to push through the rule making; otherwise, it's going to stay in 1000 forever. This way it will allow you to put it into 1000 temporarily. It will allow you to push to modify your 600, your 35.600 more performance-based, and it will be

applicable to the old Gamma Knife, as well as the new Perfexion. It will do both things at the same time. I do not want them to be separated; otherwise, 35.600 will never be modified.

CHAIRMAN MALMUD: Is that the amended motion?

DR. NAG: Yes, that was the amended motion.

CHAIRMAN MALMUD: Who seconded the motion?

DR. NAG: Ralph.

CHAIRMAN MALMUD: Ralph, would you second that motion?

MR. LIETO: I have to defer.

DR. NAG: Okay. Too complicated?

MR. LIETO: I just would -

CHAIRMAN MALMUD: Would someone else care to second?

DR. WELSH: I will second it.

CHAIRMAN MALMUD: Dr. Welsh seconds the motion. Is there any further discussion of the amended motion? In that case, all in favor of the amended motion? Any opposed to the amended motion? Two opposed. Any abstentions? One abstention. The motion -- two, excuse me, Dr. Eggli. So we have all in favor, two abstentions, two nays. Motion carries.

DR. NAG: In that case, I'll also add Ralph Lieto's advice that we have a subcommittee formed, so this will carry on at the same time. So I would favor your motion, as well. The two can go on at the same time.

CHAIRMAN MALMUD: Dr. Nag is making a second motion, and that is that a subcommittee be formed from within this Committee to deal with the issues related to 600.

DR. NAG: Right. And, in fact, no. That committee formed ACMUI and members of the regulated community, including the states.

MR. LIETO: Thank you.

DR. NAG: And including vendor.

CHAIRMAN MALMUD: Including the states and the vendor, the Agreement States. So that would be made up of Dr. Nag, Mr. Lieto, Debbie Gilley representing the states, and who else was intensely interested in this? Dr. Thomadsen. Is that subcommittee acceptable to the Committee, as a whole? Does anyone feel slighted, or -- Sandra?

MS. WASTLER: Could I ask for a clarification? Didn't I hear a discussion of inclusion of the vendor?

CHAIRMAN MALMUD: Yes.

MS. WASTLER: And what about some of the -- any of the professional societies?

DR. NAG: Yes.

CHAIRMAN MALMUD: Yes.

DR. NAG: I mean, ASTRO and AAPM are logical members.

CHAIRMAN MALMUD: All right. So Sandi recommends including them, as well. That's acceptable, so we now have a committee made up of how many external parties? There's the vendor, and ASTRO?

DR. NAG: ASTRO and AAPM.

CHAIRMAN MALMUD: And AAPM. AAPM, ASTRO, the vendor, and then -

DR. NAG: The Agreement States.

CHAIRMAN MALMUD: Yes. And the members of the committee, so Drs. Nag, Thomadsen, then the Agreement States represented by Debbie Gilley, and Mr. Lieto.

MS. WASTLER: I would just point out in this regard, we'll have to -- I, personally, am going to have to double check the rules to make sure that we're following the appropriate guidance, as far as who we can pull into the subcommittee, because I'm not -

DR. NAG: Right.

MS. WASTLER: I don't have -

DR. NAG: Within the framework of NRC regulation.

MS. WASTLER: Right. That's fine.

CHAIRMAN MALMUD: That's a motion. We don't need a motion to set up a subcommittee, do we?

MS. WASTLER: I believe so.

DR. NAG: Our committee can do it.

CHAIRMAN MALMUD: So the Chairman can do it? It's done. All right. It's done, and we'll just hear from counsel with respect to whether or not -

MS. WASTLER: Right. I will check on that.

CHAIRMAN MALMUD: Dr. Suleiman.

DR. SULEIMAN: I just want clarification for my purposes. If a new technology comes out, I'm concerned about how quickly such technologies get into the mainstream. You could license it under broad scope license, so that gives you flexibility before it even gets addressed by the regs. So when it's out there, and there's some critical mass of experience, you think it's now time to kick it in under 1000, which is what 1000 was designed for.

DR. HOWE: What happens is -

DR. SULEIMAN: At what point do you feel you need specific regulations for that product?

DR. HOWE: What happens is that, if it's being developed and used at a broad scope license, the broad scope license, under Part 33, can do a safety evaluation, it has to be reviewed and approved by its radiation safety committee before it's used. If that use goes into a limited specific licensee, and in some cases you've got a broad scope doctor that wants to now go over to a limited specific licensee, and he wants to take it with him, then it comes into where we have to develop guidance for it. And that puts it into 1000. I mean, it may be in 1000 already, but we don't see it, because it's over in the broad scope. But then it comes into -

DR. SULEIMAN: Now we also -

DR. HOWE: It comes into it under -

DR. SULEIMAN: That's already been cleared by FDA, as well, we assume, at that point.

DR. HOWE: Because it could be over in the broad scope in its investigation stage.

DR. SULEIMAN: Right.

DR. HOWE: It could also still be over in the broad scope after it goes through its final FDA approval.

DR. SULEIMAN: But it won't go into a regulatory phase unless it's an approved or cleared medical product.

DR. HOWE: That's not true, because we would -- we might have a limited specific licensee that wanted to be involved in the investigation stage.

DR. SULEIMAN: Okay.

DR. HOWE: And we license it as soon as it hits the licensee's site, either under the broad, where they have authority and review control, or under the limited specific, where we have review and approval. But you can't have a device, you can't have materials under limited specific license unless it's approved.

DR. SULEIMAN: Okay. So you're -- unless it's approved or cleared by FDA, it's not going -- you're not going to consider regulations. Still investigational is still going to be under broad license, or possibly -

DR. HOWE: We do have provisions for research involving human subjects, and we recognize that research involving human subjects does not all go through FDA. It may not be funded, sponsored, and regulated by -

DR. SULEIMAN: If it involves an FDA

medical product, it will involve FDA.

DR. HOWE: It should, but we don't enforce FDA requirements, so we might pass the information over to FDA, and FDA says -

DR. SULEIMAN: And we'll enforce it.

DR. HOWE: But, otherwise, it could come through a process that it's not FDA approved because it is coming through some other route in investigational research.

DR. SULEIMAN: But you will generally not consider a regulation change for a non -

DR. HOWE: Well, this is an interesting concept, because it could be a brand new technology, but we may already cover it under our regulatory framework. Monoclonal antibodies, monoclonal antibodies were a new technology. We looked at monoclonal antibodies and we said what isotopes are you using? Okay. Same kinds of isotopes you're using everywhere else. How is it being used? Unsealed material, written directive required. Okay? 300. Is there anything in 300 that we have to grant an exemption to, and the answer was no. So monoclonal antibodies, even though it was an emerging technology at one point -

DR. SULEIMAN: And still investigational.

DR. HOWE: Still investigational, is regulated under our normal framework. And Dr. Nag's comments about a new isotope in manual brachytherapy, if Part 400 is written globally enough, then it doesn't make any difference what isotope it is. It's okay under there, as long as it meets all the requirements in 400, so it could be a brand new isotope, and we won't put it in 1000, because we feel we already have the regulatory framework for it.

DR. SULEIMAN: But the skill is in writing the regulation so it's sufficiently broad, and not prescriptive enough. So 600 sounds like -

DR. HOWE: That's one reason -

DR. SULEIMAN: -- it's a candidate for -

DR. HOWE: More performance-based.

DR. SULEIMAN: -- backing off, but the others may be better written, so I think -- because you've got a model there that may work, and work very well, but I think right now, we're coming right up against the wall of the limitations of 600. It's too prescriptive, and it prohibits Gamma Knife II to come under it. You'd probably prefer to throw it under 600, but you can't.

DR. HOWE: Well, we do prefer it under 600, but we have to modify the regulation and go more

performance.

DR. SULEIMAN: Yes.

MS. McINTOSH: Dr. Malmud, just an administrative point.

CHAIRMAN MALMUD: I'm sorry. Who's speaking?

MS. McINTOSH: I'm sorry. Just an administrative point. This is Angela McIntosh.

CHAIRMAN MALMUD: Yes.

MS. McINTOSH: It may be helpful to identify the subcommittee chair.

CHAIRMAN MALMUD: A subcommittee chair? Who would like to -

(Laughter.)

DR. NAG: Since I did all that, I'll volunteer.

CHAIRMAN MALMUD: Dr. Nag volunteers to be the subcommittee chair. Thank you, Angela, for bringing that to our attention. The record now shows that Dr. Nag will be the subcommittee chair. Sally Schwarz.

MS. SCHWARZ: Could I just ask one question? It sounds to me truthfully like Part 600 is rather outdated, I mean, in the sense that it's not broad enough to include new modalities. I mean, that

you're talking about details that not necessarily are going to exist in these new pieces of equipment that otherwise could fit in 600. To me, it seems like, I know it will take a long time to move this into a regulatory change, I mean, that it will take a significant prioritization-wise long time, but it seems like that should be initiated, because it sounds to me like 600 really is outmoded. And that if it starts now, or if it starts in two years, I mean, there should be a plan to change that regulatory document.

DR. HOWE: That was my understanding of Dr. Nag's motion.

DR. NAG: Right. That is why I made my motion the way I did, that I was only supporting going to 1000 if you start modifying your 600 now. You start the modification process, until such time 600 is modified, it is temporarily staying in 1000.

MS. SCHWARZ: And my question is that, will the subcommittee then move this change forward, or will the staff move this change forward? How will it begin to move forward?

DR. NAG: Well, I think one of -- as the subcommittee, one of the things we might say is here are our suggested modifications on 600, and then let

NRC move with that.

DR. HOWE: I think we're -- an administrative point, we have a user-need memo. We will add it to our user-need memo, and then it will be up to the other division to prioritize when it happens, the whole thing starts.

CHAIRMAN MALMUD: In terms of the motions, we've had a win-win situation, in that your initial recommendation has been moved on affirmatively after lengthy discussion. And Dr. Nag's recommendation has been moved on to encourage Part 600 to be revisited, and we all hope for the best as we take a break for 15 minutes to catch our breath, and move forward.

DR. NAG: And Mr. Lieto's recommendation was also implemented, that we have a subcommittee to look at this. All the three.

CHAIRMAN MALMUD: That is correct. So we are now -- if all departments were adequately funded to the extent that they needed it done, this could all be accomplished very -

(Laughter.)

CHAIRMAN MALMUD: Thank you all. Let's take a break, and we'll regroup at 3:20.

(Whereupon, the proceedings went off the record at 3:10 p.m., and went back on the record at

3:34 p.m.)

CHAIRMAN MALMUD: We will begin the second half of the afternoon session as soon as one or two more people are seated at the table.

(Pause.)

And it looks as if we're going to ask Dr. Howe to take the next session as well. She has the yeoman's job this afternoon.

MS. WASTLER: I believe this was one of the sessions that was deferred.

CHAIRMAN MALMUD: Yes, it is. I should say it was.

MS. WASTLER: Different subject, changes to part 35.

(Laughter.)

CHAIRMAN MALMUD: Part 35.

DR. HOWE: Okay, we're going to be talking about potential changes to part 35 and the process is that we write a user need memo to the rulemaking group and the rulemaking group then looks at our user need memo and makes a determination on resources and whether it can proceed with a rulemaking or not. So this is -- these are not rules. These are potential changes.

We always like to have the ACMUI input,

and I think if you look in your books, in some cases you'll find additional information at the bottom of the slide, the user notes and that gives you some of the background. The last time I gave a presentation, people wondered where these problems came from.

MS. WASTLER: I would point out that it's a variety of sources. Sometimes it's the licensee.

DR. HOWE: Sometimes it's the region.

MS. WASTLER: Sometimes the region has recognized a problem. Sometimes the states will bring up things that they see. So it's a variety of sources that come to us and as part of our process as Donna-Beth said, we don't do the changes to part 35. So we put into a letter to our sister office and request that changes be made, provided the justification for that, and then they take it, prioritize it based on their budget and rulemaking will proceed based on that.

So once we put it in the user need, it will be put into the process and prioritized according to budget, need, and the like.

DR. HOWE: And so our first one that we're going to talk about today is 35.57(a) which is the grandfathering provisions for the radiation safety officer, the teletherapy or medical physicist, and the

nuclear pharmacist. We don't have the authorized medical physicist on this because it's a take-back to 2002 when occupational medical physicist was a new term.

Essentially, this part of the requirement says that if you were listed on a license or a permit, on a specific date, that you did not have to comply with the training requirements in 35.50, .51, or .55. And a concern to us is that in .50, .51, you have additional training experience requirements in that last paragraph of the training and experience section. It applies to everybody that's coming through that pathway.

So the effect is you have an AMP or an RSO listed on a license on that date. They don't have to meet the criteria and then you want to amend that license and add a full new modality. And our general counsel has interpreted this grandfathering that the person no longer has to meet any of the requirements in 35.50 or .51 and therefore those additional training requirements that would go with that new modality for that person's use don't have to be met.

This came up with the licensing question where there was an RSO at a facility that didn't have an HDR. They wanted to get a new user and an HDR unit

and the person said well, we don't need to give you any -- we don't need to specify training for the RSO because they're grandfathered. And we had to agree with that.

And so we don't believe that's the intent. We believe the intent is that if there is a new use that the person get training in that new use. And in paragraph 35.57(b) which is the grandfathering for the physicians, there is a specific statement in there as long as you are doing the same thing you were doing on the date that you were grandfathered.

So we are proposing that we add a similar type statement in 35.57(a) that says when you're using or responsible for the same materials and uses before and then we have the dates there for -- it really only applies to 35.50 and .51 because an authorized nuclear pharmacist really doesn't have any new uses of materials.

And then in 2, these are different. This adds to the April 2005 rule and we're just putting the same statement in the April 2005 rule. We're responsible for the same materials and uses because we believe if you're really getting a brand new use, you're a medical physicist and you haven't been authorized for an HDR, that you need the HDR training.

Or if you're an RSO at a place with no HDR and you're getting an HDR, you need the HDR training. If you're an RSO in a place that doesn't have a gamma knife, you get a gamma knife, you need the gamma knife radiation safety training for the RSO. So that is our proposal.

CHAIRMAN MALMUD: Thank you, Dr. Howe. That is the proposal. Is there anyone who wishes to make a motion, provided the proposal being acceptable?

DR. VETTER: I move approval.

CHAIRMAN MALMUD: Dr. Vetter moves approval. Is there a second to the motion?

DR. EGGLI: Second.

CHAIRMAN MALMUD: Dr. Eggli seconds the motion. Any discussion? All in favor? I'm sorry, I didn't see your hand. Mr. Lieto?

MR. LIETO: If I understand this, then this would make it more restrictive than the current rule is currently. The current rule, as stated, would be that if a person was approved for say, 100, 200, 300, and 400s and was going to be adding HDR under 600, that the person who was currently the RSO for all those other uses could not be the RSO for the 600 uses, with the recommended changes.

DR. HOWE: Yes, so that would take them

back to 35.50 and the part of 35.50 that they wouldn't meet would be the last paragraph that says training or experience, I think it is training in radiation safety procedures, emergency procedures, and regulatory requirements for whatever the modality is. So we're not saying that the person has to come back through the board certification or the alternative pathway. We're saying that that last paragraph, that's the additional training in the new modalities, would be the only thing required.

MR. LIETO: I have some concerns with changing the grandfathering part. I'm not sure if I have a recommendation for change or difference, but the grandfathering clause of 35.57(a), if memory serves me right, was to address anybody that was approved at that time in December, excuse me, of October of 2002. And if they're going to add new uses for which a person would be in an RSO, wouldn't the licensee, I mean, if you're the authorized user, have to get training and experience, wouldn't the RSO?

DR. HOWE: No, that's our interpretation from the General Counsel is that the RSO would not need new training, and that's what we're bringing here is we believe that the RSO would need new training on those new uses. We think the medical physicists would

need new training on the new use.

CHAIRMAN MALMUD: Does that answer your question, Mr. Lieto?

MR. LIETO: Yes, but I'm still not convinced that changing the grandfather clause is the way to go. But I don't have a recommendation for difference.

CHAIRMAN MALMUD: Are there any other comments regarding this? I'm going to call the vote. All in favor? All opposed? Any abstentions. One opposition, all the rest in favor.

Next item, Dr. Howe?

DR. HOWE: Okay, now if we do make that revision, one of the points we wanted to make was that we keep hearing that it is very difficult to get an attestation for an RSO, that a person has, and this would just be for this additional training paragraph. So we are recommending that if you are adding to 35.57(a), essentially a clause that says you need the additional training, but you don't need the -- so an experienced RSO responsible for a new medical use will be required to successfully complete the training in 35.50(e), but not required to meet the other requirements in 35.50(d) for the new medical use. That other requirement is the attestation.

The RSO would get the training, but because it is very difficult to find another RSO to attest, they will just have to document that they had successfully completed the training.

DR. NAG: Other than the attestation, are there any other requirements? Because if that is the only thing, I ask that you put it down there, not required to meet the attestation requirement. Otherwise, the word other seems a little ambiguous.

DR. HOWE: 50(e) says that you've got the training radiation safety, etcetera. The other requirements in 50(d) say you have obtained a written attestation signed by a preceptor radiation safety officer that you've completed the requirements and it lists this paragraph and have a level of competency to function independently. But since this is not really the rule language, we can take that into consideration.

MS. WASTLER: We can take that into consideration and say what the wording is in D, rather than say -- that's not a problem.

DR. NAG: That's my suggestion. That's the exact wording, only one phrase. Let's put that phrase in.

DR. HOWE: Okay.

CHAIRMAN MALMUD: Move approval?

DR. THOMADSEN: Second.

CHAIRMAN MALMUD: It's been seconded by Dr. Thomadsen. Any discussion? All in favor? Any opposed? Any abstentions? Unanimous.

Next, Dr. Howe.

DR. HOWE: Okay, 35.57. The patient release rule. 35.75, I'm sorry. It's late in the day. The patient release rule. Currently, the patient release rule says that you may release an individual not likely to exceed five millisieverts (mSv) or 0.05 rem. There is no time element there. If you go back to the statements of consideration, it appears clear that they did not put per year because they assume that a person that was receiving the treatment would only receive the treatment once in a year. So they didn't say 5 millisieverts per year, or 0.5 rem per year.

We got a question from an Agreement State, and you've got a part of the reviewer notes that says that we had a licensee that wanted to give multiple I-131 administrations and they estimated that the member of the public would receive 560 millirem per release. They wanted to give six treatments, so that would have given the member of the public 1.5 rem and they

wanted to know whether they were releasable under 35.75 because it was 0.5 rem per procedure with no accumulation. Or it should have been 0.5 rem per year, and we went back to the statements of consideration, it appeared as if the intent was that it would be per year, but we felt we didn't need to put per year because no one would get these multiple treatments in a year. So what we're proposing is adding 5 millisieverts per year, 0.5 rem per year.

CHAIRMAN MALMUD: Motion?

DR. VETTER: No, a question. This looks like to me that it reads exactly as it currently reads. Your recommended revision?

DR. HOWE: The recommended revision should say five millisieverts per year. There's a 'per year' in it. It doesn't exist in the existing regulation. So it's a very small change.

DR. VETTER: That's the change, the per year?

DR. HOWE: Yes.

CHAIRMAN MALMUD: Ralph?

MR. LIETO: A couple of questions. This situation that brought this forward, was this the dose to a caregiver or was this the dose to some, you know, postulated unknown member of the public?

DR. HOWE: No, this was the dose to the caregiver, I believe.

MR. LIETO: I think we've addressed this, I think, multiple times in the past.

CHAIRMAN MALMUD: Follow-up question, please?

MR. LIETO: I interpret this to be the caregiver.

DR. HOWE: What is the purpose of the release criteria, then, if it is not to prevent exposure from the patient to members of the public?

MR. LIETO: Just to any member of the public.

CHAIRMAN MALMUD: Caregiver is a unique situation.

MR. LIETO: The caregiver was a unique situation, which arose, that discussion arose when a relative insisted on staying with a patient who had been treated with a high dose of radioiodine and received an excess of the allowable limit. This has to do with someone who has been treated. Let's say, and the patient is now radioactive and will be near other individuals, as I understand it. This radioactive patient will not be able to give them a radiation burden, which they don't need by proximity

to them.

Am I correct in my recollection?

DR. NAG: A member of the public.

MS. WASTLER: But the build up is whether you apply the 0.5 rem limit to each administration or whether it is a total for the year, and that was the issue, what was at issue.

DR. NAG: And the year, will it be a calendar year or will it be a year from the time of the first administration because that will make a big difference especially if the treatment was given in the middle of the year?

CHAIRMAN MALMUD: From the time of administration.

DR. HOWE: I think it's the time of administration.

MS. WASTLER: So is the dose to the public, you know, can you release somebody, when you give three treatments?

CHAIRMAN MALMUD: Mr. Lieto?

MR. LIETO: Part 35.75 release went into effect in what, 2000?

DR. HOWE: No, in, I think, 1997.

MR. LIETO: Now ten years later, all of a sudden this is an issue? I'm a little skeptical. I

think that word has been used before and I just really don't understand why this is an issue unless it's this one special case of this obviously new modality and it sure smacks to me what they're talking about here is a caregiver type scenario. I really have some reluctance for making rulemaking changes, since it is supposedly very difficult, for something that it may not be applicable to.

Another point that I would like to make is that it says in your supporting narrative here that "we have a sound basis for the rule change because it is clear in the supplementary information that the intent was based on an erroneous assumption, i.e., 500 millirems per year limit was based on the assumption that a patient would not be released more than once a year.

I would probably, and I would maybe defer to the nuclear medicine people, there are a number of studies done on the same patient in the year. Especially with iodine therapy, they could have uptake studies as well as the therapy in which they are released. So it is my understanding that 35.75 applies to any patient release, not just therapy patients, but any patient. So the narrative here is an erroneous, the erroneous statement is erroneous,

okay, in that patients do receive multiple studies in the same year and are released. Therapy patients included.

MS. WASTLER: Would that have been the case in 1997 when this rule was initiated?

MR. LIETO: I think the practice, especially with iodine therapies, for decades.

CHAIRMAN MALMUD: Yes, Dr. Eggli?

DR. EGGLI: Certainly, if you count diagnostic studies as well, a typical thyroid cancer will get a low dose uptake of 5 millicurie whole body scan and then a treatment. I don't think probably most end users have been in the habit of considering the cumulative effect of the diagnostic doses along with the treatment dose. Now, the contribution is relatively small if you're looking at a typical thyroid cancer treatment ranging between 100 millicuries and 200 millicuries. We're looking between 2.5 and 5 percent of that total exposure coming from the diagnostic study.

However, in some arenas, hyper thyroid patients who are refractory to treatment are treated again at four to six month intervals and again, the doses are generally not in the hundred millicurie range, but certainly nodular goiters could be in the

30 to 50 millicurie range. I guess the question is what is the cumulative impact of those releases, and that's now coupled with the fact that since the release rule, we can't get a preceptor to admit most patients to the hospital anymore from the insurance companies since the release rule went into effect.

If I admitting, if I am treating somebody less than 200 millicuries, the chances that I can get an insurance authorization for a hospitalization to isolate them, even when I have family situations that require it, it's fighting tooth and nail with the insurance companies to get that precept.

DR. HOWE: So Dr. Eggli, did you conclude that you might exceed 500 millirem cumulatively within a year, or did you conclude you weren't sure where you would be?

DR. EGGLI: I guess my conclusion is that I'm not sure where I would be, but I think it's conceivable that that possibility could exist that you could possibly exceed 500 mR in a year.

CHAIRMAN MALMUD: Does anyone want to discuss? Dr. Nag?

DR. NAG: I think that when we had been talking about this, we were expecting it to be 0.5 rem per year. We just mentioned at 0.5 and didn't the per

year. Okay, you know, put that year back in. However, one thing I would like to point to caution, is if somebody because of therapy has already reached that 0.5 rem per year and now needs not a therapy, but a diagnostic test, will it prevent the diagnostic test from happening because you don't want that.

DR. HOWE: Do you know what a dose would be from a diagnostic test?

DR. NAG: If someone had already reached the 0.5 limit and now you needed that --

DR. EGGLI: Total body equivalent or effective dose from a diagnostic study?

DR. HOWE: The five millicurie iodine.

CHAIRMAN MALMUD: Wait a minute. Are we misreading this? It says a licensee may authorize the release from its control of any individual, meaning the patient, who has been administered unsealed byproduct material or implants containing byproduct material. If the total effective dose to any other individual, any other individual. Well, we still have the inverse square law. I mean, if the patient wants to follow our instructions upon discharge, that patient will not be exposing anyone nearby to 5 mSv or 0.5 rem per year.

Even if the patient has got 100

millicuries as an outpatient or 150 millicuries as an outpatient. If on the other hand the patient is not following the instruction, the patient could behave irresponsibly. I mean, the patient could become pregnant the next day, which is one of the things that they are not supposed to do and they can sleep next to someone.

So I don't see where this is any change from the prior except that we have inserted the prepositional phrase per year in there. Am I correct that was the only change that was made?

Mr. Lieto.

MR. LIETO: Mr. Chairman, you are correct. The issue is that what initiated this was the fact that licensees were given more than one therapy in that 12-month period. And the release was based on per treatment. So if you did the treatment A, and it was less than 500 estimate, you were fine. They come back for retreatment, you based it on that activity. They were less than 500 millirems that were released, that was acceptable.

The concern being raised by NRC staff is that well that assessment is supposed to be not on a per treatment, but rather the aggregate over all studies administered for which the patient was

released in a 12-month period.

Am I correct?

DR. HOWE: I believe the prior patient release was based on 5 mR per hour at a meter and not on 500 millirem in a year.

MR. LIETO: That's correct.

DR. HOWE: And so then we went to a dose basis and so the five millirem per hour at a meter, the cutoff was about -- well, there was also 30 millicuries, so if you were below 30 millicuries you didn't meet the 5 mR per hour and you could release them. So everybody was given 29 millicuries.

MR. LIETO: Twenty-nine nine.

DR. HOWE: Yes, 29.9 and you were releasing. So there was not a dose basis back in 1995 which would be prior to this rule. And then they put it on to a dose basis, but they also added in occupancy factors and all those other things.

MR. LIETO: This is Ralph Lieto. That's understood and I recognize -- I don't disagree with that. I think the issue is that what is being said, at least in this narrative is that what's initiating this is a special situation for a new treatment which I think should not be the premise for changing rules. And especially if we don't know that this is the dose

to a care giver, as opposed to just a member of a general public release type calculation.

The other thing is, the other point again is we're talking about all administrations for which the patient is given radiopharmaceuticals or by-product material and released, not just the therapies.

CHAIRMAN MALMUD: Dr. Suleiman?

DR. SULEIMAN: I think this is a very solvable problem. I think 500 millirem, you can easily design around it if somebody is going to get a therapy and they may get it twice. You can easily throw some conditions into what the patient is going to do, so people who may be exposed can be reduced time, distance, whatever. I think it's trivial.

I think the per year business is pretty straight forward. I mean the intent there is over a time period. So I think that was an oversight.

I share your concerns about the caregivers. It hasn't come up in this. I'd just as soon not address it and just keep it simple. So I think this is a good --

CHAIRMAN MALMUD: Dr. Vetter.

DR. VETTER: Dick Vetter. As I recall, the basis for this recommendation is NCRP Commentary 11 and I think it would be very helpful if we

postponed this and went back to the basis for this particular regulation and made this regulation consistent with the NCRP Commentary 11.

It includes the public and caregivers and that's why I think it would be helpful to go back and look at it. In fact, for caregivers, it recommends 5 rem, not .5 rem. The .5 rem is for members of the public and they recommend up to 5 rem for caregiver. So rather than changes per year at this time which is a minor change and I agree with you, Dr. Suleiman, I don't think it would be too difficult for most licensees to meet that, but rather than do that off-the-cuff, I think we should get better informed about what the basis for it and perhaps even bring some more experience to the table before we make that recommendation.

CHAIRMAN MALMUD: Thank you. Dr. Zelac?

DR. ZELAC: Two things to add to the discussion. First, when they changed to the current performance-based as opposed to being very prescriptive about this, the practice, in fact, was typically one therapeutic treatment, one administration per year. That certainly has changed with the development of some of the new radiopharmaceuticals which are available now, where

multiple treatments over a relatively short course of time are, in fact, employed.

But even more importantly, at the time that this original regulation in the late 1990s came into play, we had at that point recommendations from the NCRP and the ICRP, both of which had a limit to the dose to others on an annual basis. And that remains the case today. It is still an annual basis as opposed to a per treatment basis and that's the real thrust of this change at the moment.

If we want to consider things like changing the .5 to something else, that's another issue, but at least we should have a regulation which is consistent with the recommendations, both nationally and internationally. And that's what adding on an annual basis will do.

CHAIRMAN MALMUD: Thank you, Dr. Zelac.

We have a member of the public. Will you please introduce yourself?

MR. PFEIFFER: I'm Doug Pfeiffer with AAPM. My concern, and with all due respect to Dr. Suleiman, it's not necessarily a trivial change. Given new modalities where you know in advance how you're going to be treating them, maybe several short, possibly lower dose treatments, that's one thing. But

if you have a patient who requires a follow-up treatment that may well have been done at another facility. You don't have access to those records to know what the dose to the population was based on that first treatment.

If you're giving the first treatment, you don't know in advance whether or not they will need a second treatment later that year. So there's no way of taking that into account in your calculations to leave headroom for the second calculations. I think you have to think about the unintended consequences in what that could mean for future treatments.

CHAIRMAN MALMUD: Dr. Fisher?

DR. FISHER: Thank you. Darrell Fisher. I think this is not necessarily a good idea for a few reasons. First of all, I think if there actually is an example where this has come up that particular procedure is essentially not going to be used because it's going to require hospitalization of the patient during the full course of that treatment.

I see it as a record keeping nightmare for the institution. Remember, this is not just dose equivalent in millisieverts. It's the total effective dose equivalent which is not necessarily an annual dose limit.

If you read 35.75, it says this is the total effective dose equivalent to an individual likely to receive a dose from the patient. And I think also this would have an impact on various fractionating therapy schemes for high-dose radionuclides, so for several reasons I don't think this is a good idea. If there's one exception in ten years where this might be applicable, then it perhaps could be overlooked.

CHAIRMAN MALMUD: Thank you. Dr. Eggli?

DR. EGGLI: I think that the case involved was a fragmented treatment on a pediatric patient and I think it was, in fact, a caregiver and not a member of the general public. And again, it comes back to the distinction between caregivers and general public. I think the general public is far less at risk here than caregivers.

On the high dose iodines for thyroid cancer, we typically give them once a year because of the risk of serious bone marrow injury. There are some hyperthyroids who do get multiple treatments over the course of the year, and protecting the general public, I think I agree with Orhan is a little, is less of a problem, but caregivers and maybe what you would call the immediate family, the extended

caregivers are really where the -- I think where the exposure risk comes. And if you're going to tackle this issue, although Orhan would just as soon leave it under the rug, you may have to tackle the caregiver issue because I think that's where most of these exposures beyond five millisieverts are going to come from is caregivers and what you might define as extended caregivers or members of the immediate household, rather than generally members of the public.

CHAIRMAN MALMUD: Sally?

MS. SCHWARZ: Sally Schwarz. I would agree with Dr. Fisher in the sense that these most likely are therapeutic situations and that the treatments probably will not continue if you cannot release the patients from the hospital. I mean I believe that if you're dealing with caregivers, that's totally separate than the general public, and I think that therapies that are worthwhile shouldn't have to be eliminated from possibility of use because of a limit on an annual basis for the general public.

CHAIRMAN MALMUD: Dr. Thomadsen?

DR. THOMADSEN: I tend to agree with everybody on this.

(Laughter.)

I think it's actually a lot more complicated of a question than what it sounds like and would support Dr. Vetter's -- I don't think you made it as a motion, but suggestion that perhaps it would be best for this body to form a subcommittee to look at the recommendations that are out there and consider the situations as described by Dr. Fisher and Dr. Eggli and Dr. Suleiman and come back with some better guidance for this Committee.

CHAIRMAN MALMUD: May I make a comment? It is now not possible to treat a patient at our hospital and many hospitals in the Philadelphia area with I-131 in high doses for thyroid cancer because in order to do that a patient has to be isolated in a room which itself is isolated from the rooms next door.

Therefore, all patients are discharged upon treatment. We whisk them out the doors as fast as possible. They are given outpatient doses between 100 and 200 millicuries of I-131, depending upon the extent of their thyroid cancer and occasionally, even higher doses. Now whether they get the 100 once or 200 once or 100 twice, the members of the family will be exposed if the patient doesn't follow the instructions which are very carefully given to the

patient in written form and discussed with the patient before discharge.

The amount of radiation that a person could get from such a patient if such a patient didn't adhere to the isolation that is recommended for that individual would exceed .5 rem per year, whether it was a single large dose or a multiple smaller dose. There is a point beyond which we cannot control the behavior of the patient.

There's also an impossibility currently of keeping the patient in the hospital since the insurer will not cover it. The insurer will not cover it, will not cover the in-patient stay. It will cover the treatment, but not the in-patient stay.

So if we're going to tighten the rules and revisit the rules in a way which will lead to the tightening of the rules, we may create an unintended consequence. I would suggest recalling why this 'per year' was inserted that we move ahead, let the per year be inserted and recognize that the patient does have a responsibility. When I speak to the patients that I'm treating and I treat about I guess between two and four a week, I make it clear what the risks are to the children, parents, spouses, significant others in the house, and that this is a responsibility

of the patient to protect those who are near and dear to the patient. And the patients generally over-react and actually isolate themselves from their children and family and spouses and significant others to a degree beyond that which is necessary.

Is it possible that a patient will misbehave? Of course. But I don't think we can account for everything that goes on once the patient is discharged from the hospital, but being in the hospital today in most situations is an absolute impossibility. The nursing staff won't care for the patient. The other personnel in the hospital don't want to be near the patient. The hospital doesn't want the patient in the hospital. More than one room has to be reserved for a patient. It's an impracticality.

I suggest that the wisdom of this Committee was that we insert the per year to clarify the issue, that we clarify it and move on to the next subject. Otherwise, you will be opening a Pandora's box. That's just a suggestion from someone who has been experienced both medically and administratively. That is a suggestion.

Dr. Welsh and Mr. Lieto?

DR. WELSH: As I read the exact wording

here, I see there's a potential for a bit of confusion where it says "any other individual" because we do make a distinction between the general public and health care providers. And perhaps the wording "any other individual" could be changed to "any non-health care provider."

Would that make sense or is it not making the point?

DR. HOWE: Our current regulations are based on any other individual likely to see.

DR. NAG: The general public?

DR. HOWE: It does not say the general public. It says if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed.

CHAIRMAN MALMUD: I think, Mr. Lieto, that you were next?

MR. LIETO: Mr. Chairman, what you were saying, I don't think there is any disagreement on that point about if a member or a patient doesn't comply with the guidance that is given to them. The issue, I think, is actually the situation where multiple administrations, therapeutic and/or diagnostic are given to an individual in what is being recommended at a 12 month period, that even following

the guidance, the estimate that they may likely give 500 millirems or greater, that we would run into problems and that there are scenarios where this is a possibility and as of course, as a result, the patient's treatment would have to be, or maybe withheld or changed in some course.

CHAIRMAN MALMUD: In theory, if I may, in theory you are correct. The patient getting a smaller dose could leave a hospital and decide to stay in bed for whatever reason for the next 24 hours with a significant other figure. We can't control that. But within the hospital, this patient is an unwelcome guest currently. Uninsured, their wonderful insurance stops because it is no longer necessary for them to be an inpatient.

The health care employees are concerned and the hospital will not allow them to stay. I think that we should just move ahead, make the necessary correction that was recommended, and not move into another area in which you may be opening an area which you simply don't want to deal with. We can't control the behavior of every human being with whom we have contact. We learn that in the case that you moved into when you inherited that problem. There are things beyond our control.

Patients, in my experience, behave extremely responsibly with regard to their loved ones and the people they know. We have to make some assumptions about that behavior. And therefore, I would once again, for the last time, recommend that you accept this change because it does follow what we had discussed last time and not enter into a whole new world in which there will be many, many unintended consequences. Just advice from someone who has been doing this for a long time. I think someone else had something.

Dr. Zelac?

DR. ZELAC: I think you've made the point amply that most therapies which will be administered will not have a problem in conforming. Or it is not expected that there will be a problem in conforming with this slightly changed requirement.

However, let's recognize that there well may be a therapy where there will be a problem with conformity and NRC is aware of this and has a policy in place already for the regions who may receive requests from a licensee who foresees that meeting this will not be possible to get an exemption.

Granted, we do not regulate by exemption, but there is certainly the possibility of an

exemption, one that is called for and as I said the plan is in place and can be used now on a very timely basis so that no one is put in a bad situation.

CHAIRMAN MALMUD: So that, currently there is an option existing?

DR. ZELAC: Yes.

CHAIRMAN MALMUD: Thank you. Dr. Suleiman.

DR. HOWE: Could I just say a quick thing? I believe the exemption is for part 20, which is a hospitalization stay, isn't it?

DR. ZELAC: It could very well be extended to a circumstance with the release of a patient. It was intended for the hospital stay, where there would be caregivers in close proximity to the patients. But I don't see any reason why it couldn't be extended if conditions were appropriate.

CHAIRMAN MALMUD: Dr. Suleiman?

DR. SULEIMAN: I didn't mean to trivialize it, but I think there are enough professionals out there who could come up with specific guidance for the patients when they go home to minimize the dose that other people may get and to meet that. It may cause a bit of a challenge, but I think that's the challenge. That's why you have these people.

This thing also states is not likely to exceed. It doesn't say absolutely, positively, under no circumstances will it exceed. Also, most people don't undergo multiple therapies. However, having said all of that, with cancer staging using PET drugs, an area that you're about to have authority, the doses from these PET nuclides are very intense for short periods of time. These are the very same patients that will be receiving therapies.

So this whole issue of how much radiation other people may get is probably an issue that's going to have to be paid attention to, but this is a safety criteria. I think it ought to stand and it ought to be addressed in terms of how if circumstances have changed out there in the practice of medicine where this has to be revisited, you know, then so be it. But I think the NRC just wants us to clarify this.

CHAIRMAN MALMUD: Is there any further discussion of the issue?

It has been moved and seconded, right?

DR. SULEIMAN: No, there is no motion on the table.

CHAIRMAN MALMUD: Is there a motion on the table?

DR. WELSH: Put forth the motion that we

accept it as written.

CHAIRMAN MALMUD: Dr. Welsh moves that it be accepted as written.

Is there a second? Dr. Nag seconds it. Any further discussion? All in favor. All opposed.

All in favor? How many were in favor? Three, four, five, plus me.

All opposed? Two, three, four, five.

DR. NAG: Tie-breaker.

CHAIRMAN MALMUD: Do I break the tie?

DR. EGGLI: Point of order. The Chairman can't vote.

(Laughter.)

CHAIRMAN MALMUD: Therefore it is tied. Chair can't vote. It's tied.

DR. HOWE: Moving on.

CHAIRMAN MALMUD: Can NRC clarify it?

MS. WASTLER: Yes, that's what I'm looking for.

DR. NAG: I think only when its a tie that the Chairman can vote in the tie-breaker.

MS. WASTLER: Just to point out, if you look at the by-laws, 1.3.5, it says the decision should be by majority vote of those members present and voting, with the tie permitting continued

participation of the Chair in the discussion. But that's all it says.

DR. FISHER: The Chair can discuss this matter.

(Laughter.)

CHAIRMAN MALMUD: Dr. Van Decker, you were going to say something?

DR. VAN DECKER: Well, I was going to try to help out your position here, as a piece of help. I mean, obviously, I believe no clarity means that it will get clarified for us as a regulated community. I think it will probably behoove us to get some more information beside what's the best thing to do here, and obviously gathering more information is a better way to maneuver people's opinions on the statements being said.

And having said that, I guess I'll come back to a Dr. Vetter approach from the beginning with saying that maybe we should take this just as an item for study and bring back some more information and see if more information and science on the table allows a better decision that allows us to be in control of where this is going.

MR. LIETO: I would second that.

CHAIRMAN MALMUD: Is that a motion? Is

that a second?

MR. LIETO: Yes.

CHAIRMAN MALMUD: Dr. Van Decker has made a motion. Mr. Lieto has seconded it. Any discussion of their motion? All in favor of their motion?

I think that's the majority. And do you recommend a subcommittee for this Dr. Van Decker? Do you recommend it?

DR. VAN DECKER: I'm always scared because I know what that usually leads to. I would recommend, in your judgement, whatever you think would bring that science to the discussion better from within this group of a subcommittee of a subcommittee so does it which might be a good modality than I think that that's not unreasonable.

CHAIRMAN MALMUD: Thank you. I see that Sally Schwarz had her hand in the air. Were you volunteering?

(Laughter.)

MS. SCHWARZ: I was volunteering Dr. Vetter.

(Laughter.)

CHAIRMAN MALMUD: Dr. Vetter had volunteered as well, actually.

MS. SCHWARZ: I will go back to my room

and get online and see if I can find that document or if you have it online, can you tonight find the answer?

DR. VETTER: I don't think commentary 11 is online.

MS. SCHWARZ: Okay.

CHAIRMAN MALMUD: Dr. Vetter, would you be willing to chair this small subcommittee?

DR. VETTER: Depends on who else is on it?

(Laughter.)

CHAIRMAN MALMUD: You, you, and you.

DR. VETTER: Yes, I would be happy to.

CHAIRMAN MALMUD: Let's see, Dr. Vetter, Dr. Eggli, any other party that's interested would be the radiation oncologist who has released a patient with seeds, right? But the seeds don't really generate that much of radiation. How about a physicist, is that it? Another physicist?

DR. FISHER: This is a major issue for the patient. I'm also involved in high-dose therapy treatment planning, which is impacted by this.

CHAIRMAN MALMUD: You're volunteering, Dr. Fisher?

DR. FISHER: I would volunteer.

CHAIRMAN MALMUD: By all means. You have

a subcommittee of three. That's Dr. Vetter as chair, Dr. Eggli, and Dr. Fisher.

DR. VETTER: Thanks.

CHAIRMAN MALMUD: Thank you.

DR. HOWE: Dr. Zelac?

DR. ZELAC: Just a point of information, as special employees of NRC, do have access to our technical library and I'm sure commentary 11 is in there.

CHAIRMAN MALMUD: I couldn't hear what you said. I'm sorry, Dr. Zelac.

DR. ZELAC: Commentary 11 should be available in our technical library right next door.

CHAIRMAN MALMUD: Thank you.

DR. HOWE: Moving right along to an area that you were so happy about this morning, in this case we have a new ophthalmic eye applicator and we had a presentation from Dr. Nag about -- I think Dr. Nag gave the presentation, in our spring ACMUI meeting. And the question came up at that point whether this should be a 1000 device or should be a 491 device. And I think Dr. Nag felt pretty strongly that it should be a 1000 device because it is not the same as the existing ophthalmic applicator.

And so at this point you have a

possibility of making a decision that will put this into a user need memo that might actually put this into the regulation, but we would consider it 1000 while this is happening.

And that is we don't have experience with the device yet, but in our first look at it, we believe that the major area that we would be focusing on would be training and experience and that an individual that met the training and experience criteria in 35.491 using the existing ophthalmic applicator, would not be qualified to use this new device because it's used differently. It's used inside the eye. It's used -- we think it's a more risk type of procedure.

So what we were proposing was to change the training and experience criteria in 490 and recommending that we split the A pathway is the Board's certification pathway. The B pathway is the alternate pathway. And changing the B pathway, if we kept this device in 491 to address superficial ophthalmic treatment which would be the existing ophthalmic treatment and we essentially just repeated the criteria that are in the existing regulation, and then at a new (b)(3) which would be for intraocular ophthalmic radiotherapy device and this would be the

treatment that goes into the eye itself. And so we mimic the wording from (b)(2) into (b)(3) for this other type of ophthalmic procedure and we essentially used, I think, pretty much the same criteria. We could go back and look. There were four things: examination, calculation of dose, administration of the dose, and then follow-up review and this has examination, calculation of the dose, administration of the dose, and then follow-up review.

And then we would modify (3) which is the preceptor statement and the preceptor statement now would address paragraph (a) which is the certification; (b) which is one ophthalmic device; and the next (b)(3) which would be this intraocular one. It's primarily the supervised clinical training experience.

CHAIRMAN MALMUD: Dr. Nag.

DR. NAG: Okay, right, the way you have written -- can you go to the previous slide, please?

DR. HOWE: Yes, I can.

DR. NAG: Okay. Now which is the one that can be used by the ophthalmologist. Why would that then be -- okay, 491, okay. And then isn't the one currently done by the ophthalmologist?

DR. HOWE: Yes.

DR. NAG: And that's how many hours, 18 hours or something?

DR. HOWE: No, it's 24 hours of classroom/laboratory training.

DR. NAG: All right, in the next one, 491(b)(2), I have no problem with that slide. Now let's go to the next slide. Then for this (b)(3), the intraocular, will someone with only 24 hours of training plus supervision in this applicator would be allowed to use that? That we do not want. This requires more than just 24 hours of training. So I'm not clear whether the way you have written --

DR. HOWE: I have included the 24 hours of classroom/laboratory because that's radiation physics, radiation protection, and mathematics. And --

DR. NAG: Well, I very serious problem with the way it is written. The (b)(3) should be someone with 491, but more like a 490 kind of experience, plus experience in handling the intraocular device. But someone with only supervision and that 24 hours should not use this device.

DR. HOWE: Okay.

CHAIRMAN MALMUD: So are you recommending changing the wording?

DR. NAG: Yes, I recommend changing the

wording on the (b)(3) to be such that all the training that is required in 490, not 491, but 39.490(b) plus being knowledgeable in this equipment.

CHAIRMAN MALMUD: Ralph?

MR. LIETO: Well, could we just move it to 490?

DR. NAG: Yes.

MR. LIETO: Put this device under 490.

DR. NAG: Right, this should be under 490.

MR. LIETO: The source or device under 490 because it's intraocular -- not intravascular.

DR. NAG: Intraocular.

MR. LIETO: Intraocular, so it lends itself to that type of brachytherapy.

DR. THOMADSEN: Intravascular, since you're treating the blood vessels.

DR. NAG: Yes, not intra -- this should not stay in 491. 491 is just superficial.

DR. HOWE: Okay, we have a couple of options here. One would be to try to find a place for it and move it right into the regulations. The other would be to leave it in 1000 to get some experience.

DR. NAG: I would say leave it in 490 because this would be straightforward, you know, 490 divided -- it's immaterial. It's used with therapy

and it has all the risks of any other 35.400 usage. But this, this is just what we were discussing this morning. Like what it was said, it's like any other manual brachytherapy.

This is the final thing I was wondering if we could do for Perfexion, that if in 600 A or B or something like that so that 600A would be the regular gamma knife and 600B would be, well, let's not go back to that.

(Laughter.)

But here, this should be placed under 490, not 491.

DR. HOWE: Dr. Nag, just as a kind of a point here. We would probably make a change to 491 and say training for superficial ophthalmic use is strontium 90 --

DR. NAG: Yes.

DR. HOWE: So that made it clear that it was a very limited use, and then we could go in and we could add something in 490 that was specifically for this device.

CHAIRMAN MALMUD: You will come back to us with a new proposal? Or do you want to do that right now?

DR. NAG: Not a new proposal, I mean --

DR. HOWE: I'm thinking that I might not be able to come up with the exact words. But I could go from here to the user need memo with the concept that we want to add the devices additional training in 490 and then make a minor revision to the title of 491 and that could move it forward and then we could figure out rule language later.

CHAIRMAN MALMUD: Would that satisfy --

DR. NAG: Because right now the only thing, my suggestion is if you go back to the previous slide, that is applicable for superficial. That one word for 491, which means that for the intraocular therapy, it has to go automatically through 490 and you just say for any new device in 490, you need training anyway. So you could add training.

DR. HOWE: No, you don't. Not for 490, but I'm thinking you would put this as an additional training --

DR. NAG: Additional, yes.

CHAIRMAN MALMUD: So slide 8 would be exactly as you have proposed it, Dr. Howe, with the insertion of the word superficial?

DR. HOWE: Yes.

CHAIRMAN MALMUD: Whereas slide 9 would go into 35.490 rather than 491.

DR. HOWE: Yes, and I would make a recommendation that the title for 491 be changed so that superficial goes in the title also.

DR. NAG: Yes.

CHAIRMAN MALMUD: So that is Dr. Nag's proposal. Is there a second to it?

DR. WELSH: Seconded.

CHAIRMAN MALMUD: Seconded by Dr. Welsh. Any further discussion? If not, all in favor? Any opposed? It's unanimous.

With regard to the second slide, which is number 9 here, that that would be reworded to go into 35.490 so that the intraocular and the superficial ocular are distinctly separate under two different groups.

Is that your motion?

DR. NAG: Yes.

CHAIRMAN MALMUD: All in favor of that motion? All opposed? Carries unanimously.

Dr. Howe? Next item.

DR. HOWE: Now we move into 35.400, .500, and .600. And at the beginning paragraph for each one of these, at the beginning sentence for each one of these paragraphs it says that the licensee should use sealed sources and whatever the use is as approved in

the sealed source and device registry. This case came up with the Perfexion, and it is out there with many other devices. But the Perfexion is probably the clearest use.

When the Perfexion was reviewed on the sealed source and device review, it was accepted for certain uses that the manufacturer sent in. I think head. The FDA approval does not include trigeminal neuralgia and doesn't include neck. Now the lack of the trigeminal neuralgia is because FDA made an actual decision and said you didn't provide enough information to support this. The neck part, I think, just was not included. I'm not sure. But it went through FDA as a 510K.

Our understanding is that now puts it into the practice of medicine and that a physician, if they choose to, can use the gamma knife for a treatment in an appropriate area and can go off label.

By saying only as approved in the SSDR, the approval is much more limited and we are effectively saying you can only use it as approved in the SSDR. The SSDR people are not really reviewing medical use and practice, so they're engineers. Whatever the manufacturer sends in, they'll repeat. They aren't making a value judgment on that. They're

making a value judgment on the source, how well it's put together, the device, how well it's put together. So they're making an engineering decision. And what we'd like to do is we'd like to separate this out so that we get the practice of medicine issues out of the SSDR approval process.

I don't know exactly how to do that word-wise, so I am proposing that this first sentence in each one of these paragraphs be revised to exclude the specific medical indications for use provided by the manufacturer while retaining the type of medical use, in other words, 400, 500, 600 and any physical conditions of use or any other important factors that have really been evaluated by the SSDR, but not the medical use.

CHAIRMAN MALMUD: Dr. Nag?

DR. NAG: Dr. Howe, I do agree with you wholeheartedly. We are not in a medical decision and this is -- the NRC only has a safety point of view and therefore it's similar in the microsphere. Microsphere negation is for hepatic cancer -- or the Therasphere® is for hepatic cancer and the Sirsphere® is for (indiscernible) only, but they are used interchangeably in practice and therefore we really have no right to say that this is only for this

medical use and I agree with you.

DR. HOWE: Now for the microspheres, I would caution that we do have a regulatory role in that and that is that if you use the Therasphere® outside of the humanitarian device exemption, that puts it into research and we have 35.6 that says if you're going to do research involving human subjects, then you have to do certain things.

So for the microsphere, it's slightly different, but you're right about the Sirsphere®.

DR. NAG: The Sirsphere®.

DR. HOWE: The Sirsphere® was approved by FDA for certain treatment. We don't care really what you use it for.

DR. NAG: I'm aware of that and I agree with you, but in general I am supporting your statement and I think the word thing is something you have to work on so that it -- you don't take the word of SSDR. You don't take that word, but it's used for this purpose without saying well, what medical indication.

DR. HOWE: So conceptually, I have the right idea, it's just going to be a question of getting the right wording, because I don't have the wording either.

DR. EGGLI: Move acceptance.

CHAIRMAN MALMUD: Motion for acceptance made by Dr. Eggli.

DR. NAG: Second.

CHAIRMAN MALMUD: Seconded. Any further discussion?

Mr. Lieto?

MR. LIETO: So the change in the SSRD, the sealed-source registry, device registry, is that required change from rulemaking?

DR. HOWE: We can't change the SSDR. The SSDR can only be changed if the manufacturer wants a change and either the NRC or the Agreement State that issues the SSDR makes a change.

What we're proposing is a change to 35.400, 500, and 600 that makes it clear we want you to use something that's in the SSDR. We want you to use it under the right conditions of use and whatever the radiation safety issues are, but the medical part that's in that SSDR is not what we're tying into.

CHAIRMAN MALMUD: Dr. Suleiman?

DR. SULEIMAN: I understand the indication part of it. I understand the off-label use of it. If it's being used off-label, it's ignoring the indication. If it's being used off-label, why can't

it be ignoring the SSDR? So I'm wondering does this wording have to be changed at all?

DR. HOWE: Yes, because our wording is it has to be used as approved in the sealed-source and device registry and so that, for us, means you have to use it as the sealed-source and device registry.

DR. SULEIMAN: NRC does not acknowledge off-label use.

DR. HOWE: We don't have the same --

DR. THOMADSEN: This is adding.

CHAIRMAN MALMUD: So Mr. Lieto.

DR. SULEIMAN: So you're taking that requirement out of those specific sections of the --

DR. HOWE: Yes, that's the intent. I don't know how the wording will be, but that's the intent.

MR. LIETO: Final question, can maybe a suggestion for the future be that as the NRC approves or reviews and approves these registry entries that it would not put in the approved uses.

DR. HOWE: We really don't have any control over that. We do have control over the ones that come through the NRC, but not through the different Agreement States, and generally the engineers will look for some kind of use and they'll

just copy over what the manufacturer gives and the manufacturer sometimes gives detailed things, sometimes just sketchy -- we can't change those.

CHAIRMAN MALMUD: Dr. Nag?

DR. NAG: Yes. I have a request. Once the wording has been changed, you know our intent. We agree with your intent, but sometimes the devil is in the detail. Once the wording is done, we would like to have a look at it before it finally goes out.

DR. HOWE: Well, Dr. Nag, this is a potential change. It has to go into user need memo and then it has to be accepted and you will have many chances to see it before it goes final.

So that is not a worry. You'll be involved.

CHAIRMAN MALMUD: Are you looking for a motion?

The question is called, all in favor?

(Chorus of ayes.)

CHAIRMAN MALMUD: Any opposed?

(No response.)

It's unanimous. Oh, any abstentions? No.

Very good, thank you. Next.

DR. HOWE: I think this is my last one. This is essentially -- the issue came up because we

have very few 200 users that have generators. And we have 200 people that want to be new authorized users, switch to 200, are they are required to get generator training.

And so what's happening now is they're providing the training, but those that don't have a generator make arrangements generally with a nuclear pharmacy, and they send their physicians over to the nuclear pharmacy and the nuclear pharmacy provides them with the generator training.

And then in some cases we've had calls where the licensee wants to put the authorized nuclear pharmacist down as the supervising individual for our regulations in 35.290, but the supervision can only be done by an authorized user with 290 authorization. So therefore, the ANP cannot be the supervising individual of record. The authorized user can be.

And so we're looking at it and we're saying well, in reality, the person that's really providing this training is the authorized nuclear pharmacist. They're more than qualified to provide the training. Why can't we go in and propose that this -- this one section, eluting the generator, that the supervising individual could be the ANP, and they could be recognized as the supervising person.

DR. VETTER: I move approval.

DR. EGGLI: Second.

CHAIRMAN MALMUD: Any discussion?

(Laughter.)

MR. LIETO: I hate to disappoint the Committee, but I think this is becoming a little overly prescriptive, because what this means to me or what this is stating is that you're specifying the tasks that can be performed by an authorized nuclear pharmacist. The rule as it just currently states says that the training is under the supervision, so whether that supervising AU delegates that to a nuclear pharmacist, because I can see the other sections there for the instrumentation, what happens if they're provided by a medical physicist? Now do we need to go in and amend part 290 so that instrumentation can be provided under the supervision of a medical physicist? I just see this kind of becoming overly prescriptive and I think the rule, as it currently states, is perfectly adequate because it just says that the training and experience under the supervision of an AU for those uses. If they delegate the training for the eluting of the generator systems to a nuclear pharmacist, I mean it's still being done under their supervision, they're just not doing it.

DR. HOWE: I think the questions come up -- Ralph, we're getting a lot of questions from the regions and from the outside too, is they're not understanding our concept of supervision. And they're saying that the authorized user has no relationship to this authorized nuclear pharmacist at the commercial pharmacy. And they would feel more comfortable if they could recognize that this nuclear pharmacist is the one providing the training here, and they don't have the unit and are authorized for it and that's part of what we're getting. As part of that no relationship as far as being part of the same group.

We tend to recognize that the supervising individual, if they make arrangements with the nuclear pharmacy is essentially supervising, even though they're not physically there and they're not looking over their shoulder. So we have accepted that and this is a clarification.

CHAIRMAN MALMUD: Dr. Eggli was next.

DR. EGGLI: I think I represent the average paranoid authorized-user-preceptor and that I think this is a good thing.

I am personally reluctant to delegate any responsibility to somebody that I don't own, that I don't have any kind of administrative authority over.

And to clearly state to preceptors out there that it is okay for an authorized nuclear pharmacist to preceptor this piece of the work, I think is a very good thing to relieve the worries of preceptors who are worried about getting caught doing the wrong thing.

And I realize, Ralph, I don't think this is overly prescriptive. I think this clarifies a bit of freedom that these people have and essentially NRC is saying it's okay. This other person is qualified to do this as well, and it doesn't stick you personally.

CHAIRMAN MALMUD: Thank you, Dr. Eggli. I think Debbie Gilley is next.

MS. GILLEY: I think this has been a common practice in the Agreement States for quite some time, that we've allowed authorized users to visit authorized nuclear pharmacists and do their elution of generators under the supervision of people that know how to do them best. I don't think this is new territory necessarily for the Agreement States.

CHAIRMAN MALMUD: I think you wanted to speak again, Ralph?

MR. LIETO: I'm just concerned that this is just going to be sort of the first step and that

all the other sections that people are going to want to come back and ask for this because of some paranoia by the regions and what they want to accept. I really think it could just be handled as a guidance statement from Headquarters, saying this is perfectly acceptable. If you get to recognize this training experience, I think to put it out -- I just have this reluctance in playing with the rules any more than we need to. They're in bad enough shape as it is and I just think that where it's at right now is fine and it's just simply a guidance statement from Headquarters.

MS. WASTLER: We always do have the option of putting out an information notice or RIS, whichever is the appropriate one or generic communication to clarify this. That would be an option as well.

MS. SCHWARZ: Or even something on the web? I mean is there a way that information could be formally transmitted, even without -- on the web?

MS. WASTLER: Any information would go out on the medical list server to all the participants, yes. We could make it well known. It would be on the web. Medical tool kit.

DR. VETTER: This change, this is Dick Vetter, this change certainly doesn't make -- this

proposed change doesn't make things any more restrictive. It makes them less restrictive. It makes them easier for a practice that doesn't have a generator. They send them over to another licensee where they get the training.

DR. NAG: I would accept this. I think it makes it more clear and I have no problem with that.

CHAIRMAN MALMUD: Sally?

MS. SCHWARZ: I think this is fine and in light of the fact that it will take how many ever years to get this accomplished, maybe we could just put the notice out on the web now and then the information is there.

(Laughter.)

And then you can proceed to change it and regardless, in the interim period, it would be finished.

CHAIRMAN MALMUD: Any other discussion of the motion?

All in favor of the motion? All opposed to the motion? Any abstentions? So it's one negative, no abstentions.

(Laughter.)

Thank you. Dr. Howe, I think that was the last item, wasn't it?

MS. WASTLER: I think it is. We do have a response back with the question on the subcommittee and whether you're allowed to have non-ACMUI members, what the FACA requirements are. We did get clarification from John Szabo on that.

MS. TULL: This is Ashley Tull. I got an answer from OGC, so on the subcommittee, only ACMUI members can actually comprise the subcommittee. So we'd have three ACMUI members, then what you can do is consult with anyone you want to. So they can participate to whatever extent they want to. You just can't name them on the subcommittee, and then you're also going to have to report, obviously, back to the full Committee.

CHAIRMAN MALMUD: Thank you. That's very useful information.

MS. TULL: I have another announcement. I have several others.

DR. NAG: Just for clarification, in that case I would like to join the subcommittee rather than consult with another member of ACMUI. Can we add him to the subcommittee?

CHAIRMAN MALMUD: Sure.

MS. TULL: Let me add his name to my notes. Okay.

The second announcement is that the chairman can vote, and the chairman can vote in the case of a tie. The chairman can vote, unless we find something that's particular to ACMUI which you didn't seem to find anything in our by-laws, Sandi, then there's nothing, as far as FACA requirements or anything like that that would prevent Dr. Malmud from voting.

MS. WASTLER: Does not the by-laws supersede or go on top of or in addition to the FACA requirements?

MS. TULL: They would in this case, since there's nothing in FACA that would prevent him from voting.

MS. WASTLER: According to the by-laws, it's majority vote.

MS. TULL: Right.

MS. WASTLER: That rules.

MS. TULL: So he could vote.

MS. WASTLER: He could vote in that, but as far as -- he's not a tie breaker. It has to be a majority -- he has to carry the weight.

MS. TULL: He can vote.

CHAIRMAN MALMUD: I carry the weight all right.

(Laughter.)

MS. TULL: The answer from OGC was that he can vote in the case of a tie, unless there's anything that specifically in the bylaws that states he can't vote.

MS. WASTLER: It must be ACMUI by-laws specifically state that he cannot.

MS. TULL: Then he can't.

MS. WASTLER: There's nothing that prohibits him under FACA from casting a vote in the event of a tie.

CHAIRMAN MALMUD: Do any of these committees state that the procedure for the committee is standard Roberts' Rules of Order?

MS. WASTLER: Not that I'm aware of, but then --

MS. TULL: No. The by-laws are in the back of your binders. I don't know if we want to take the time to look at them now.

DR. NAG: We can look at them later.

MS. WASTLER: It does not reference that, no.

CHAIRMAN MALMUD: So the ruling is that I could have voted?

MS. TULL: Yes.

CHAIRMAN MALMUD: I did vote.

MS. TULL: So it would have been 6 to 5 if you voted then?

DR. SULEIMAN: It says in here Roberts' Rules of Order will govern in the preamble.

MS. WASTLER: It's in the preamble..

MS. TULL: I see at the end of the first paragraph, okay, then ACMUI does prevent him from voting then, but FACA does not.

MS. WASTLER: I think we got to the bottom of that. I'm going to read this from front to back just to make sure.

MS. TULL: Yes.

MS. WASTLER: I didn't look at it the first time.

CHAIRMAN MALMUD: The chair serves at the pleasure of the Committee. If the Committee wants the chair to vote, he voted. If the Committee wants --

DR. EGGLI: Half the Committee wanted the chair to vote.

(Laughter.)

DR. NAG: What was the Roberts' rules --

MS. TULL: Okay, I have one last announcement as well. I think you requested the NCRP Commentary 11. I have a copy, but you can't make

copies and this is it, so if you want to look at it this evening or something that's fine, but that's all we have right now.

So Dr. Vetter, I have NCRP Commentary No. 11.

DR. VETTER: Thank you.

MS. TULL: If you want it, you can have this. You can't make copies, but you can look at it.

DR. VETTER: Could I borrow it overnight?

MS. TULL: Yes.

DR. VETTER: Then we might be able to get together at lunch tomorrow?

MS. TULL: Okay, come see me.

DR. VETTER: I'll look it over tonight and we'll meet tomorrow and get this resolved.

CHAIRMAN MALMUD: We understand that pending a review of Roberts' Rules we will know whether or not the chairman votes.

MS. WASTLER: We'll look at it more closely.

CHAIRMAN MALMUD: I want you to know that the chairman will sleep well tonight either way.

MS. WASTLER: Okay, we'll take that under advisement.

CHAIRMAN MALMUD: Is there any other

business for today's meeting?

If not, I want you to note that the chairman brought this Committee to a conclusion five minutes before the deadline and that we will meet promptly tomorrow morning at the appointed hour, at 8 o'clock. Thank you all for a very lively discussion today.

(Whereupon, at 4:59 p.m., the meeting was adjourned, to reconvene tomorrow, Tuesday, October 23, 2007, at 8 a.m.)