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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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MEETING

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OPEN SESSION

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TUESDAY,

APRIL 29, 2008

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The Committee met at 8:00 a.m. in Room T2-B3 at Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, LEON S. MALMUD, Chairman, presiding.

MEMBERS PRESENT:

LEON S. MALMUD, M.D.	Chairman
RICHARD J. VETTER, Ph.D.	Vice Chairman
DOUGLAS F. EGGLI	Member
DARRELL R. FISHER, Ph.D.	Member
DEBBIE B. GILLEY	Member
RALPH P. LIETO	Member
STEVE MATTMULLER, R.Ph.	Member
SUBIR NAG, M.D.	Member

MEMBERS PRESENT (Continued):

SALLY WAGNER SCHWARZ, R.Ph. Member

ORHAN H. SULEIMAN, Ph.D. Member

BRUCE THOMADSEN, Ph.D. Member

WILLIAM VAN DECKER, M.D. Member

JAMES S. WELSH, M.D. Member

NRC STAFF PRESENT:

STEPHANIE BUSH-GODDARD, RES

MARK STEPHEN DELLIGATTI

CINDY FLANNERY, FSME

SANDY GABRIEL, Region I

MERRI HORN

DONNA-BETH HOWE, Ph.D.

TONY HUFFERT

PENNY LANZISERA, Region I

ROB LEWIS

ANGELA R. McINTOSH, FSME

DENNIS RATHBUN, DILR

ASHLEY TULL, FSME

DUANE WHITE, FSME

RON ZELAC, Ph.D.

INDUSTRY PARTICIPANTS:

SAMUEL PUTNAM, M.D., Sirtex

RIAD SALEM, M.D., MDS Nordion

ALSO PRESENT:

TOM BURNETT, MDS Nordion

HUGH CANNON, SNM

ANN WARBICK CERONE, MDS Nordion

BRIAN ERASMUS, MDS Nordion

LYNNE FAIROBENT, AAPM

EDNA GARCIA-PENA, Walter Reed

EMILY GARDNER, ASNC

MIKE PETERS, ACR

DOUG PFEIFFER, AAPM

AMANDA POTTER, AAPM

SERGIO SANTIVIAGO, ACC

HARRY SKENE, Geisinger

GARY STAPOLKSY, Walter Reed

KEN THURSTON, Sirtex

CINDY TOMLINSON, SNM

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

(8:09 a.m.)

CHAIRMAN MALMUD: Good morning, everybody. Welcome to the second day of the session. We will get started with the first item on the agenda this morning, which belongs to Cindy Flannery.

MS. FLANNERY: Has the agenda changed?

CHAIRMAN MALMUD: Do I have the wrong agenda?

PARTICIPANT: Yes.

CHAIRMAN MALMUD: Okay. Sorry.

MS. FLANNERY: I'm sorry.

CHAIRMAN MALMUD: Okay. It's actually Mr. Delligatti, right?

MR. DELLIGATTI: Right. Good morning.

CHAIRMAN MALMUD: Rulemaking 101.

11. RULEMAKING 101

MR. DELLIGATTI: Yes. Cindy and the staff asked me to come down and spend a little time with you talking about the rulemaking process. There have been some slight changes to the process that you might not be aware of, but I think the simple fact is we are just about always doing a Part 35 rulemaking. There is either one in the works, one being done, one just being finished, and one on the books.

And, of course, in the last couple of years, we have also had several petitions for rulemaking, which depending on how they are resolved may result in further rulemaking on Part 35.

So we thought we would come down. This is actually an abbreviated version of a course that one of the members of my staff gives twice a year to the NRC staff, to anybody on the NRC staff, who wants to learn about rulemaking.

So basically those are my discussion topics: what is rulemaking; the types of rulemaking; the technical basis, which is something that we have placed increased emphasis on recently; talk about the proposed rule; the final rule; and the rulemaking time frame.

Rulemaking. It is described best as a collaborative and a deliberative process. And what we mean by that is we gather together the experts within NRC and from the agreement states when it's a rule that will affect them, from our regional offices.

And they take their time to make sure that the changes that they are making to the Code of Federal Regulations are the correct ones, are robust, and will stand the test of time and will stand any legal challenges that might come along. That is

because NRC rules impose the requirements the applicants and licensees must meet to use nuclear material to operate a nuclear facility.

And, of course, our regulations also impact the wider stakeholder community of people who must undergo medical treatment using nuclear medicine or things like that.

There are basically four types of rulemaking. The last of the four is the one that we are most interested in generally here. Administrative rulemaking, making minor corrections to the rules, a good example of that is if NRC reorganizes, one of the things that we have to do is to do an administrative rulemaking, put the right names in. If one of the NRC regional offices moves, they will have to do a rulemaking to put the new address in.

If there are minor editorial corrections necessary to a rule, it will generally be handled by an administrative rulemaking. There is one big one that the Office of Administration does each year to cover all of those things.

Direct final rulemaking is something that we can do in certain cases where we anticipate that a rule will not be controversial and where we do not anticipate getting any significant or adverse comments

on the rulemaking.

What that does, in effect, is it allows us to put both the proposed and the final rules out at the same time for public comment. If we don't receive any public comments on a direct final rule, then we are able to go final with it. And it saves us a great deal of time.

However, all it takes is one comment determined by the Office of the General Counsel to be significant and adverse. If we receive one, then we must withdraw the final rule. And we, in effect, default into our regular rulemaking process of reviewing public comments, resolving public comments, and then putting out a final rule.

Enhanced public participation rulemaking is something that is -- it depends on who you ask what exactly this one means. It's a rulemaking where we go out of our way to find new and better ways to involve the public in the rulemaking.

Where it becomes difficult is that the Administrative Procedures Act makes it very clear that public participation must be very broad and we can't treat any single public differently from any other public in the rulemaking process.

So we don't really call rules enhanced

public participation rulemakings too often. The kind of rulemaking that we generally see is the notice and comment rulemaking. That is the process by which we develop a technical basis, we develop a proposed rule, we put the proposed rule out for public comment, we get the public comments, we resolve them, and then we put out a final rule.

The initiation of the process for a notice and comment rulemaking, why did we decide to do a new rule. Sometimes the staff makes the determination. For instance, the medical staff may be collecting issues that need resolving in Part 35. Sometimes this Committee brings to the medical staff ideas that they think might need to be changed in Part 35.

Sometimes, as with the Energy Policy Act of a couple of years ago, Congress tells us specifically, "Staff, you will do a rulemaking" on a particular subject, in which case we have to initiate the rulemaking and do it. Often Congress will give us specific time frames for completing that rulemaking when it comes through legislation.

Sometimes the Commission will direct the staff to do a rule or do a rule in a particular way or to choose certain aspects of the rule that the Commission believes need our attention.

And, finally, there can be a petition for rulemaking, where a stakeholder, a member of the public, submits to the staff a request that we change our regulations.

The staff then goes through a process of resolving that petition. And if the staff determines that any of the issues raised in that petition warrant consideration in the rulemaking process, the staff will put that into the rulemaking process. And that will start with development of a technical basis.

Previously, until a few years ago, it would have started with a rulemaking plan, which was a document that the Commission had asked the staff to prepare for each new rulemaking so that the Commission had a good idea of what rulemaking was on the staff's plate.

We found that the rulemaking plan often took a lot more time than was really necessary and got to be cumbersome. And we proposed to the Commission that we replaced rulemaking plans with the development of a technical basis document, a document that will, in effect, describe what is it that you are doing, why are you doing it, what is the problem, why do you think you've got the right solution to the problem.

The Commission has sort of been generally

supportive of replacing the rulemaking plan with a technical basis in that they have delegated to the directors of NRR and the director of FSME the authority to waive rulemaking plans. Dr. Miller has, in effect, waived rulemaking plans in most cases and allows the staff to use the technical basis.

The Commission also gets better information during the budget process now as to what is on the rulemaking plate. Now, the staff admits their best plans for rulemaking to the Commission each year.

For instance, right now we are working on the F.Y. '09 and F.Y. '10 submittal to the Commission, which will tell the Commission "These are the rules we think we will be doing in the next two years" and "These are the resources we think we will expend on it."

I will get back to technical basis shortly, but after we develop a technical basis and it's accepted, then the staff -- we gather a working group. Either my branch or the other rulemaking branch will appoint a project manager, who will then ask for members of the staff to be put on a working group to develop a proposed rule.

After the proposed rule is completed, we

put it out for public comment. We will send it out to the agreement states for their review. We get all the public comments in. We resolve them. We go to the final rule. And we put the final rule out. And generally there is a period before the final rule becomes effective. And then we've got a new regulation.

Technical basis. Technical basis is very important. And it is very important for the advisory committees because of a determination made by Marty Virgilio, the Deputy Executive Director for the materials and research areas, about a year ago. And I will get to that in a moment.

The technical basis, as I said, is the document that tells why do we want to do a rulemaking. The requesting office or the requesting division has the lead to develop a technical basis.

For instance, if there is a new Part 35 rule, the branch that Cindy is in will be responsible for developing this technical basis. Technical basis has to be the foundation. If the technical basis is deficient, it always ends up making us take longer to do the rulemaking, and we have less confidence that the rulemaking will really be appropriate and we won't get 4,000 comments on it.

We have made a determination that rulemakings should not start without a complete technical basis, a robust technical basis that my organization, the Division of Intergovernmental Liaison in Rulemaking, has determined to be correct.

As I said, an adequate technical basis, the latest rulemakings just cause us all kinds of problems. A robust technical basis can make the rule more defensible in court should it come to that, as sometimes happens.

Now, about the role of the advisory committees, this was fairly significant. The various advisory committees, ACRS, the former ACNW&M, and this Committee, have always been involved in the rulemaking process and have always had a great deal of interest in the rules that are coming into the area of their concern.

About a year ago, in looking at this, the Deputy Executive Director thought that the best way that we can involve the advisory committees in the rulemaking process is for the requesting organization to get them involved during the development of the technical basis.

If we are going to change a rule, we want to know that the advisory committee, the people who

are the experts in these particular areas, agree that we need to undertake a rulemaking and agree with the process that the staff is proposing and gives the staff the benefit of their expertise at that time.

So that as the staff then goes forward and develops a proposed rule and puts that proposed rule out, we will know that we have got a rule that is supported by our advisory committees.

The concern that we did have was, would this seem to the advisory committees that we were somehow shutting them out later in the process. We hope not. As you know, there is always a public comment period on a rule. And if the advisory committee or individual members of the advisory committee have concerns with the way that the rule, the proposed rules come out is absolutely appropriate and absolutely useful to us to get those comments during the public comment period so that we can look at them along with all of the stakeholder comments that we receive and modify the rule as necessary to reflect those public comments.

When we get public comments, we have to resolve them. We either have to tell the public, the stakeholder who made the comment, why we agree or why we disagree with their comment or with the group of

comments, a similar group of comments.

We will often get, you know, 50, 100, 150. If there's a postcard campaign, we can literally get thousands of comments on a rule that are all the same or very similar. Regardless, we need to address the issues in those comments and resolve them. And that resolution is generally documented when we put out the final rule in the Federal Register notice.

As we are developing the fact of the technical basis itself, that last bullet, that refers to my group. We are not responsible. We take over the rulemaking once we accept the technical basis.

But what we tell the technical staff, the divisions, the other offices is please involve the rulemaking staff early when you are developing the technical basis. Come to us for advice. Come to us for guidance. Make sure that the technical basis you are developing is going to be something that we can accept at the end of the day because if they don't do that, what happens is they send us a technical basis, we find that it's not acceptable to start rulemaking. And then all of our schedules are delayed.

And one thing is we are under, as everybody in this organization is, a great deal of scrutiny to make sure that we are doing our job as

efficiently and effectively as we can. And that often means as timely as we can.

So if we can get a good technical basis, we can get the rulemaking done in the time that the Commission has allotted for us. And that timing I will discuss later. But for a proposed rule, from the time we get a technical basis and the working group begins preparing those documents, we have about a year.

And in that year, we have to get that rule ready. We have to get all these documents ready to go up through either the EEO or the Commission depending on who is signing out the rule.

The documents we have to prepare include a Commission paper explaining what the rule is, why we are doing it; a Federal Register notice, which, again lays out the language of the proposed rule and also tries to anticipate the questions that the public will have.

In fact, we have now gone to a format for Federal Registers which is a Q&A format. The Federal Register notice will say, "Here is the proposed language that the staff is proposing to change in the Federal Register." And then we follow that with a bunch of questions and answers about how this rule

will affect the regulated community and the wider stakeholder community.

Of course, in most cases, if there is going to be an environmental, any kind of environmental, impact, we have to prepare an environmental assessment document.

We also have to prepare a regulatory analysis. And this is a document that looks at what are the financial impacts of the new regulation, who is this going to hit, and how is it going to hit them, what is that dollar impact. And we hire and try to hire regulatory economists, who can help us with that.

And we have been very lucky for the last couple of years to have some really sharp regulatory and financial analysts working both in FSME and in NRR to help us make sure that these analyses are strong and robust.

We have to prepare a separate Office of Management and Budget package when an OMB clearance is needed. In cabinet agencies, the OMB has a real strong role in approving and denying a rulemaking and is really much more involved than they are in our rulemakings as an independent federal agency, but they still need to review and clear our rules. So we have to prepare a package that gets down to them.

If a rule is going to affect the agreement states, we try to get an agreement state member on the rulemaking team so that they can be involved. And we send the rule out, as I said, for the agreement state to review and to make sure that they are prepared for what is coming their way if the rulemaking particularly is one that they are going to have to change their regulations to look like ours.

Once we have completed the proposed rule, once it has gone up to the EEO, the Commission, we send it out for public comment. The Administrative Procedures Act, which is the basis for all rules and activities of the federal government, requires that we have a public comment period on the proposed rules. Proposed rules contain specific requests for public comment on the major issues.

What we will do is we will say, in particular, public, when you are looking at this rule, please let us know what you think about this provision or that provision, where we anticipate a particular provision is bringing in, for instance, a new regulatory requirement that vastly changes something that the regulated community and the stakeholders are used to.

Rule documents for public comment are

placed on the federal e-rulemaking Web site. And this is something new. This http://www.regulations.gov is a government-wide system. We used to put our rules on our Web site. Everybody put their rules on their own Web sites. Well, this is something that is happening more and more in the federal government is there is a standardization. Everybody uses the same resource.

And they believe that this will be in the long term more effective, more efficient, and probably allow I think -- and this is just my own opinion -- the best software to be put in place more quickly if there is one system, rather than having, you know, 30 or 40 federal agencies all trying to put their own software packages together.

When you comment on proposed rules, we try to make this as easy as we can for anybody who wants to comment on a rule. We will accept the comments via standard U.S. mail or snail mail, I guess, as it's called now; e-mail; fax; or through the e-rulemaking site.

Copies of the comment letters can be obtained on the federal e-rulemaking Web site. So you can go into this Web site and see what the other comments are.

In some cases, what we will do is we will

go out and we'll hold public listening sessions where stakeholders can provide comments to us verbally. This is sometimes useful. Sometimes it's not.

What we have to do is when we go out and do that, we really have to get a court reporter in there. We've got to transcribe the session. But we can't enter into a debate with the public during that period because that would give any particular public, the three or four places that we chose to go for these sessions, they would be having more opportunity for commenting, for interacting with us than everybody else would if we were allowed to get into a give and take with them.

So when we go out for these public listening sessions, what we can basically do is give an overview of the rule, which has to stay within the confines of what is said in the Federal Register notice. And then we can just sit there and listen to the comments.

On a very controversial issue, on an issue where there is a great deal of public concern or anger or passion, sometimes this is useful because sometimes we get a better idea of where the stakeholders are coming from when we go out there.

It also tends to be very frustrating for

the stakeholders if they don't understand or realize that we can't respond to them. They can't ask me a question about "Why are you changing that particular provision when I think you shouldn't? Here are my reasons for your not changing it. Give me your reasons for changing it." We can't enter into that kind of dialogue during the public comment period. So I kind of feel those sessions are really best held for very, very limited occasions.

After we have got the public comments in, maximum public comment period is usually 75 days. Then, as I said earlier, we have to review and resolve the public comments. Be very clear on that. And then we have to develop a final rule.

The Federal Register notice for a final rule contains the final rule language. If it involves the agreement states, they have a 30-day comment period. The final rule is then approved by the EEO or Commission. And this also takes about a year, as does a proposed rule.

There's always a lot of questions about how long does rulemaking take. And it's usually in terms of why does it take so long to do a rulemaking. Particularly we will hear a lot from anybody who is working on the Hill. They will tell us, "You know, we

wrote that act. It's 800 pages long. And we took a one-night session and wrote that act. How come it takes you two years to develop a new regulation?"

Well, it takes that long because we want to make sure that we are doing it right. As I said earlier, when we do a technical basis, that could take anywhere from a few months to a year to complete a technical basis before we even get started on the rulemaking. And then it takes us about a year to do the proposed rule, a year to do a final rule.

Again, as I said in one of my earlier slides, it is meant to be a collaborative and deliberative process. We are impacting stakeholders. We are impacting people's real lives. We want to take the time we need to do it right.

When we get a lot of public comments, it can taken up to six months to develop the proposed rule and supporting documents. This is followed by a lengthy concurrence process, including several weeks for the agreement states.

When I say it's a lengthy concurrence process, again, everybody in the NRC from the staff that works for me all the way up to the commissioners and their staffs takes very seriously this responsibility of adding or deleting or changing

federal regulations and regulatory requirements.

So each step up the process, the managers and the commissioners want to have enough time to review these documents. And these are very lengthy documents. You probably have seen some of the Part 35 rulemakings. These can be hundreds and hundreds of pages. So it takes time.

And each step up, if anybody has a significant concern or comment, it has to come back down. We have to resolve that comment before we go up the next step.

So, you know, if it takes us six months to develop the rules, believe it or not, it can take us another six months to get through that process and get the rulemaking approved.

That's just the way it is. Sometimes they go quicker. Sometimes they go longer. If it's a really big rule and it hits the Commission at a time when the Commission has a lot going on, the Commission sometimes just in order to get it onto their docket and get it reviewed can take months to review a rulemaking.

Again, there are just anywhere up to five people, sometimes three people, sometimes four people with a lot to do. And if it's a big rule, it's

important to them, they're going to take all the time that they need to take to make sure that they are happy with this rulemaking before it goes out.

Finally, before our rules can go final, the Office of Management and Budget must clear many of our regulations, make sure that they don't have any problems with them.

As I said, it takes up to a year to develop a final rule. This is very dependent on the number of public comments received.

We have literally received thousands of comments on some rulemakings. Again, often this involves postcard campaigns, advocacy groups trying to get their opinion in, but we still have to go through each one of those comments, bin them, make sure that every issue is resolved. And this can take a lot of time from the staff.

As a result of the public comments, the staff may have to do additional analysis or research. And sometimes this can be a very lengthy process going out, going to the Office of Research to get assistance on issues. And so this can extend the time frame until we get to the final rule.

So why does it take so long? As I said, as a collaborative, deliberative process, agreement

state and public comment periods have to be adhered to. Staff has to resolve the public comments that we get in. And the Commission takes very seriously its role in review and approval of the new regulations. So it takes as long as it takes for a good reason.

Again, I want to say that the important thing is commenting on proposed rules, this Web site, www.regulations.gov, if you're interested in commenting on any federal reg, this is where you want to go. And, again, we will have public listening sessions sometimes but not always.

In the back of this presentation, I'm not going to go into these, but for your information, I have included the key documents on federal regulations. These are the acts, the procedural requirements, what the Atomic Energy Act says, what the Administrative Procedures Act says.

And then, as we tend to do as bureaucrats, we use lots and lots of acronyms. And I have given you a list of some of our favorites and some of the ones that you will most likely see in the rulemaking process.

So that is my presentation. I would be happy to answer any questions you might have.

CHAIRMAN MALMUD: Thank you, Mr.

Delligatti. That is a pretty clear and thorough description of the process, explains a lot of questions which have been asked in the past.

Are there any comments? Dr. Vetter?

MEMBER VETTER: Not a comment but a couple of questions, if I may.

CHAIRMAN MALMUD: Please?

MEMBER VETTER: You explained the technical basis for rulemaking. Is there a technical basis for orders?

MR. DELLIGATTI: Not in the same way. I would say that the way that an order is developed is generally the reason that it is an order and not a rule is that it is something that needs to be done quickly.

What you saw, for instance, with the security rules after 9/11, there were immediate issues that needed to be resolved. And what the Chairman at the time, Chairman Diaz, said as well as the General Counsel was, "We will come back and we will do the rules. We do not regulate by order. We will come back. And we will take these orders, and we will put them through the rulemaking process."

And that is actually what we are doing today. We're taking those orders and modifying them

as appropriate to represent what is going on today. And now they are going through that whole process, and there does have to be a technical basis to begin that rulemaking process.

MEMBER VETTER: But you said that you do not regulate by order?

MR. DELLIGATTI: Not long-term, only as an emergency issue, an emergency measure. You do an order because you have an immediate issue that needs to be resolved. The long-term response is to take the requirements in those orders if they are still appropriate, to put them into a rule.

MEMBER VETTER: So there is no financial impact analysis done prior to an order?

MR. DELLIGATTI: I believe not. It depends on how much time they are and how serious the issue is. I would say at the time after 9/11, the concerns were other than financial that were primarily on people's minds.

MEMBER VETTER: May I ask one more?

CHAIRMAN MALMUD: Please?

MEMBER VETTER: Getting back to rulemaking now, where along the way does ACMUI have an opportunity to input?

MR. DELLIGATTI: The best time is during

the development of the technical basis. Where what we would anticipate -- and Robin and Cindy can certainly correct me on this -- is getting your input before we even start down the road to rulemaking to make sure that the topics that we are proposing to put into the next Part 35 rule are considered then and there. That is the best time.

As I said, that is when upper management has said, "Go to your experts before you start. Make sure they support this effort. And make sure you know what their issues and concerns are."

And then, again, as I said, during the public comment period, of course, your comments are, individually or as a group, anticipated and welcome.

MEMBER VETTER: Good luck during the pre-decisional. We get a pre-decisional just before it gets published.

MR. DELLIGATTI: Just before it gets published, we send you a "for your information" copy of what we are proposing to put out. At that point in the process, again, because of the timing issues and the efficiency and effectiveness issues, we are not looking for comments then because a month or two later, it is going to be out for comments and we are going to be getting all of the comments in. We would

have to stop the process then and expand it greatly if we were to have a separate administrative committee period of comment then.

And that was one of the things that the Deputy Executive Director was trying to resolve. That was an area where get them in early, get them involved early, and listen to them is the other half of that. And so the proposed rule that comes out should reflect your concerns and interest.

MEMBER VETTER: Yesterday we had an issue come up that was based on a pre-decisional, you know, information notice that we got.

MR. DELLIGATTI: Right.

MEMBER VETTER: And I'm just wondering. Do we really have an opportunity to comment on that?

MR. DELLIGATTI: Only during the public comment period. Again, that is sent to you for your information, not seeking comment from you. But it is to give you an earlier opportunity. "Because you are valued members of the NRC staff, here is what is going out for public comment. Get ready for it and have some extra time, in effect."

CHAIRMAN MALMUD: Dr. Suleiman I think was next.

MEMBER SULEIMAN: I'm with FDA. And it's

interesting we have the same federal government, but the rules are a little bit different.

We do on occasion come out with an interim final rule, which is effective immediately, only because Congress doesn't always spell out. They say, "You shall do this."

MR. DELLIGATTI: Right.

MEMBER SULEIMAN: When the lawyers look at it and we look at it, it takes a while to interpret. And then you go through that whole -- that takes effect immediately until you come up with a final rule.

MR. DELLIGATTI: We are allowed to do those. Our Office of General Counsel generally believes that's not the best way to go. But if we need it, for example, if the kind of thing you're talking about comes up, we can do an immediately effective rule. And it sort of puts the rule first and the process afterwards.

MEMBER SULEIMAN: It's done very rarely.

MR. DELLIGATTI: Yes.

MEMBER SULEIMAN: The other thing is we are not an independent regulatory agency. And our OMB process sometimes adds an extremely longer element of review. And it has been frustrating.

The other thing we do -- and I haven't figured out the NRC analog -- is we will come out with guidance. Up until a few years ago, we were challenged. And we basically were told that you can't determine policy without public comment.

So our guidance policy is very analogous to the rulemaking except that guidance isn't binding on anybody, but at least it puts down our thinking. But we go through the same proposed rulemaking.

And how I explain it to my colleagues is the proposed rule -- the comment period allows everybody to participate. But once the period is closed, it's like a trial by jury. The jury convenes. And then it's up to the staff to sort of take all the --

MR. DELLIGATTI: That's a very good analogy.

MEMBER SULEIMAN: And at that point, we don't take any more input from anybody, be it the advisory -- everybody has had a chance to input. But once the period is closed, then we take all the information and try to come up with a decision.

MR. DELLIGATTI: Very good analogy. Absolutely.

CHAIRMAN MALMUD: Dr. Nag?

MEMBER NAG: You had mentioned that the rulemaking period, first you got the input of the ACMUI; for example, for the technical basis. Now, once that input is there, do you then go back to the ACMUI and say, "Is this what you meant?" because some of these are really complicated.

It's not, you know, yes or no. It's really complicated, requires a lot of interpretation and so forth. Do you then go back and say, "Is this what was meant?" or does it go on from there and then the only opportunity you have is during the public comment period?

MR. DELLIGATTI: Well, I would hope that during the interaction on the technical basis, we got a fairly clear indication from you of what you meant. And I would think that if the technical staff -- for instance, this would involve the medical group coming to ACMUI and discussing the proposed rule.

I would think that if they were confused, they would come back to you as they were developing the technical basis and ask you a particular question on it. But if they think they understand you, they probably wouldn't necessarily think that there was a reason to come back and talk to you. That is what makes that kind of a difficult issue.

Cindy, is that sort of the way you guys have been doing it?

MEMBER NAG: What I have seen is they get the input before the development process, which is what is required. But then after that, there is no further interaction until we see either a pre-decisional or the actual rule. So that is the way we give the opinion. But then, finally, we only hear about it during the final rulemaking time.

CHAIRMAN MALMUD: Mr. Lieto?

MEMBER LIETO: Yes. I have a few questions. The snail mail faxes comments that come in. Are those scanned into the electronic Web site so that you would be able to see those or however it's done?

MR. DELLIGATTI: Yes.

MEMBER LIETO: Okay. And how long is the comment period? In other words, when you have a comment period, is it the rulemaking group that says, "Yes. We think 60 days" or "45 days" or "90 days"? How is that determined?

MR. DELLIGATTI: Merri, what do you think about that? This is Merri Horn of my staff. She's a senior, probably our most experienced rule maker and the woman who keeps me honest in all such things. So

I will turn to her.

MS. HORN: Basically we typically use a 75-day comment period. The Free Trade Act with Canada and the others requires that. There is a provision that if it is anything that could impact Canada or Mexico, we have to do a 75-day comment period. It's kind of by default that's what we use.

There are exceptions. The direct final rules, we have I think it's a 45-day comment period. But then the rule doesn't become effective for a little bit longer.

We can use less in some circumstances, and we can always use more. So occasionally we may go out and say, "This is a really complex issue. Maybe we'll give you 90 days." But the typical standard is 75 days.

MR. DELLIGATTI: Thanks, Merri.

MEMBER LIETO: I have a couple of more questions. The format when the rule, proposed rule, comes out always tends to generate a lot of angst with this Committee because you sort of had this format, quote, dot dot dot, the language, dot dot dot, and you're trying to plug that into the current rule.

Has there been any consideration of sort of the strikeout/underline type of a format of

displaying what the rule is to show in its actual context that --

MR. DELLIGATTI: I was going to just say because the support group here, Angela, Cindy, and Ashley, seem to be very good about trying to put things together like that for this Committee.

It seems like it would be a -- for someone who is looking at the rule, the proposed rule, for the first time, it would be nice if there were either some location on a Web site that they could look at this in that type of context.

MEMBER LIETO: From the rulemaking.

MR. DELLIGATTI: We are really constrained by what the Federal Register requires on how the rule needs to look in order to be published in the Federal Register. So that's not something that we could change in the Federal Register notice.

But it's an interesting point. It's something I think we can talk about. You know, I don't know where it might go, but I can understand where that would be confusing to someone who is not immersed in this all of their lives.

MR. LEWIS: In the Federal Register notice, we do have a section by section analysis that describes in great detail exactly every change in

every single word.

MEMBER LIETO: And that's very helpful, but sort of I guess it is a corollary to what Dr. Nag was saying that when you actually see how in the actual language how it is going to be interpreted by the affected community or stakeholder and it may come out a little bit different to have an interpretation that may not have been intended when the rule was written.

We just find that very, very helpful in that type of a format if that were some type of standard location or a way of having that -- I guess we'll call it that strikeout bold type thing that would indicate the addition changes and so forth.

A follow-up question to what Dr. Vetter asked. You said that rules always follow orders.

MR. DELLIGATTI: That is certainly the model we try to follow.

MEMBER LIETO: Is there a limit on how long orders are in effect --

MR. DELLIGATTI: Yes.

MEMBER LIETO: -- before the rules have to come into place?

MR. DELLIGATTI: Security orders. Rules always follow security orders. And I should have been

more specific on that, yes.

MR. LEWIS: For example, we can order an individual licensee to shut down. We wouldn't make a rulemaking.

MEMBER LIETO: Okay. But, I mean, those that --

MR. DELLIGATTI: Where you're making a change to the way a particular group of licensees has to operate.

MEMBER LIETO: Is there a time limit on how long those orders are in effect or is it basically up to the Commission?

MR. LEWIS: The orders that we issued modified the license. So as long as the license exists, that order is no condition on that license. In a future rulemaking, we could put them into the regulations for future licensees.

But presumably the conditions that went into the original license could still exist, even after the rule.

CHAIRMAN MALMUD: Does that answer your question?

MEMBER LIETO: I've got one last one.

CHAIRMAN MALMUD: One? All right.

MEMBER LIETO: You mentioned that you are

currently working on proposed rules.

MR. DELLIGATTI: Yes.

MEMBER LIETO: When is the next group of Part 35 proposed rulemaking on your docket for --

MR. DELLIGATTI: We have one in process. And, as you know, you can't be working on a reg -- you can't have two rulemakings going on at once in one part of the regulation.

So we have got one now that's in process that I would say is getting close to going out for public comment. And as soon as that rule is completed, we have another larger Part 35 rule that we would anticipate undertaking.

MEMBER LIETO: Any time frame when that larger one is being -- is that in your '09-2010?

MR. DELLIGATTI: It would depend. It would really depend on when the current rule that is being developed right now by the staff is completed. But I believe it would be beginning, certainly beginning, in the '09-'10 time frame.

MEMBER LIETO: Thank you.

CHAIRMAN MALMUD: Dr. Howe?

DR. HOWE: This is just a follow-up on one of Ralph's questions. And that is about redline strikeout. One of the logical next steps would be to

say why not put it on the Web site.

And what we found with a revision to volume 9 and volumes 13 and the addition of 21 is that the Federal Act on American Disabilities prohibits us from putting things on the Web site that are difficult to read, like redline/strikeout, or highlighting text that is different.

So that is one reason you don't for the most part see those things on the Web site. That's just a follow-up.

CHAIRMAN MALMUD: Thank you for clarifying that, Dr. Howe.

Dr. Nag?

MEMBER NAG: You have the NRC rulemaking. And then you have the state. Does the state have a similar rulemaking or do they automatically adopt? What is the difference between the two rulemakings?

MR. DELLIGATTI: It depends on what level of compatibility there is with the rules. There are some rules that have to be adapted exactly, some rules that can be adapted so there is a similar result.

And as you go through the Federal Register notice, you will see a part on compatibility. And that will tell you exactly what those levels are.

CHAIRMAN MALMUD: Debbie Gilley?

MEMBER GILLEY: I have two questions. Do you do a technical basis for orders?

MR. DELLIGATTI: We don't do, my group doesn't do, orders. So I can't really speak to that. That is really dependent upon the individual organization within NRC that is doing the orders. How much time they have, how urgent the issue is as to what the basis is for doing that order, I would say it would be very dependent on the particular issue and whether it's answer the security office in NMSS for materials facilities, NRR/NRO for reactors.

MEMBER GILLEY: Okay. The second question I have, in your interim final rule process, is there a time for public comment?

MR. DELLIGATTI: In the --

MEMBER GILLEY: Interim final rule.

MR. DELLIGATTI: In the interim final rule. The direct final?

MEMBER GILLEY: Yes.

MR. DELLIGATTI: In the direct final rule, yes, we put the rule out for public comment. And that is what determines whether or not we can actually take the savings of time. What that process does is if we don't get public comments, we put it out for X number of days.

If we don't get a single significant or adverse comment, then that rule can become effective. And we don't have to go back and revise it because the public has indicated, the stakeholders have indicated by their silence that they don't have any concerns with it.

So there is a public comment period. But if we get that one significant or adverse comment, then we pull back that final rule. We have to resolve that. And any other comments we receive, basically it becomes a regular notice and comment rulemaking.

CHAIRMAN MALMUD: Thank you, Mr. Delligatti.

MR. DELLIGATTI: Thank you.

CHAIRMAN MALMUD: Oh, excuse me. Bob Lewis?

MR. LEWIS: Just quickly. I think Ms. Gilley's question and some of the other questions may leave a false impression that the security orders that were developed and issued did not have a thorough investigation of the issues associated with those orders.

And that would be an unfair representation of what actually happened. The security orders were developed in consideration of security vulnerability

assessments that were done in consideration of threat information that existed.

And very detailed Commission papers and attachments were developed and sent up to the Commission. And I would go so far as to say they included almost all of the information that would have been in a technical basis for a rulemaking.

They did not include a regulatory analysis in all of the financial pros and cons, which would necessarily have to follow in the rulemaking that would codify those orders. But those orders were very thoroughly vetted throughout.

CHAIRMAN MALMUD: Thank you for clarifying that for the record. Dr. Vetter?

MEMBER VETTER: Would that information be available to us to review?

MR. LEWIS: The information that is on the public record would be available. The information that is protected for security reasons I'm not sure, but we could check on that.

CHAIRMAN MALMUD: Thank you.

Go ahead and move on. The next item on the agenda is the Y-90 microsphere guidance. And that is going to be discussed by Ashley Tull, Sam Putnam, and R. Salem. I think the introduction will be done

by Ashley. Thank you.

12. Y-90 MICROSPHERE GUIDANCE

MS. TULL: I have several handouts to give you, and there are plenty of handouts for members of the public as well in the back. This is my presentation. It's the one page that is coming around. It's the guidance, the same guidance, that is in your book, but I had changed the font and a little bit of formatting.

So the pages are going to be different. When I start talking about page 2, line 2, this is going to match my presentation. So tear out what's in your binder for the microspheres guidance.

You already have the presentation from Sirtex in your binders. This one is the one from MDS Nordion, and it's two pages.

CHAIRMAN MALMUD: Are you ready to start with the issue?

MS. TULL: Sure thing.

CHAIRMAN MALMUD: Thank you.

MS. TULL: Okay. So for today, I am going to give a presentation. I am going to present an issue on new AUs and new facilities. We're having problems getting new AUs and new facilities started. I am going to propose a solution as well. And after I

do that, I will have the manufacturers talk about how they could meet that new proposed route.

So that is what I will do: introduce both of the manufacturers. We will have a discussion on the new AU facility issue. And then I have two additional changes that are in the guidance. And then we will discuss the nine issues that were incorporated from last year. And hopefully we get all of that done in about an hour and a half.

And then the same path forward. As soon as we are out of here, I will try to revise the guidance quickly, send it to the Office of General Counsel to get a "no legal objection." And then we will publish the guidance on the Web again. And it will be effective.

The issue that we're dealing with, we have had several calls from RSOs, medical physicists, manufacturers. I would say on a weekly basis I get one to two phone calls at a minimum.

The issue is that there is no pathway for physicians to become an authorized user for yttrium-90 microspheres at a specific medical use licensee facility that is not currently licensed to Y-90. So we are not talking broad scopes here.

So you have a new facility. They don't

have Y-90 on their license. And they want to have an AU. As the guidance is currently written, a physician cannot be named as an AU on the license until they have completed the three cases, work experience. That was an ACMUI recommendation. It's been incorporated. That's how the guidance reads.

Problem is the physician is not able to complete those three cases at their facility because the facility is not licensed for Y-90. They can't order it. They can't use it.

The physician is not able to complete three cases of work experience at another facility because they can't practice medicine at another facility. This leads us to a facility cannot be licensed for Y-90 until an AU is named on the license. Now we go back up to the top. You see, we are going in a circle here.

So I have tried to spell it out. Are there any questions on the issue that we are trying to address here? This has been very confusing and months and months of discussion. So I've tried to simplify it. Dr. Fisher?

MEMBER FISHER: Darrell Fisher.

A question has come up in my experience in the last week from an outside institution whether or

not the same issue also applies to yttrium-90 Zevalin.

MS. TULL: I haven't worked on anything with that. I worked specifically on the microspheres. But Donna-Beth?

DR. HOWE: Dr. Howe.

Zevalin is a 35.300 product. And if you have a physician that's authorized for 35.300, then they can use Zevalin. We do not distinguish in the 35.300 area what the specific drug is.

Now, the licensee may have to add the isotope that is bound to the Zevalin, but that is covered under 35.300.

MEMBER FISHER: Thank you.

MS. TULL: So, for clarification, the microspheres are under 35.1000. Any other questions?

(No response.)

MS. TULL: Okay. So now, the proposed solution is two pathways. The same pathway as before would read, "The yttrium-90 microsphere-specific training and experience requirements may be satisfied by satisfactory completion of a training program provided by" -- originally this is what it said -- "an AU who is authorized for the type of microspheres for which an individual is seeking authorization. Training should include at least three supervised work

experience cases for each type of Y-90 microsphere for which the individual is seeking AU status." That is what we are going to call the AU pathway.

The second pathway that we are proposing is that the satisfactory completion of a training program may be provided by a Y-90 microsphere manufacturer. The training should include at least three supervised *in vitro* simulation cases for each type of Y-90 microspheres for which the individual is seeking AU status. The *in vitro* simulation cases should demonstrate issues that are encountered during Y-90 microsphere administration procedures.

Questions on that? I'm seeing lots of puzzled looks.

CHAIRMAN MALMUD: Well, as Chairman, I will ask the question. What is an *in vitro* simulation in this case?

MS. TULL: That's what I'm going to have the manufacturers talk about specifically. I know what NRC's idea of it was, but there are several interpretations. And so we want all of those to be presented to the Committee.

The idea is that you don't have to be an AU to handle material that's not hot. So if we do *in vitro* simulated cases, we're dealing with cold

microspheres.

It could be a kit. You know, they have, just for an example, kits that they can put together. They're not hot. Put the whole kit together and run through the whole thing, talk about the issues that would be encountered. I'm going to let them go through that in detail, but that is sort of the gist of where we were going.

And this could be done at the licensee's facility. This can be done at a manufacturer's training facility. It doesn't matter where it is because you don't need to be licensed for Y-90.

This doesn't stop the manufacturers from coming to the licensee's facilities and doing the three proctored cases. We're not being that prescriptive in saying that still has to be done, but they have basically both indicated that they would still continue to do that. They would be there for those first three cases.

Mr. Lieto?

CHAIRMAN MALMUD: Thank you.

Mr. Lieto?

MEMBER LIETO: Two questions. Then this "*in vitro* simulation," both the NRC and the manufacturers are both indicating that this is

nonradioactive cases?

MS. TULL: Correct.

MEMBER LIETO: And my second question was, this suggestion here in number 2 of the proposed solution, so we're not going to act on this until after the vendor presents or are we supposed to discuss this now and --

MS. TULL: I think I would like to let them make their cases and kind of see more in depth about their training programs and how they could incorporate this simulated cases idea.

We were really stuck last December. We started getting phone calls saying, "We can't open facilities." This is a problem. This is a major problem.

We talked with the regions, you know, other NRC staff, both manufacturers. This has been a very open dialogue. And this is kind of what we came to as an out-of-the-box how do we solve this problem of getting new facilities and new AUs.

CHAIRMAN MALMUD: Thank you for the introduction.

MS. TULL: All right. So now the purpose of the manufacturer presentations, like I said, is to describe what they can offer in their training

programs to meet the simulated cases pathway.

First we are going to have Dr. Samuel Putnam from Sirtex. He's the Medical Director for Sirtex's operations in the United States. Sirtex is a manufacturer of SIR-Spheres' yttrium-90 microspheres.

Dr. Putnam joined Sirtex in 2007, after nearly a decade as a practicing interventional radiologist at Fox Chase Cancer Center in Philadelphia, where he helped develop the center's SIR-Spheres program.

Dr. Putnam is Board-certified in diagnostic radiology, with a certificate of added qualification in vascular and interventional radiology.

Please welcome Dr. Sam Putnam.

DR. PUTNAM: Thank you, Ashley. Thank you, Dr. Malmud, for having me here, and members of the Committee.

I will take you through our current training program and also how we can incorporate some revised techniques to hopefully meet the demands of obtaining authorized user status for the new sites.

Now, I'm representing Sirtex radioactive microspheres. And, as you remember from previous discussions, these are the resin microspheres, not the

glass microspheres. So they are different properties for both. We understand the different training requirements for both.

Dr. Salem will discuss TheraSpheres. And thank you for scheduling me before Dr. Salem because he is always a tough act to follow.

(Laughter.)

DR. PUTNAM: Though the way this works currently and how we can incorporate this into future regulations hopefully, a new site will contact SMI. SMI is Sirtex Medical, Incorporated, which is the U.S. subsidiary of Sirtex Limited, which is the Australian company, the father company. And we are the distribution company for the United States, SMI.

A regional sales manager or a senior account manager then gets involved. And we will do a site visit. We will talk to all interested parties, be it the interventional radiologist, radiation oncologist, physicist, anyone who expressed an interest in having this treatment on site.

At that time we will confirm any regulatory and licensing requirements, he will, he or she, actually, will, tour and confirm that the physical and personnel ability to start a SIR-Spheres program are in place at that institution and then

would initiate the training. And this starts.

I send out a letter to all the sites explaining our training program, which is similar to these slides here, actually. We supply a training manual, which is also the users' manual. And then the regional sales manager or senior account manager will schedule and perform on-site in-service with the interested users, usually an interventional radiologist or two, authorized user, often either nuclear medicine or radiation oncology.

Nuclear medicine staff is pretty much always involved because of the hot lab use. IR staff as well become familiar with the product and, of course, a radiation safety officer and a physicist at the institution.

The initial in-service includes didactic presentation. The sales managers and account managers all have a slide deck, where they go through the patient selection process, dosimetry issues, and then radiation safety issues, use of the devices; and then hands-on training, which we have been doing with basically setting up the delivery device, explaining and going through how to actually draw out the doses.

We are not a unit dose-delivered product. As you know, we ship it in a dose vial, which then

has to be transferred into the actual delivery vial, a little different than TheraSpheres.

We go through the cold delivery set, hooking up everything. We have a checklist that we go through with abort points. And these with the new guidance or hopefully new regulations, we would have the on-site authorized user set up and practice delivery three times with the abort points demonstrated.

And Ken Thurston and I came down last week. We met with Ashley and others, gave a demonstration, and talked about how we could actually simulate those abort points.

So as we go through the checklist for the actual delivery, which in this case we feel is really the crux of the use of SIR-Spheres, it is as much a radiation procedure as it is an embolization procedure. So we have to be very careful with our delivery and teach all of the potential abort points, I would say, possible malfunctions.

So, to go through the checklist, the first thing would be to check required inventory for the angiography suite, make sure we have signs on the doors, tacky paper on the floor, double booties for all the staff, RSO procedures. And we would prepare

the site under those guidelines.

SIR-Spheres delivery setup is essentially those in the hot lab, as I mentioned, where they draw out the prescribed dose, transfer to the delivery vial. This would be a potential abort point if there is a large leak contamination, so much so that you don't feel it's safe to actually leave the hot lab with loose spheres.

Priming involves priming the delivery set. We would have the prospective authorized users go through that themselves, prime it at least three times, clear all the air out of the system, understand how it works, the stopcocks, and very clear on the use of the delivery set.

So after we would connect everything before we actually deliver the spheres, we check the system again. This would be a potential abort point. Check for any leaks in the system, the stopcocks, which can happen at any connections, either catheter to needle or catheter-to-catheter connection going into the patient.

So at this point we would be completely hooked up. We can simulate that in an *in vitro* environment and also simulate increased back pressure so that we could identify abort points and actually

show what could potentially happen and would force you to at least stop the procedure temporarily, if not entirely.

And then we could simulate -- and we do, actually -- the actual SIR-Spheres infusion. And potential abort points would again involve either leakage from the stopcocks, leakage from the catheter-catheter connection, rising meniscus within the delivery vial, which is a sign of increased outflow pressure, which usually means either there's a kinked catheter or there is blood in the catheter, it's clogged, too many spheres, and how to assess that, how to respond to it, how to treat the problem. We could certainly do that in an *in vitro* environment.

And then post-procedure checklist, we would go through, check personnel for any contamination before leaving the angiography suite, check the suite itself, and then measure post-dose for any residual. And that's how we actually calculate the final delivered dose.

So, going through all of this *in vitro* with a didactic portion covering dosimetry, patient selection, use of the devices, and *in vitro* administration, we would hope that that would be

enough to at least credential a site to the authorized users.

We don't stop there with our training. We don't stop at all. In fact, after that, a patient would get scheduled. At that point, one of our Sirtex authorized proctors -- we have 12 of them -- would be assigned to review the case and be scheduled to be there for the administration.

So they would discuss with the authorized user the IR before actually going on site and coaching, if you will, for that case, be familiar with the patient that is going to be treated, discuss dosimetry issues.

It is a very simple calculation, actually, for us to calculate the dosimetry based on BSA method, but there are other factors that need to be discussed because of the embolization issues of SIR-Spheres.

We are injecting on average about 40 million spheres. So we really want to look at the arteriogram, look at vascular capacity, look at the enhancement characteristics of the tumors.

So there is more that goes beyond the radiation issues but also the embolization issues that need to be discussed. And that's why we would absolutely continue with the three proctored cases to

help the new users understand and be able to deal with these issues.

So we have progressed to the on-site training, a proctor, M.D. proctor. Eleven out of 12 of them are interventional radiologists. Half of those, I think six of those, are AUs. And then we have one radiation oncologist who is an authorized user proctor, would be there for the actual case delivery, coach, if you will, as they go through it.

And then after three completed cases, the way we have been doing it is I send a letter to the interventional radiologist essentially, certifying his training in the three proctored cases.

And, again, the BSA method for dosimetry we utilize based on many things, but one is the REBOC meeting in 2006 that I think Dr. Nag was one of the chairmen of.

And that's all I have for a presentation. Hopefully that would meet our requirements.

CHAIRMAN MALMUD: Dr. Vetter?

MEMBER VETTER: Thank you for an excellent and succinct presentation. Considering the range of complications that can occur in these cases, based on your experience, do you consider three cases adequate to train a physician to be able to react to that range

of cases?

DR. PUTNAM: Three cases minimum. We say minimum. It may be more than that. I mean, it's really up to the proctor and for me to really assess the particular physician, the setup, the facility, the whole delivery program, whether we do feel that after three cases they are ready to go.

Now, remember, these interventional radiologists need to be highly qualified. They have a lot of embolization experience under their belt. They have done chemo embolizations. They are very experienced in international oncology. Otherwise they wouldn't really be interested in doing this procedure.

So we are hoping after three cases -- and it's up to us to assess that -- that they are ready to fly on their own. And we do get a lot of calls after that third case and do help people continue on after three cases. And if they want another proctor, we will freely provide that.

MEMBER VETTER: But we have established the minimum as three. In your opinion, is that adequate?

DR. PUTNAM: Well, I think three *in vitro* for the AU side of it, the radiation side of it, I think absolutely. We can demonstrate the abort

points, possible malfunctions, go through the basic issues, and get an authorized user on site.

As far as the delivery because with our product, the embolization issues, we would continue on with more training.

CHAIRMAN MALMUD: Question, Mr. Lieto?

MEMBER LIETO: Two questions. So what I gather is that you would recommend at least three of the *in vitro* plus three minimum of actual patient administrations?

DR. PUTNAM: Well, that's our product. I'm not talking about TheraSpheres. I think with our product, that is what we will continue doing but not for the AU issues, really just for the delivery issues.

CHAIRMAN MALMUD: Second question?

MEMBER LIETO: Second question. Could you clarify because on your last slide there on new site initial training, it seems to indicate that what you are saying is that the AU is the interventional radiologist.

DR. PUTNAM: No, no. I wish I could say that, but I'm not. IRAU means either IR or AU.

MEMBER LIETO: Okay. Well, I guess what I am trying to understand is you state that you would

send a letter of demonstrated training and experience to the IR, the interventional radiologist.

DR. PUTNAM: That's what we've been doing, yes.

MEMBER LIETO: Well, the NRC licensed the AU, --

DR. PUTNAM: Right.

MEMBER LIETO: -- the authorized user. So I'm a little confused. Where is the AU's demonstration of training and experience in this presentation?

DR. PUTNAM: Whenever requested, we have sent that letter for the AU as well. And we could easily do that after our *in vitro* training, send a letter to the authorized user who was present for that training.

MEMBER LIETO: It's the NRC licenses the AU. Okay?

DR. PUTNAM: I understand.

MEMBER LIETO: So there is still a disconnect here. Am I missing something?

MS. TULL: All right. Let me clarify. This brings up a whole other issue about who was actually performing these procedures. In the agreement states, it's very different than NRC states.

And we are getting lots of mixed stories.

But basically it's the interventional radiologists that are interested in this procedure. They are the ones seeking authorization for it. They are jumping through hoops to get AU status.

It's a completely separate issue that I would kind of like to not address at this -- just to clarify, the three proctored cases are completely separate from the cases that we are talking about.

DR. PUTNAM: Right, yes.

MS. TULL: NRC does not want to be prescriptive and say what the manufacturers have to go do at the site for those initial cases. That's in the manufacturer's best interest to have their product appropriately used, and they are going to continue to do that.

What we are really trying to focus on is the piece where how you get a person who is AU-eligible. The RSO can send in that application and say, can we please have a license amendment for the persons we named on the license for this material.

I figured this was going to get muddied. I understand your point, though.

CHAIRMAN MALMUD: Sam, it might be helpful if you explain to the group as a whole how this works

clinically in its entirety. For example, what is the nature of the disease of the patient?

DR. PUTNAM: Okay. While we're --

CHAIRMAN MALMUD: I'll ask a series of questions that might clarify.

DR. PUTNAM: Okay.

CHAIRMAN MALMUD: What is the patient's disease?

DR. PUTNAM: Right. We're FDA-approved for treatment of colorectal metastasis to the liver.

CHAIRMAN MALMUD: Very good.

DR. PUTNAM: So that is generally what we see. There are other disease processes that people treat, but it's generally metastatic disease throughout the liver, as opposed to HDC.

CHAIRMAN MALMUD: Now, we know that the patient now has a tumor in the liver. How are we localizing the tumor in the liver before this process begins?

DR. PUTNAM: CAT scans, MRIs. They've had their screening arteriogram. We know the vascularity. We know the location. We know the size of the tumors.

CHAIRMAN MALMUD: Are any tests necessary using standard nuclear medicine techniques, let's say

MAA or other material in order to localize the tumor's vasculature within the liver?

DR. PUTNAM: Well, when we do, we do a screening arteriogram usually a week or two before the actual delivery. We do an MAA injection, MAA tech-99 injection, essentially looking for lung shunting. But that also does demonstrate tumor vascularity.

CHAIRMAN MALMUD: So the first thing that is done diagnostically is the angiogram of the liver, which identifies the tumor. And then --

DR. PUTNAM: Well, after a CAT scan.

CHAIRMAN MALMUD: After a CAT scan. The CAT scan, perhaps angiogram, then the nuclear medicine technique is used with standard approved radiopharmaceuticals to determine if there is shunting because that would affect the ability to use the microspheres and also would affect the dosimetry; and then, in addition to localize, further localize, the branches of the blood vessels perhaps in the liver that need to be catheterized in order to --

DR. PUTNAM: And embolized.

CHAIRMAN MALMUD: Embolized in order to achieve a therapeutic goal. Okay? So so far involved in this we have a radiation oncologist, and we have perhaps a nuclear physician who may be doing the

nuclear study and the radiologist, of course, the interventional radiologist, perhaps a radiation oncologist and perhaps a nuclear physician.

In addition, there should be some input from one of those individuals, who is the AU. Now we're getting into the NRC area. That may be the nuclear physician. It may be the radiation oncologist or it may be the physicist at the institution. Am I correct so far?

MEMBER NAG: Physicist cannot be the AU.

CHAIRMAN MALMUD: Okay. So it's not the physicist. So it's either the nuclear physician or the radiation oncologist.

MEMBER NAG: Either 390 or 490 user.

DR. PUTNAM: Or interventional radiologist.

CHAIRMAN MALMUD: It might be a radiologist.

MEMBER NAG: Yes.

CHAIRMAN MALMUD: Okay. So it might --

MEMBER NAG: It might, then, have to be 390 or 490, so interventional radiologists who had a 390 license.

CHAIRMAN MALMUD: But I'm trying to explain it in terms that are not highly technical but

that are practical. So it would be one of three physicians: a radiation oncologist, an interventional radiologist, or a nuclear physician. And that individual would have to be physically present during the procedure.

MS. TULL: To clarify, there are no physical presence requirements.

CHAIRMAN MALMUD: No physical presence requirements.

MS. TULL: Nothing written in the guidance right now for this.

CHAIRMAN MALMUD: So the AU would not have to be present in the process of getting AU authorization to do these procedures?

MS. TULL: They would not have to be standing in the room at the time it was injected.

DR. PUTNAM: But they would have to be there for the *in vitro* training.

MS. TULL: Right. They would be doing the *in vitro* training.

CHAIRMAN MALMUD: Yes. Okay. All right.

MS. TULL: But they could be in the next room or standing next to the person or three buildings down, as long as they're aware it's going on, they're supervising it.

CHAIRMAN MALMUD: And the AU would be one of these three M.D.'s?

MS. TULL: Typically right now the guidance only authorizes your nuc. med. physicians and your rad. oncs. It is very difficult for your interventional radiologists to come in and meet the 390 criteria that Dr. Nag was referring to.

CHAIRMAN MALMUD: What if the interventional radiologist is also Boarded in nuclear medicine?

MS. TULL: Then you have a case where they can come in under that pathway. Yes, they would be authorized. But there are very few.

CHAIRMAN MALMUD: There are few of them.

MEMBER NAG: If I may, about what, about a year and a half ago, it was only the 490 user who was an AU, that being radiation oncologist. About a year and a half ago, the NRC increased that to include the 390 user, which basically would be the nuc. med. or some of the interventional radiologists, who do have 390 licenses. So this was enlarged.

CHAIRMAN MALMUD: But the majority of interventional radiologists --

MEMBER NAG: Do not have.

CHAIRMAN MALMUD: -- who would be doing

this procedure in the future undoubtedly are not AUs currently.

MEMBER NAG: Right.

MS. TULL: Correct. And they would not meet the 390 criteria.

CHAIRMAN MALMUD: Okay. So now we have gotten through the three training cases. In theory, now there's approval to do this. If this is approved and the three training cases are completed, then the institution can move forward, in theory.

What constitutes the *in vitro* is what puzzles me. I think we should explain that in practical terms. What does *in vitro* mean in this particular case? Are we using a mechanical model? Are there animals involved?

DR. PUTNAM: No. We're really just using the catheter. The catheter going out into the little bucket of water is really going to be the patient.

MS. TULL: You're going to have a plexiglas box. Your vitals are all hooked in it, all your catheters coming in and out.

DR. PUTNAM: It's a simulation.

CHAIRMAN MALMUD: It's a simulation. Is there a phantom patient? Is there a lucite phantom patient or something, the kind that we sometimes used

to use in nuclear medicine?

DR. PUTNAM: No. Remember, we do this --

MS. TULL: We're looking at it from --

DR. PUTNAM: -- on site. Every place that is interested, we go on site and do this. So I guess we could look into that, but that would get very complicated.

CHAIRMAN MALMUD: But you have a list of equipment that is necessary at each site.

DR. PUTNAM: You have a kit with a box --

CHAIRMAN MALMUD: Yes.

DR. PUTNAM: -- and delivery vial and pigs and everything that we use --

CHAIRMAN MALMUD: It's all there.

DR. PUTNAM: -- for the administration other than the patient.

CHAIRMAN MALMUD: Okay. So I am just trying to clarify this in case anyone here has a question as to what we were discussing in practical terms, not in technical terms. Does anyone now have a question as to what the process is? Yes, Steve?

MEMBER MATTMULLER: Steve Mattmuller. I'm curious about the *in vitro* setup. Does it mimic best case scenario or is it designed to have capabilities for -- okay. If you see back pressure and it can

create issues and problems.

DR. PUTNAM: We can clamp the tubing and simulate back pressure very easily. We can simulate a leak. We could create some defective stopcocks and show what a leak is. So currently we haven't been doing that, but as we progress and we are required to do that, we could actually do that.

I mean, to clamp it is no big deal. You would actually see the meniscus rise pretty quickly. And then you would see leakage up around the top, the stopcock and the delivery vial.

So that can be simulated, and you can feel the increased back pressure, which every interventional radiologist already knows what that feels like because they have done a lot of embolizations. But we can simulate the potential abort points and malfunctions fairly easily.

CHAIRMAN MALMUD: I'm still trying to clarify. Not the simulation but the actual product, is it clear, cloudy, or a color?

DR. PUTNAM: Sand colored.

CHAIRMAN MALMUD: Sand colored?

DR. PUTNAM: Cloudy, yes. You can see it.

CHAIRMAN MALMUD: And will the simulation use the same color material?

DR. PUTNAM: Yes. It's the same beads.

CHAIRMAN MALMUD: Same beads.

DR. PUTNAM: They are not radioactive.

CHAIRMAN MALMUD: Thank you.

Any other questions about the *in vitro* process? Let's see. I think you were next, Dr. Nag and then Dr. Fisher.

MEMBER NAG: Having done this, I think the *in vitro* simulation you are doing will reduce accurately many of the steps. One place where it will not reduce would be the stasis. I mean, that's something you cannot reduce unless you have a patient with the blood flow and so on.

DR. PUTNAM: Right.

MEMBER NAG: And, therefore, I agree with you that even though the NRC requirement is only the three simulated cases, I think it is in the best interest of the manufacturer to, in addition, also have or supervise three additional cases where basically it is involved so that you see the problem coming in about stasis went to start -- those are the decisions that are very difficult to make unless you have gone through it.

CHAIRMAN MALMUD: May I ask a question now? Isn't the issue of stasis one that the

interventional radiologists deal with routinely --

DR. PUTNAM: Absolutely.

CHAIRMAN MALMUD: -- in other situations?

DR. PUTNAM: Yes.

CHAIRMAN MALMUD: So is there really a need for the interventional radiologist who already has experience with stasis to have three additional cases?

MEMBER NAG: Well, remember, this is a case where the AU would be either a nuclear medicine would be the interventional radiologist or the radiation oncologist.

In the situation where I was, I was working with the interventional radiologist and it was between the two of us, we were deciding when we should point to you. Maybe we can get a little bit more. Here is the give and taken.

CHAIRMAN MALMUD: I understand, but my question remains with regard to your point. You said three additional cases demonstrating stasis. Stasis is an issue that interventional radiologists confront routinely in the practice of interventional radiology without radioactivity. What makes it different in this case?

DR. PUTNAM: I can tell you what makes it

different and why we do want to continue this. We're not mixing the beads with contrast. Everything else that we put in is an embolic particle or substance we can actually visualize as it goes in.

Here we're visualizing in between injections of contrast. We inject it blindly, but then we give a few doses of contrast to assess flow intermittently throughout the procedure. And that is the part of it that we want to really teach the interventional radiologists.

CHAIRMAN MALMUD: Are you in favor of three additional cases above the baseline, three, as Dr. Nag is suggesting?

DR. PUTNAM: Well, again, this is not TheraSpheres. We're not talking about TheraSpheres, totally different.

CHAIRMAN MALMUD: Yes.

DR. PUTNAM: But for SIR-Spheres --

CHAIRMAN MALMUD: Yes.

DR. PUTNAM: -- we will continue doing this, regardless of the regulatory issues.

CHAIRMAN MALMUD: Three *in vitro* plus three cases. Is that what you're suggesting?

DR. PUTNAM: Well, the problem is we're going to have still back to not having an AU off the

bat.

MS. TULL: Can I say if you start requiring three more cases --

CHAIRMAN MALMUD: I'm not requiring anything.

MS. TULL: Okay. Well, the Committee suggests.

CHAIRMAN MALMUD: I'm not requiring.

DR. PUTNAM: I mean, these are two different things. We're trying to get our AU status quickly based on the *in vitro*.

CHAIRMAN MALMUD: And I'm trying to help you.

DR. PUTNAM: And then --

CHAIRMAN MALMUD: That's why I'm questioning this.

DR. PUTNAM: As far as, you know, the embolization component and delivering the dose safely, not the radiation component so much, although, of course, they are intertwined. We will continue the proctoring after the hopefully AU status is settled.

CHAIRMAN MALMUD: I think some questions have been raised. Dr. Thomadsen?

MEMBER THOMADSEN: If I can put words in your mouth, what you are saying is you would recommend

a requirement for the three *in vitro* cases.

DR. PUTNAM: Yes.

MEMBER THOMADSEN: In addition, your company would still stand by the fact that they feel they need to do the three proctored cases?

DR. PUTNAM: We would do three lab cases as well.

CHAIRMAN MALMUD: Dr. Fisher?

MEMBER FISHER: Thank you. Darrell Fisher.

For the new site initial training and three simulated cases, how long does this take?

DR. PUTNAM: The whole process from the phone call to SMI to the actual in-service and --

MEMBER FISHER: No. How long does the training take on site to do your new site initial training plus three simulated cases?

DR. PUTNAM: I think we could do that in a day.

MEMBER FISHER: In one day?

DR. PUTNAM: If we had everything lined up, we should be able to do that in one day.

CHAIRMAN MALMUD: Additional questions? Dr. Welsh?

MEMBER WELSH: Jim Welsh.

Dr. Malmud, I would like to address your question about the need for the interventionalist, interventional radiologist, to get these three cases, even though he or she may have done hundreds or thousands of cases and be very familiar with stasis.

The physical properties of SIR-Spheres differ from the physical properties of TheraSpheres in terms of density, size of these microspheres, and the probability of stasis. And the probability of stasis being a clinically encountered situation is very different for SIR-Spheres as it is for TheraSpheres.

Therefore, although an interventional radiologist may have done hundreds of cases of something that is not microsphere-based, he or she will not have already had experience with the kind of stasis that might be encountered here. There is no guarantee at such experience prior. And, therefore, I do favor the additional training: the three *in vitro* and the three patient cases.

For our purposes here, Nuclear Regulatory Commission, the authorized users are typically those with 390, 490 training. And this is something that is independent of the stasis concern. And the additional cases may not be really crucial to the AU. But for the IR, this is an important experience.

CHAIRMAN MALMUD: Thank you for clarifying that. Then the question that I raise is, are the three additional cases, the *in vivo* cases, at all a radiation issue or a medical practice issue? Which of the two are they?

MEMBER WELSH: I personally do not think that they are radiation-related issues.

CHAIRMAN MALMUD: That's what I wanted to get on the table, that you do not believe they are radiation issues. And, therefore, they are not technically of our concern with regard to NRC issues here from what you have said.

Dr. Thomadsen seems to want to say something about this.

MEMBER THOMADSEN: Well, I would disagree as far as them not being radiation issues because injection host stasis means that the radiation is going to be delivered to some other location.

CHAIRMAN MALMUD: Thank you.

Dr. Suleiman?

MEMBER SULEIMAN: I have a point that I would like to make. When you use the term "dosimetry," I think I finally accepted the fact that these are being dosed by conventional chemotherapy drugs.

In other words, radiation-absorbed dose is not anything near conventional external beam therapy or brachytherapy. The dose that the organs receives is estimated with extremely high uncertainty.

So your administering activity, I think we have to be real careful. I see lots of inconsistency among the use of the term "dosimetry" depending on whom you're speaking to, depending on the day of the week with whom you're speaking to. So I think it's extremely important, especially for emerging radiotherapeutics, that this discipline somehow will eventually be incorporated into the practice.

So when you use the term "body surface area method for dosimetry," it's a little bit bothersome to me personally because dosimetry means multiple things to multiple people. So we don't want to see mistakes happening because the terms are being used interchangeably incorrectly.

CHAIRMAN MALMUD: Thank you.

MEMBER NAG: I agree with you. It's not dosimetry in the strict sense of the word. Dosing, a dosing requirement, you know, how much those are really -- how much of what activity you're putting in because the microspheres were according to the blood flow.

I had a question, basically more for Ashley. You know, you have a catch-22 situation that you are trying to solve. Could that catch-22 situation be solved by saying that the facility licensing would be there? Even though you do not have an AU on file, you can say that an AU application is on file.

MS. TULL: No. We went to our Office of General Counsel on this. And you have to have an AU on the license. That's the legal requirement.

And can I make one more comment? We do have another manufacturer presentation. It's all on the same topic. I know we're going with a discussion here.

CHAIRMAN MALMUD: Yes.

MS. TULL: But I want you guys to have all the information so we can continue the discussion. If I can have Dr. Salem up here?

CHAIRMAN MALMUD: But we do have a few more questions. Can you complete those?

MS. TULL: Okay.

CHAIRMAN MALMUD: I think first Dr. Eggli.

MEMBER EGGLI: I want to second Dr. Welsh's comment. And I understand Dr. Thomadsen's point that when you hit stasis, the radiation goes

somewhere. But I think the radiation going somewhere is not an NRC issue, that the safe handling of the administration set is the NRC issue. And I think that the solution NRC is proposing to solve the AU problem is a reasonably good solution and that the Committee should endorse that solution.

I also understand that it is in the manufacturer's interest to make sure that physicians understand and are trained in the stasis issue as a function of medical practice and that the manufacturer is going to train the administering physician how to respond to a stasis issue.

So I think that they are, as Dr. Welsh said, somewhat separate issues. The regulatory issue is the safe handling of the administration unit and the radioactive material. The other is, although radiation will have an effect if they continue to dose after stasis. That is a medical practice issue involving radiation and not a regulatory issue for NRC.

CHAIRMAN MALMUD: Thank you.

Two more comments. Dr. Van Decker I believe was next.

MEMBER VAN DECKER: I just have a question. Is it your expectation that in these three

live cases, both the AU and the interventionalist would be present for those, even though there seems to be some indirect supervision for the future, so that at least all of these people see this on this go-around training period?

DR. PUTNAM: Yes. If not present at the case, at least present for the discussions. But it would be nice, actually, if the authorized user were present.

CHAIRMAN MALMUD: I would guess so.

DR. PUTNAM: And in my experience, most of the time they are but not always. But for the first three cases, I think we would expect that just to make sure.

CHAIRMAN MALMUD: *In vitro* cases?

DR. PUTNAM: For the actual cases.

CHAIRMAN MALMUD: Dr. Welsh?

MEMBER WELSH: I've heard the term "AU problem" discussed here a couple of times. And I'm not sure I really understand the AU problem. Is there a shortage of potential authorized users? Is that what we're talking about is the problem here?

Because I just don't see that there would be people who aren't trained in 390 or 490 who could serve this. So would you please clarify what is meant

by this?

CHAIRMAN MALMUD: I'll ask Ashley to do that.

MS. TULL: It's the three cases. You have someone, a physician, who is qualified to do these procedures, but they have no way to do the three cases that are currently required by the guidance because they can't order hot material to their facility because it's not on their license, not that they're not capable of doing a procedure, just that legally they can't write up a written directive that says, "I want to do this procedure" because when they don't have the authorization to order the material, it's not on their license.

And Y-90 microspheres cannot be added to the license until there is an AU. The region is not going to approve a license amendment to add Y-90 microspheres to a license. They're going to say, who is the responsible AU? Oh. Well, we're ordering it so they can get their three cases.

MEMBER EGGLI: Jim, the issue is broad scope versus --

MS. TULL: Specific.

MEMBER EGGLI: -- specific scope licenses. And the issue addresses only specific scope licenses

because those of us who are broad scopes are unaffected.

MS. TULL: Broad scopes already have Y-90 basically on the license. You get a qualified AU. Now you can order the material.

CHAIRMAN MALMUD: Thank you.

Donna-Beth?

DR. HOWE: Dr. Howe.

Just to clarify one point. And that is Ashley is saying that you cannot have a license unless you have an AU. We do have another mechanism, and I believe it is in the guidance now. That is for the notification procedure.

MS. TULL: It doesn't work for new facilities, though. It only works for a current facility that is licensed for Y-90.

DR. HOWE: But it should work for a new one if you --

MS. TULL: Notification does not help in any way for new users and new facilities, which is why we came up with simulated cases back in December.

DR. HOWE: Okay. I was under the impression we wrote the notification procedure so that you --

MS. TULL: Thought it would help.

DR. HOWE: -- could use it.

MS. TULL: When we started going through the logistics, it doesn't help for a new license with a new user.

CHAIRMAN MALMUD: Thank you. If we may, can we move on to the second presentation? And then we can have questions related to all of this. Thank you. Thank you, Dr. Putnam. And we now invite Dr. Salem to join us.

MS. TULL: Dr. Salem is an interventional radiologist at Northwestern University. He has performed over 2,000 procedures using yttrium-90 microspheres. Dr. Salem is the Director of Interventional Oncology in the Department of Radiology at the Robert H. Lurie Comprehensive Cancer Center of Northwestern Memorial Hospital in Chicago. Dr. Salem is certified by the American Board of Radiology and is focused on complex cancer therapies, including liver cancer therapy, for the past ten years.

Today Dr. Salem is speaking as an expert on TheraSphere, Y-90 microspheres manufactured by MDS Nordion. Please welcome Dr. Salem.

DR. SALEM: Thank you, Ashley. Thank you for the opportunity to present this morning. I wanted to share that I support Dr. Putnam's position on what

he was describing as the training requirements for SIR-Spheres. I have been involved in this therapy for about ten years now.

So I have a lot of experience in terms of things that we have learned in terms of what constitutes training and certainly have a lot of insight in terms of some of the issues that have come about over the last ten years.

I will be talking today about what the program has been working with MDS Nordion over the last four years for training. This has been identified as a crucial step in microsphere therapy for years now.

And in 2004, we created what we call TheraSphere University. And what this means is a one-day pretty intensive course. And I'm going to go through the whole step today that involves sort of the radiation aspects, the clinical aspects, the real practical nuts and bolts of how this therapy is applied.

I've had about 350 attend over the last 4 years, 60 institutions worldwide in attendance, Europe, Korea, sites in Canada. So we have a lot of experience training. And we've learned a lot about what sites certainly want.

Speaking on behalf of Nordion in terms of the issue that exists at hand now in terms of at what point, at least for TheraSphere should someone be -- has the training been completed to permit application and application to become an authorized user for an institution, because of the catch-22 situation Ashley was describing.

So what we will be discussing here today is sort of a two-step process, very similar to what Dr. Putnam was describing. There is the one-day training course in Chicago at TheraSphere University. And also, like Sirtex, there are three proctored cases on site following this one-day training. I will go through that step.

To give you an idea, this is Ashley and Cindy attended a few months ago in terms of what the course is. There is a portion of on site at the course on physics, one hour on physics by our medical physicist, Vanessa Gates.

We go through clinical care of the patient, indication, outcomes, what sorts of things you might see. And then I go on for about five to eight hours depending on how long we have and who has got flights to take on the real issues in treating patients with hepatocellular carcinoma, which is the

focus of the course.

So we are discussing here sort of the indication. I go through the anatomy, the issue that people will have in terms of embolizing vessels, where to place the catheter, what sorts of issues you might encounter from a technical standpoint.

We then go through -- and I'll use the term loosely -- dosimetry, as has been discussed before aut, really, the methodology that has been accepted and validated for about 30 years now for this technology on how you calculate activity to be injected and then calculate dose administered.

We then go through sort of the 3-D reconstruction models, volume calculation, tumor calculation, assessment of catheter position, and how that correlates with 3-D imaging because these are completely interrelated, particularly as you use the MRD dosimetry model.

Once that is completed, we then go through three cases of actual patient dosimetry. The group is asked to actually solve these problems. These are three cases that we put together to try to comply with some of their requests and discussions we had had with Ashley in the past. But these are three real cases, real anatomy, real volumes. Attendees have

calculators and are asked to sort of as best we can determine the dosimetry. And we go through all of the problems. And those are handed out to the attendees.

They then witness two to three live infusions on that same day. So we have gone through all the physics, all the dosimetry, all the calculations, three live cases, three simulated cases, as we would call them, with the dosimetry that I just described in the calculator. And the entire day ends with this hands-on approach, which involves the actual administration kit, which you can see here.

We have a small corner in the hospital. And here we demonstrate what we have in terms of how the dose arrives, what it is we do, where we do the calibration, how the vial comes in, how the kit looks, how it is put together.

We then identify the priming systems, really go through every step. Notice here Dr. Malmud is asking about the microspheres. For the training, we use cold and colored microspheres. They are black.

So you can see the flow dynamics and things extending out the catheter. So you can see, in fact, while we do the actual injection during that day, you can see the microspheres come out of the vial and into the micro catheter.

We then demonstrate here the complete administration kit, what it looks like immediately before injection to the patient from a simulated standpoint.

The other thing we do is we really go through this checklist. As Dr. Putnam was saying, a checklist I think is very important for this therapy because, again, it gives you the abort points. It tells you what area you might have a problem with. And these are all spots where you should just as a routine continue to check things off as you are putting the kit together.

We created this about eight or nine years ago. It's now pretty much become the standard. You are able to measure your sort of local activity pre and post sort of local activity, pre and post-injection readings and pressure, how many flushes, what pressure you measured, any issues you had. So pretty much everything is very well-documented.

And, again, this list was created to really -- you know, when you do many of these, you know, habit. You know, we're all human. We can make mistakes. So because of that, we have this list. And we strictly follow that to make sure we don't make any

mistakes.

Ultimately I think this is sort of one of our sessions that we had sort of walking back to the classroom. Usually we have interventional radiologists present, radiation oncologists, nuclear medicine, clinical coordinators, really depending on who the drivers are, who the people are that are most interested, most motivated, who depending on the local center will be the authorized user and will be involved in the process.

So to address the real question this morning in terms of when, at least for TheraSphere, or the position of MDS Nordion is when have they accomplished sufficient training to become authorized user. Well, that point is really right after TheraSphere University.

The day they have completed that day where they have done three dosimetry calculations, live testing, they have seen patients, they have done dosimetry, they have calculated is when at least MDS Nordion believes that the prospective site should be able to apply for AU status because of the catch-22 situation that exists.

However, Nordion also stands by, similar to Sirtex, three added on-site proctored cases. That

has been going on for years and will continue to go on again because that permits sort of an extra step of sort of team building and identifying the real issue on site. Every site is going to have their areas of inefficiencies that need to be reconciled. Only the manufacturer can help with that on site.

So, at least the answer to the question for today for TheraSphere, I would propose that this is the defined point at which AU status can be or somebody can apply for AU status.

To summarize, I think this one-day course is quite comprehensive. It involves all the medical issues, the radiation safety issues, failure checks, the injection, the bench testing.

Really, you have got the kit in front of you. This provides, really, sort of a live and simulated approach. You are really sort of seeing all of the issues, written directive, what you need to do with that.

And the other thing we do is the centers bring their own cases. So that day they will bring their CDs and patient examples, and we will run through those as well. And so we will look at their own three live cases.

In fact, many times those are the cases

they want to treat immediately after they are done with training. The problem is that sometimes it can take a while for the authorized user status to come in. And so they may not be able to treat these people. But they actually come in with live cases, patients they want to treat, and discus it.

But basically, again, once TheraSphere University is completed, at least from an MDS Nordion standpoint, they should be able to apply for authorized user status.

Now, I did want to sort of briefly mention -- this is my last slide -- some of the issues that have come up since there has been some discussion with "the AU status." This was information requested by NRC from MDS Nordion in terms of the authorized user.

There are 47 sites in the U.S., of which 20, the interventional radiologist infuses TheraSphere. But I did want to say that I don't know how much time we will have today to discuss or whether that will be tabled for the next meeting, but a few years ago with many of the members sitting here, we came and we discussed the ability of the interventional radiologist to become authorized users under 390. Nobody will need 490.

We have learned a few things over the last

few years. I think there are some limitations that exist with some of the regulations that really prevent interventional radiologists from being more integrally involved in this process.

Chairman Malmud was sort of describing the real clinical reality of what is going on. I think we have to potentially entertain a dynamic regulatory process for this therapy. This is still new therapy.

There are thousands of patients that have been treated. But in my opinion, sort of the exact position where this fits I still think needs to be determined. I am personally uncomfortable with many models of authorized users, either nuclear medicine or radiation oncologists, elsewhere from the procedure, but sometimes the regulations have forced people to do that. And, as Ashley was saying, physical presence is not required.

I am personally uncomfortable with that, but I think this is sort of an area that really needs some discussion, again potentially tabled for the next meeting. But, really, I think we need to reconcile some of the differences that exist from the regulatory standpoint from a real clinical practical standpoint.

Thank you for your time.

CHAIRMAN MALMUD: Thank you.

Questions? Dr. Eggli?

MEMBER EGGLI: In 390, there are special case training and experience requirements in 392 for iodine under 30 millicuries, 394 for iodine over 30 millicuries. Would a similar approach of not a full 390 certification but a special subset created appropriate to sphere administration be an appropriate long-term resolution of this question?

MS. TULL: My initial thought on that is that since microspheres are not a 300 use, there's not a good place for it in 390. I mean, technically it's permanent implant brachytherapy. So it's going more towards your 490.

DR. SALEM: But if we could entertain it, I mean, the reality of it is if you entertain it, it would be --

MS. TULL: Yes. We're working in the guidance space. So adding 290, say 290, 390, or 490, NRC wasn't comfortable with wide open any interventional radiologist who wants to do it can or any diagnostic radiologist.

I think we have mixed feelings. I think we are open for discussion on that. I would say, though, like Dr. Salem said -- and I have had numerous discussions about this. I said I really don't want to

get off track on that for this particular meeting. I want to have a recommendation from ACMUI as to whether or not getting the AUs, 390s and 490s with simulated cases, is a good approach.

So I would agree with Dr. Salem that we could have a full discussion on this at a later date. But we would entertain the idea, yes.

CHAIRMAN MALMUD: The next hand was Mr. Lieto.

MEMBER LIETO: Yes. Before I ask my question, could you restate what the guidance document is proposing for licensing --

MS. TULL: Yes. You would have --

MEMBER LIETO: -- specific licensees, the non-broad scope --

MS. TULL: You would have to be a 390 or 490 user. So you would need to be a nuclear medicine or a radiation oncologist currently practicing on license and you would need to get three cases either under an AU, who is already at your facility doing these things. They could train you or go to the vendor, go to the manufacturers and get three simulated cases, then apply it to be added on to the license.

MEMBER LIETO: I appreciate your

discussion on dosimetry. As a physicist, I found that very informative. And in knowing Vanessa Gates, I think what you are doing is very good.

Also, being a specific licensee and I know that we have also looked at getting a license for this and the issues associated with it, my comments are going to address this from the standpoint that the real radiation safety issue, which the NRC should be looking at, is that this is like an unsealed source. These are microspheres. We have been dealing with technetium microspheres for 20-plus years.

The radiation safety considerations, the patient safety considerations, I strongly feel should be addressed as if this is an unsealed radiopharmaceutical. And that's where my comments are going to come from.

The issues about whether this should be a 390, a 300 use, I absolutely agree with. What I would like to propose is that sort of a two-tiered approach to licensing that the AU, the interventional radiologist at a minimum must go through three simulated cases at the vendor's training.

When they get the documentation of completing training from that, they would be able to apply for a license amendment to the region, to the

NRC, or agreement state, submit that training and experience for the authorized user.

Then on site the authorized user and the team, as indicated in the guidance document, which I believe is someone in cancer management and the AU complete three proctored on-site cases and that they notify the licensing agency when those three cases have been completed.

I am strongly against the AU not participating in all phases of the training and experience. As an hour or so, the buck stops with them. And if they don't know what is going on, they don't know what their responsibilities are and the team's responsibilities, they should not be licensed, period. And that's my suggestion.

CHAIRMAN MALMUD: Thank you.

Dr. Nag?

MEMBER NAG: I am also concerned that the AU is not at the site because as far as my understanding was, the AU and whoever is injecting, like the interventional radiologist if they are not one and the same person, both of them are there together at the place where I was doing it. We were always together. There had never been any case where I as the AU was not present.

So I am very concerned that I am hearing that AU is somewhere over there overseeing but there are not there, at least to start off with.

CHAIRMAN MALMUD: Other comments regarding the AU's presence? Dr. Welsh?

MEMBER WELSH: Yes. I feel the same way as Dr. Nag's opinion, but I would like to go back to your question earlier, Dr. Malmud, about what is the real difficult part in all of this. The most difficult part by far is what the interventional radiologist does dealing with the infusion, the difficulties with stasis.

The AU with 490 experience, training 200 classroom hours, 500 experience, this is relatively simple stuff for somebody who is Board-certified as a radiation oncologist. And I do think that you can get the necessary understanding in three cases.

Therefore, I think that the solution that was proposed by Dr. Salem is reasonable, perhaps with the modification put forth by Dr. Lieto about having a couple of on-site proctored cases as a solution.

CHAIRMAN MALMUD: If I may, you support Dr. Salem's recommendation with the requirement that there be some on-site experience as well. And the question that I ask you for clarification is, are you

suggesting that the AU be physically present for those on-site cases or not?

MEMBER WELSH: So for those on-site training experiences, absolutely. It is mandatory that the AU demonstrate that he or she has the competence and the experience and the knowledge to do these cases for real.

The reality is that the AU's role is so relatively minor compared to the interventional radiologist's that in some institutions, the AU is in another room or down the hall, instead of being right there in the room looking over the shoulder and physically supervising this.

I can tell you from my experience when we were getting started with this program a number of years ago, the authorized user, the radiation oncologist, was trying to infuse the microspheres.

And it became obvious very quickly that the person that should be infusing the microspheres is the person who has done this thousands of time with other materials, rather than the radiation oncologist, who has never done the infusion but knows the details of radiation safety and radiation materials handling.

So the process was quickly transferred to the interventional radiologist being the one that

infuses the material under the supervision of the authorized user. And that was the model that we continue to use. And that's the one that I support.

CHAIRMAN MALMUD: I think that there is unanimity of opinion regarding the infusion by the person with the talent, meaning the interventional radiologist.

The question that arose I would like to get some closure on is, should the authorized user be required to be physically present for the first several cases that are performed at the institution that has already completed the TheraSphere University or the other program. So that let's say the stopcock comes undone during the procedure.

MEMBER WELSH: In my opinion, the answer is yes. And in my opinion, the answer is that the authorized user should be present for every real case as well.

CHAIRMAN MALMUD: Well, that's another jump forward. But do you want me to stay with at least the first initial cases at the institution. And Dr. Thomadsen had a comment.

MEMBER THOMADSEN: It's a question to the NRC staff. Is there a mechanism that you can require after licensing the authorized user for this material,

the specifics of the three case proctored cases?

MS. TULL: I can write it in the guidance.

CHAIRMAN MALMUD: So the answer is --

MS. TULL: I mean, it's really based on your recommendation. We were just trying to be as non-prescriptive as possible and focus on getting the AUs on board, but if we are in agreement that we have AUs on board now, we will simulate cases. If you guys want to take it another step, that's an ACMUI input. NRC is not going to initiate that.

CHAIRMAN MALMUD: Dr. Salem, you wish to make --

DR. SALEM: Yes. Can I just make a quick comment? I just want to point out that this is already going on. It has been going on for years, the training by Sirtex and Nordion and the three added cases.

This is not new. So it's just Ashley has asked us and the Committee, I believe, to point out where because of the Catch-22. So it's not that we're doing anything new. This has already been going on. I just wanted to clarify.

CHAIRMAN MALMUD: Thank you.

Sally?

MEMBER SCHWARZ: I do have a question. In

reality, is the authorized user present for these cases, at least for the first three training cases?

DR. SALEM: In reality, for the first few cases, the authorized user is present. But as the program evolves and time goes on, that person disappears, which then leaves the issue of the discomfort because --

DR. PUTNAM: Can I --

DR. SALEM: -- what people are doing. It's just meeting the requirement and then really not following through.

DR. PUTNAM: Can I comment on this?

CHAIRMAN MALMUD: Sure. Dr. Putnam?

DR. PUTNAM: I do this procedure at two hospitals. And at both places, we require the authorized user to be present during the administration. They serve a very limited role, as Dr. Welsh elaborated on.

There's really no requirement, at least practical requirement, for them to be there for this procedure. We're often waiting for the AU to show up. It's holding up our patients. It's holding up the delivery very often. You have to schedule on days when they are available. You know, it really does limit the ability of many institutions to deliver this

product.

Now, I have a good working relationship with the ones I work with, but it's still a problem. And I think at other places, where they don't have that relationship, maybe they should but they don't, it's really going to limit the ability to deliver the product if you require that an AU is present for every single administration.

CHAIRMAN MALMUD: Thank you, Dr. Putnam.

I was trying to limit this discussion to the first several cases that are performed at the institution after the *in vitro* cases. And my concern -- and I suspect that it is a concern of the Committee from what I hear -- is that if the authorized user has not physically seen the procedure, at least on several occasions, then he or she is required to be present because of some contamination or issue, may not know what his or her role would be in this because they will not have known what went wrong by having witnessed it. That's the only issue.

I would agree -- well, my opinions are not relevant here. But that's what I'm trying to limit it to, the --

DR. PUTNAM: Yes. I think the first three is fine.

CHAIRMAN MALMUD: Having the authorized user present long term would be additional expense and also creates a problem of how do you get the team together when the authorized user may be covering more than one institution, which is apparently not an uncommon situation?

Dr. Nag?

MEMBER NAG: I would definitely or I would strongly recommend that the authorized user be present during the initial three cases that are on site. I would definitely recommend that.

CHAIRMAN MALMUD: Is that a motion?

MEMBER NAG: Yes.

CHAIRMAN MALMUD: Is there a second to that motion?

MEMBER WELSH: Second.

CHAIRMAN MALMUD: Is there discussion to that motion? The motion is that the authorized user be required to be present for the first three cases.

MEMBER NAG: Yes. Three is what we have as a minimum, that three cases.

CHAIRMAN MALMUD: Mr. Lieto?

MEMBER LIETO: I'd like to come back to the initial issue, which is the problem with getting someone licensed on a specific license at a new site.

And it's not just the proctored cases. It's the simulated cases. I don't like the term *in vitro* but the simulated cases.

I would like to sort of get that problem resolved and then look at the issue of ongoing and --

CHAIRMAN MALMUD: What's the problem with the simulated cases that you want to address?

MEMBER LIETO: Well, I --

MS. TULL: I need a motion.

MEMBER GILLEY: We have a motion on the table already.

MEMBER LIETO: Yes.

CHAIRMAN MALMUD: We do have a motion on the table with regard to the presence of an authorized user at the first three actual cases at an institution so that the authorized user would be physically familiar with and visually familiar with the procedure should there be an issue in the future.

MEMBER NAG: And I do not want to put a physical presence requirement on the subsequent cases, but it should be understood that the authorized user is overall supervising those. But, you know, I mean, in --

CHAIRMAN MALMUD: The motion is specifically limited to the first three cases.

MEMBER NAG: Right.

CHAIRMAN MALMUD: Is there discussion? Dr. Thomadsen?

MEMBER THOMADSEN: I will be making a motion to table this because I think we should look at this in the context of a motion addressing the whole issue in the first place, which is what we are here for.

And I will make a motion to address this whole thing, including the proctor issue in that. But to do that, we need to table this motion at the moment.

MEMBER NAG: I table my motion.

MEMBER THOMADSEN: You have to withdraw it.

CHAIRMAN MALMUD: Dr. Nag's motion is tabled. Now we can go back to the initial issue. Dr. Thomadsen?

MEMBER THOMADSEN: I would make the motion that we can approve authorized users following the three simulated cases that are provided during the education by the vendors. We can then recommend that all users, authorized users, and members of the team participate in the three proctored cases.

CHAIRMAN MALMUD: That's a motion. Is

there a second to the motion?

MEMBER WELSH: Second.

CHAIRMAN MALMUD: Any discussion of that motion? I see two hands. Dr. Zelac had his hand up before as well. So we will ask him first.

DR. ZELAC: Thank you.

In the presentations from Dr. Putnam and Dr. Salem, I picked up on what I think is a significant difference. And I would like some clarification.

Dr. Putnam, I think you indicated that the persons receiving the training, the one-day training, will indeed have hands-on experience with the infusion apparatus. Is that correct?

DR. PUTNAM: That's what we discussed. And that would be the plan, yes.

DR. ZELAC: And, Dr. Salem, that is not the case at TheraSphere University?

DR. SALEM: No. That is the case.

DR. ZELAC: That is the case?

DR. SALEM: Yes, hands-on.

DR. ZELAC: So hands-on they simply are not observing someone else do it. They're actually physically having an opportunity --

DR. SALEM: It's right there. No. People

handle, manipulate the entire set. Absolutely.

DR. ZELAC: Thank you.

CHAIRMAN MALMUD: Ashley?

MS. TULL: Could I clarify? I have, if you could say, done the training for both of these programs. Cindy and I attended TheraSphere University about a month ago. And Sirtex came last week. Like Ron was indicating, that's why my name was raised earlier. There is a difference.

NRC, our interpretation was the physician is actually putting the stopcocks -- well, they are already glued together but putting the catheters to the stopcocks, putting the vials into the case, all those types of things, and doing that three times, basically set up three kits. And the first one would have a leaky stopcock. The second one would have a clamp on it, simulate that pressure. So they would do each one of those things. And one of them would work.

When we went to TheraSphere University, we did the dosimetry cases. And then that was in the hotel. And then we went over to the hospital, and we watched Vanessa basically do the whole thing and put it together.

I am not a physician. Maybe you guys would be more familiar with it. But I know for Cindy

and I, there were numerous places for errors. We wouldn't have been able to replicate that I don't think. That was our agreement.

It was very confusing. There was a lot going on. And for someone who has done it over and over, maybe it is not a problem. But that's why I said there are multiple interpretations of three simulated cases. TheraSpheres' take on this was doing the dosimetry of actual patients in a classroom setting and then watching the physicists go through all of this.

So I think Dr. Salem could speak to more, but --

DR. SALEM: I must reply, of course, after hearing a few statements like that.

(Laughter.)

DR. SALEM: Yes, there was a lot going on. The course was put together quickly. By no means was this sort of standard flights. It was raining. So there were some issues.

Indeed, what Ashley points out is correct in the sense of, at least for MDS Nordion and for TheraSphere, yes, the most important portion because stasis is not an issue for TheraSphere. The most important portion is, in fact, the dosimetry

calculation, how that is done, how you order your vials, where the catheter is placed.

The Sirtex product, as Dr. Putnam said, is different. And so there are different training requirements at that end. And so, indeed, for TheraSphere, most of the push is for how do you calculate the dose, what vessels, where are you going to put your catheter.

And then, in fact, at the end, Vanessa does put the kit together. And there is an opportunity for hands-on. When you have 15 people standing around, it is difficult to say, "You push the syringe. You clamp here." There are some practical aspects.

Most of that portion is actually undertaken when the three on-site training cases are done by MDS Nordion physics staff, where, in fact, all of that stuff happens the day before the training.

So it is complementary. It doesn't replace one versus the other. But there are imperfections in the system. I would not lie about that.

MS. TULL: My question to ACMUI, then, is, are you comfortable with an open interpretation as far as what the manufacturers deem important? They know

the product the best. They are familiar with this. They have been doing it for years. You've got experts teaching other physicians how to use this.

That's why I didn't want to define simulated cases. I either want ACMUI to define it or to leave it open so that the manufacturers can determine. That's what we're looking for from you on simulated cases.

CHAIRMAN MALMUD: The question is now on the table from Ashley. Ralph?

MEMBER LIETO: Well, obviously I think from a radiation safety standpoint, you want them to go through the hands-on work of what they need to do. These, unfortunately, still are considered brachytherapy cases.

And so you need to have I think them go through the simulations hands-on. They need to know where things go, what types of problems they're going to get if there is resistance. I'm sure if you're going to do anything where you're injecting and so forth, you want to get a sense of the resistances and all these other types of nuances to the situation.

You know, again I am going to go back to the radiation safety aspects to emphasize to the NRC here that the issues I think with this need to be

approached again as an unsealed radiopharmaceutical.

And I think all those aspects that go with doing assay and safety, either up front with the assay, which I think on both sides I think they need to clarify -- maybe it was just because of the setting here, but I am assuming that that goes into more detail with the on-site licensee.

We're still getting away from I think the initial problem, as I see it, is getting that initial AU in a non-broad scope license authorized. In other words, the first domino has got to fall. And that is what I see to be the issue that the guidance document is revolving around.

I agree with what Dr. Thomadsen proposed there, but there is a licensing piece here. As an RSO and the person who is going to have to make this license amendment to get this individual, you have to include that amendment process. And that means you have to tell the NRC how you're going to get that first domino to fall for someone who is not authorized.

And I would propose, as Dr. Thomadsen first suggested, that there be three simulated hands-on training of the team. And when that training and experience is completed and documented, a license

amendment can be submitted to the appropriate licensing agency to get that AU authorized. The initial AU becomes authorized. Then you have the three on-site proctored cases with the entire team.

CHAIRMAN MALMUD: Is that a motion?

MEMBER LIETO: It's a motion.

CHAIRMAN MALMUD: Dr. Thomadsen?

MEMBER THOMADSEN: With respect to that motion, since there is a motion on the floor, that was the intent of the motion that I made. And so I would accept that as a friendly amendment to the motion.

CHAIRMAN MALMUD: The motion has been moved and seconded by Mr. Lieto and Dr. Thomadsen. It is now open for discussion. Dr. Vetter?

MEMBER VETTER: A question for NRC. Would this motion preclude anyone from obtaining training through the traditional academic route so they could still --

MS. TULL: I'm keeping number one, which is currently in the guidance. That is one paragraph that's written. All I'm doing is saying by either and adding a two.

MEMBER THOMADSEN: Okay.

CHAIRMAN MALMUD: And I would ask a question for clarity. Your motion requires three *in*

vitro or three cases?

MEMBER LIETO: Three simulated, step one, three simulated cases, training and experience with a team, documented; step two, license amendment submission and approval. Step three would be the three on-site proctored cases of the team.

DR. SALEM: Of the simulated cases as defined by the manufacturer because they are slightly different.

CHAIRMAN MALMUD: Okay. So it's three simulated cases defined by the manufacturer followed by the application process followed by the three clinical cases. Is the AU required to be present for the clinical cases?

MEMBER LIETO: They're part of the team, yes.

CHAIRMAN MALMUD: For the first three cases. And that is the motion, limited. Discussion? Dr. Eggli?

MEMBER EGGLI: Yes. Ralph, there has just been a contradiction to the motion. Ralph's initial motion said that the training and experience on the initial three phantom cases had to be hands-on. MDS Nordion does not do that.

You just accepted this statement that

said, "As provided by the manufacturer." The manufacturer does not provide with TheraSpheres direct hands-on. The person simply observes the handling of the administration unit.

Is that what you meant, Ralph, or did you really mean hands-on?

MEMBER LIETO: I said hands-on.

DR. SALEM: Well, I would like to challenge the definition of hands-on because, I mean, now we're getting a little bit into --

CHAIRMAN MALMUD: Rather than challenging it --

DR. SALEM: Okay.

CHAIRMAN MALMUD: -- you pointed out to this group earlier --

DR. SALEM: Yes.

CHAIRMAN MALMUD: -- that there is a difference between the two --

DR. SALEM: Yes.

CHAIRMAN MALMUD: -- spheres.

DR. SALEM: Yes.

CHAIRMAN MALMUD: And in your case, you are stressing the radiation dosimetry in the educational process in the *in vitro*.

DR. SALEM: Yes.

CHAIRMAN MALMUD: And in the other case, they are stressing the actual handling because of the difference in the nature of the product. So if Ralph were to accept the recommendation of the manufacturer in each case, that would account for the difference in the two products if that is acceptable to you and Dr. Thomadsen. Dr. Thomadsen?

MEMBER THOMADSEN: I would like to challenge Dr. Salem in that when were at the courts, we had every opportunity and we took every opportunity to have hands-on working with the device. Even with the 15 people there watching, there was ample opportunity to go up and to assemble the kit to play with the injection. And it's just a matter that users just have to do it, that they provide plenty of opportunity for the hands-on.

CHAIRMAN MALMUD: Thank you.

Dr. Salem, would you care to respond?

DR. SALEM: No. That clarifies. I just wanted to put on the record that we do have hands-on training on site, to clarify.

CHAIRMAN MALMUD: This will require a change in your definition of your course to be actual hands-on, not merely observational.

MS. TULL: There would be no change.

CHAIRMAN MALMUD: No change?

DR. SALEM: There would be no change, right.

MS. TULL: It's based on the physician coming up to do it themselves.

MEMBER EGGLI: Well, the difference would be the physician would be required to.

CHAIRMAN MALMUD: We're hearing two different --

MEMBER LIETO: And that is what the motion on the table is.

CHAIRMAN MALMUD: The motion on the table would require that the physician who attends your course not have the option of observing or doing but must participate and do.

MS. TULL: Yes.

MEMBER LIETO: And I am sticking to that motion.

CHAIRMAN MALMUD: And that is what you are saying. Yes.

MEMBER LIETO: Yes, sir.

CHAIRMAN MALMUD: Dr. Howe?

DR. HOWE: This is Dr. Howe.

I would just like to clarify that in the majority of medical events that we have with

TheraSpheres and with SIR-Spheres, it is a problem with putting the device together, stopcocks together where the hands-on with the device is incredibly important.

CHAIRMAN MALMUD: Thank you.

Dr. Salem?

DR. SALEM: That is true. I have seen all of the medical events as they have been reported or many of them as they have been reported, but I would say and I would point out that compared to three, four, five, six years ago, this number has significantly decreased.

And, in fact, out of the thousands of patients that get treated, that have been treated, last year I believe there were eight medical events that describe the problem with the registration.

Now, medical events will always occur. I think the manufacturers have provided very detailed mechanisms to minimize those medical events, but you're right.

Medical events will always occur. I have had medical events. I have made mistakes. But I think there are ample areas where we can report that and we can minimize that.

And eight out of I don't know how many

thousands of patients treated last year is really a competitive number I think if you compare it to other types of therapies that exist.

CHAIRMAN MALMUD: You realize, Dr. Salem, that the majority of this Committee feels that the hands-on requirement is reasonable? Can you accommodate to that in your course?

DR. SALEM: I believe that as the course stands now, this provides both the important dosimetry aspects and the hands-on aspects, the hands-on being the administration kit, seeing where all of these connection tubings are. As Dr. Thomadsen said, this is provided at the training.

Ashley's experience was a little bit different. And I'm sure she would agree that it wasn't the standard approach. But the course does provide with hands-on training. I don't want to undermine the importance of that. Having had medical events myself and reported them, this is important.

CHAIRMAN MALMUD: If I understand the Committee, though, the Committee says it's one thing to offer an opportunity. It's another thing to require it. And I have a feeling the Committee would prefer that your course require hands-on by each participant so that there is a record that the

participant actually did have hands-on experience.

And the reason is that it is our goal to try to protect the public as much as possible. And an incident in one in 10,000 that could be reduced to one in 100,000 or one in a million is an incident worth reducing.

And, therefore, the concern remains -- and Dr. Thomadsen has had a felicitous experience at your course in which he did have an opportunity for hands-on, but this feeling is that everyone who attends a course for the purpose of being certified by the course should have that hands-on experience.

How many minutes does it take for each individual to have the hands-on experience?

DR. SALEM: Well, it depends on which portion. If you mean just hold the syringe and plunge it down, that takes 15 seconds.

CHAIRMAN MALMUD: No. Dr. Thomadsen described putting the equipment together, I believe.

DR. SALEM: The whole area where the time for the administration kit put together and discussion of the whole thing is between 30 and 45 minutes.

CHAIRMAN MALMUD: And how many people attend the course on the average?

DR. SALEM: As few as 3 and as many as 20.

CHAIRMAN MALMUD: So it might require as few as 3 times 15 minutes or 20 times 15 minutes?

DR. SALEM: Right.

CHAIRMAN MALMUD: And, therefore, you may have to have more than one setup if you're going to handle more than --

DR. SALEM: Right. But I would like to -- sorry, Bruce.

MEMBER THOMADSEN: That session takes that long, but the assembly of everything after watching the assembly and going through that doesn't take that long. That takes a matter of about five minutes to put everything together.

DR. SALEM: I mean, first of all, I want to reassure again the Committee that this is a two-step process, right? The first step, the initial issue here was, in fact, when can someone become an authorized user.

But I do want to reassure Dr. Lieto that, indeed, the second portion does involve a much more involved day-before-infusion training and proctoring by MDS Nordion from a radiation safety standpoint in which all the kit is, in fact, also much more in detail put together.

CHAIRMAN MALMUD: Mr. Lieto?

MEMBER LIETO: In my opinion, that is too late. I don't think you want to do it and have that assurance the day before you're going to do the procedure. That is why I believe that the simulations, the -- I forgot the term that Dr. Putnam used, these points of potential problems.

Those should all be simulated in a nonradioactive situation so that the authorized user, the IR, the interventional radiologists have the opportunity to get a sense of how to respond in a nonradioactive situation.

So I guess I am becoming a little more strong and digging in my heels a little bit more here on this point, but I really strongly feel that that should be a hands-on responsibility of the authorized user.

I mean, to me it's no different than any other brachytherapy case that a radiation oncologist is getting trained for. They go through and do the actual -- they do simulations and setups beforehand as a part of their training.

CHAIRMAN MALMUD: Dr. Nag?

MEMBER NAG: Having been on both sides, having been the trainer and having used this, I think if it is a two-part issue where you are finally able

to use it on your own after both the parts have been done, I do not have any objection if the actual setting up of the catheter was done with the trainer on site because then you are having the trainer on site.

Perhaps it would be better to do it on the same day because if you did the training a month or two ago on a simulated site, a month later you really cannot remember all those details. So you remember it much better if you're doing it. And most of the time you do it just before the case is started. You try and set up. You do all the setup an hour or two before the actual case starts. Then you are more likely to remember that thing.

So I would be in favor if it, indeed, is a two-step process, but if the authorized user is left on his own about the simulated cases, then it would not work.

CHAIRMAN MALMUD: I am getting the feeling from the Committee -- and I hope you will correct me if I am incorrect -- that the Committee would be very supportive of endorsing the recommendations if your course would include required hands-on experience in phase 1, in the *in vitro* and that you will probably be able to achieve your goal if you can make that

accommodation because the other manufacturer already has that part in his training program. Therefore, you would achieve your goal by making that accommodation.

But Dr. Thomadsen wanted to say something.

MEMBER THOMADSEN: I'm supporting Subir Nag, who was not expressing that, in that I think, once again, just what Subir had said, that the actual hands-on the day of the treatment with the proctor, which that training because I think about two to three hours as he steps through it with great detail when we are discussing the possibilities that can go wrong each step, is much more valuable and germane than having the hands-on, which we did at the training site well before our first case.

I think having the opportunity for hands-on and a good demonstration at the training, at the college, is quite adequate followed by the requirement for the proctored cases and the training and hands-on at that time.

CHAIRMAN MALMUD: Thank you. Did you not suggest earlier that you thought that it was important that you had that experience when you took the course?

MEMBER THOMADSEN: No. I was expressing the fact that we had that opportunity. We could take that. I didn't express that I thought that was

extremely important. I was just clarifying the situation.

DR. SALEM: Well, I mean, based on the commentary, I can assure the Committee that the accommodations can be made to enhance that portion of part one, training. That can be easily accommodated.

MEMBER VETTER: That would take care of it.

CHAIRMAN MALMUD: Would that satisfy you, Mr. Lieto?

MEMBER LIETO: Yes, it would. And what they are saying about doing the training on site right before it, this would not preclude it, I mean, and would be actually strongly encouraged, but what we're looking at is sort of the minimum requirements to get into a guidance document. So we can get these AUs on a license is what I am proposing.

CHAIRMAN MALMUD: I think Dr. Zelac wanted to make a comment.

DR. ZELAC: I believe that leaving any hands-on experience for after you already have somebody authorized is not a good regulatory approach. That individual if they have the authorization now goes somewhere else and present themselves as fully qualified when, in fact, if you had this two-step

process, they would not have had the experience that is required in order to be the AU.

CHAIRMAN MALMUD: Thank you for your comment, Dr. Zelac.

I will tell you what my concern is, that a third party, those to whom we report, would look at this and say, "Wait a minute. What they are proposing is that we train pilots in the air and we don't have simulators beforehand."

And we are trying to achieve the same safety record in terms of its positivity as airliners. And, yet, we are going to eliminate the simulator experience, the hands-on simulator experience.

So I think that you are in a weakened position by making a proposal. And even if this Committee approved the proposal, I'm not sure that when the Committee makes a recommendation higher up, it will be approved.

So what I am trying to do is to persuade you that the parties interested in public safety would be more satisfied. If you were willing to require the hands-on in phase one, which is the *in vitro*, and then move on, that would more than satisfy each of the parties here who has raised his or her concern and I suspect would satisfy those to whom we report who

would have this concern.

DR. SALEM: Please rest assured that I have been persuaded.

(Laughter.)

CHAIRMAN MALMUD: Thank you. We are trying to be helpful. The concern is the delivery of health care to the public in a safe fashion as is humanly possible from the perspective of radiation exposure.

DR. SALEM: Yes.

CHAIRMAN MALMUD: And, with that accommodation, is there someone now able to make a complete motion?

MEMBER EGGLI: We have a motion on the floor, which reflects that. And I would like to call the question.

CHAIRMAN MALMUD: And the question is now called. Yea or nay with the understanding that there will be hands-on experience in the course that is being offered now by both parties? All in favor?

(Whereupon, there was a show of hands.)

CHAIRMAN MALMUD: Any opposed?

(No response.)

CHAIRMAN MALMUD: Any abstentions?

(Whereupon, there was a show of a hand.)

CHAIRMAN MALMUD: You have a unanimous --

MEMBER EGGLI: No. Subir abstained.

CHAIRMAN MALMUD: Oh. You abstain?

MEMBER NAG: Yes.

CHAIRMAN MALMUD: One abstention. Otherwise you have unanimity. Thank you all.

Yes?

MEMBER GILLEY: I have an implementation question with this decision that you have made. When am I going to amend the license for them to be able to receive the SIR-Spheres? And usually we require the authorized user to have already completed the training.

So now you are going to ask me under a guidance document to amend the license for possession of the yttrium microspheres without having the cases completed. Is that correct?

CHAIRMAN MALMUD: No. I'll let that question go to an NRC staff member. Ashley?

MS. TULL: The step would be simulated cases. In the case of TheraSpheres, when you walk out of TheraSphere University, you can do a license amendment.

That AU is eligible to be an AU on a license. They go back to their facility, put in a

license amendment for NRC. Ninety days later you have an AU who is authorized for Y-90. So both the AU and the Y-90 are on the license. Then the manufacturers come in and do three proctored cases. Your AU is right in the middle.

Does that answer?

MEMBER GILLEY: That answers.

MS. TULL: Okay.

CHAIRMAN MALMUD: Dr. Nag?

MEMBER NAG: May I be allowed to explain why I abstained?

CHAIRMAN MALMUD: Always.

MEMBER NAG: Okay. The reason I abstained was that we are trying to fix a problem in two steps because of some regulation that is not correct in the first place. And my preference would be, even though it may take a long time, -- this would be a temporary fix -- in the long run, we fix the regulation itself.

What I would like to do is to know what would it take for the facility licensing to be allowed such that that an authorized user who is going to apply -- you know, you can have the facility licensing, I think -- there may be some way whereby a facility -- what I am saying is if we take the regulation itself, what are the ways to change the

regulation that will allow a facility to be licensed, saying that the AU has applied and is on the file?

So I am opposing that as a long-term solution. This would be a short-term solution.

MS. TULL: First clarification, it's not a regulation. It is guidance. First point, ACMUI came up with three cases and made the requirement for three cases. If you take out the requirement for three cases, which isn't going to happen, -- I understand that -- now you have an AU. You either have to be 390 or 490, go through a training program provided by the vendor. Now you are AU-eligible.

When the ACMUI said, "We want three cases," that is where it stops. And NRC realized that for specific medical licensees and said, "Let's do three simulated cases so that we don't stop at this point."

Does that answer your question?

MEMBER NAG: Not really.

MS. TULL: Yes. It's guidance. We can write it any way we want to. And this is how ACMUI has created it so far. Since I have been in charge of it, that has been the changes that I have made. It's based on ACMUI recommendation.

CHAIRMAN MALMUD: Dr. Howe?

DR. HOWE: I'm not sure I understood your question, Dr. Nag. If you want to put this into regulatory space, then you have to go through a rulemaking. And the first step to go through a rulemaking is for us to add something to the user need memo that notifies the rulemaking that we have interest in pursuing this particular aspect. That is your ultimate long-term decision and process.

MS. TULL: Can I respond to that to give the Committee information?

CHAIRMAN MALMUD: Yes.

MS. TULL: This is rapidly changing. How many times have I published this in the past year? Three times? This is not the time to put this into regulation. That is the past forward.

And I know that we want 1000 to go to regulations, but we need to get these problems solved in guidance space, where I can go back to my desk, type this, get it published a month from now. It's not you're going to do two years at a time.

DR. HOWE: I was in no way recommending that you not pursue guidance because guidance is your flexible method to as you learn experience to change what you are requiring. And it gives you the flexibility that you need right now, especially with

an emergent technology.

But, Dr. Nag, I think your long-term question was, how do we solve this long-term?

MEMBER NAG: Yes.

DR. HOWE: And long-term is the rulemaking process. And that is years.

CHAIRMAN MALMUD: Dr. Zelac?

DR. ZELAC: Just to state the obvious, this would be absolutely unprecedented that there be a possibility for a facility to be licensed for medical use without there being an authorized individual present at the facility who is qualified for the use of that material.

CHAIRMAN MALMUD: When you say "This would be," what did you mean by "this"?

DR. ZELAC: "This" meaning if Dr. Nag's suggestion that it be possible to license the facility before there is an authorized user.

CHAIRMAN MALMUD: Yes. Thank you. Thank you for making that point.

We understand your concern, Dr. Nag. And we as a Committee each have the same concern regarding consistency and practicality long-term. But to alter the approach to this particular problem using that method would delay it by probably a year to two years.

And our goal is to try to deal with the issue in the interest of the public being able to achieve therapeutic benefit under the best circumstances with regard to radiation.

And I think we have achieved that with this recommendation of Dr. Lieto and Dr. Thomadsen and yourself. And, with that, we thank you. And may we take a break now?

MS. TULL: Sure. It's your call.

MS. FLANNERY: We have not finished this presentation.

MS. TULL: There are two new proposed changes and nine from last year that have either been incorporated or are incorporated in part.

CHAIRMAN MALMUD: Do you want to do that before or after the break? It's up to you. Cindy, would you rather do it now?

MS. FLANNERY: I guess it's really up to how everybody feels, whether they need a break. I am fine either way.

CHAIRMAN MALMUD: Break. Take a break, just ten minutes. Ten minutes. We will be back here at 10 of 11:00.

(Whereupon, the foregoing matter went off the record at 10:40 a.m. and went back on the record

at 11:01 a.m.)

CHAIRMAN MALMUD: Thank you, everybody, and we will resume the morning session now as we continue with Item No. 11, excuse me, Item No. 12. Actually, you told us there's more things to be covered.

MS. TULL: Correct. These are new proposed changes and so the first one is to add wording throughout the document that reads similar to the licensee shall commit to. So that means that this, whatever is in the guidance will be written as a license condition in the licensee's license.

Two good examples, written directives, medical event reporting. As it currently stands, the licensee -- I'm not saying they won't, but they don't have to report medical events. If we say the licensee commits to, they're going to add a piece into their license that says we will report medical events in accordance with 35.3045, similar to that.

CHAIRMAN MALMUD: Does someone care to make that motion?

DR. VETTER: So moved.

CHAIRMAN MALMUD: Second?

MR. LIETO: Second.

CHAIRMAN MALMUD: Any discussion? All in

favor?

(Chorus of ayes.)

MS. TULL: Good.

CHAIRMAN MALMUD: It's unanimous.

MS. TULL: For the next one, this is based on the current permanent implant brachytherapy rulemaking where the wording of that for written directives reads, "the written directive shall include the date, the signature of the AU" and then everything else that was currently listed in the microsphere's guidance, so we're adding the words "the date and the signature of the AU" which is similar to the current rulemaking that's going on.

DR. VETTER: So moved.

MR. LIETO: Second.

CHAIRMAN MALMUD: All in favor?

(Chorus of ayes.)

CHAIRMAN MALMUD: Any opposed? It carries unanimously.

MS. TULL: All right, if you have any problems with commas or periods throughout the document, let me know. I made lots of changes there.

Now we're moving on to the recommendations from 2007 on this guidance document. The first recommendation was training should include at least

three supervised work experience cases. This was accepted. It's on page one, paragraph two, sentence three. I don't need any response from ACMUI really on that, just letting you know that it's incorporated.

CHAIRMAN MALMUD: Thank you.

MS. TULL: For the next point, the three cases do not have to be with a particular type of microspheres. We did not accept that recommendation. That was a 5-4 vote on the Committee and NRC staff decided that if you wanted to do TheraSpheres, you need to do TheraSphere training. If you want to do SIR-Sphere, you need to do SIR-Sphere training.

The next one, three cases do not have to be under the supervision of an AU. Under the old guidance, this would not have been accepted, but with the simulated cases pathway, we're not determining who has to supervise those three simulated cases.

For the last one, replace supervision paragraph with existing language from 35.690(c), this is accepted and I took some exact wording from 690 for supervision. That's on the first page of the guidance documents.

Next slide. Sorry I didn't have those up there.

For recommendations 12 and 13 from last

year, delete the sentence so that there's no attestation requirement for yttrium-90 microspheres users. There's no attestation requirement currently in the guidance document.

Next one, add a sentence, "the Applicant must provide and retain T&E documentation for an individual seeking authorization." This was Dr. Williamson's recommendation last year. That's accepted, and I just added a very brief sentence that said, "the Applicant must provide documentation for the above training and experience."

For number 13, add a paragraph to incorporate the team approach. This has been incorporated and was in there as at the last meeting, I believe everybody is okay with that.

For recommendations 38, 39, and 40, insert the wording "allow activity administers in the written directive." This was accepted. All throughout the document we had those dose versus activity issue. that has been incorporated throughout. So for written directives, it can be in activity administered.

Yes.

CHAIRMAN MALMUD: Mr. Lieto?

MR. LIETO: NRC, in their terminologies, use the term dosage rather than activity. It's in the

regulations and I guess I would just encourage you to maybe use that same terminology when referring to the activity as opposed to the absorbed dose.

MS. FLANNERY: Can I respond to that?

CHAIRMAN MALMUD: Cindy.

MS. FLANNERY: I don't think we can use dosage in this case because it's a sealed material. So dosage really only applies to unsealed material and since this is brachytherapy, we can only use the terminology activity administered.

CHAIRMAN MALMUD: Thank you.

MS. TULL: It's specified as N millicuries. I understand your point, Ralph.

MR. LIETO: I won't get on my soapbox.

(Laughter.)

CHAIRMAN MALMUD: On another occasion.

MR. LIETO: On another occasion.

MS. TULL: But the intent of ACMUI's recommendation of having dose-based -- sorry, activity-based has been incorporated throughout the document.

MR. LIETO: Thank you.

CHAIRMAN MALMUD: You're not alone, Ralph.

(Laughter.)

DR. THOMADSEN: On page two of the first

bullets where you do refer to -- oh, this is Thomadsen -- prescribed activity, you say millicuries or megabecquerels. Usually, it's in gigabecquerel unless you just like to say EG millicuries.

MS. TULL: So change M to G?

DR. THOMADSEN: That would be fine.

MS. TULL: Okay.

DR. THOMADSEN: Although if you wanted to free it from --

MS. TULL: Easy fix.

DR. THOMADSEN: Okay.

MS. TULL: No problem there. So for recommendation number 39, add a paragraph for medical event reporting. This has been added. I took basically the words from 35.3045 and made it fit microspheres incorporating the -- if the written directive is based on activity, then you need to have medical event report based on activities. Those two, they talk to each other.

Number 40, reinsert the paragraph procedures, should be performed in accordance with the written directive. This is something that was inadvertently was omitted last year. We propose adding it back in and ACMUI made a slight modification to just say it's done in accordance with the written

directive.

All right, the next one, 41, 42, and 43. Forty-one is to add a paragraph, experienced AUs. Experienced AU for medical use of certain type of microspheres can become an AU for the medical use of the same type of microsphere on a different license. This is similar to 35.14, which is the notification provision. So if you're at one facility and you're using them, you can go to another facility. That facility, the RSO could notify the NRC or the regulating authority within 30 days. This would need to be a licensed condition. So in the license, it would need to say we want to be allowed to use notification if we so choose. So it would be in there and then any time another AU comes in to use those microspheres at that facility, the facility could notify the regulating authority.

CHAIRMAN MALMUD: Okay.

MS. TULL: Very similar to what's being done for other uses. We just want it to apply to microspheres.

Okay, for 42, add a paragraph, training in the manufacturer's procedures, commensurate with the individuals' duties to be performed. ACMUI supported this recommendation as I proposed the change last

time. ACMUI supported the change. I just incorporated it word for word.

Number 43, revise the paragraph, "the written directive should include after implantation, but before release of the patient from licensee control." This was partially accepted. I think NRC tried to get to the gist of what ACMUI was saying, but the actual wording that we picked was before the patient leaves the post-operative recovery area. And Ron, if I'm not mistaken this is similar to rulemaking that's going on right now, words in current rulemaking. This mimics from that. So if you had an in-patient, they aren't actually out of the licensee control leaving the building. This addresses in-patient and out-patient.

I see some puzzled looks.

CHAIRMAN MALMUD: Just say it again, slowly.

MS. TULL: Okay, the way it would read, let's go to page two, bullet two, number two. So to say "the written directive shall include after administration, but before the patient leaves the post-operative recovery area, the date, the signature of the AU, the total dose activity", everything else that's included in the written directive.

CHAIRMAN MALMUD: Thank you. Ralph?

MR. LIETO: This post-operative.

MS. GILLEY: Weren't they done in a virtual suite?

MR. LIETO: Yes, they're done in the angio suites and there's not --

CHAIRMAN MALMUD: Post-procedural?

MR. LIETO: Well, you know, I guess if they're still in the hospital's premises, let's say they have a complication and have to be admitted for some bizarre reason. They've never really left the licensee's control. There's just something about that terminology that bothers me and I'm not really sure if I can put my finger on it. I would -- I guess I would like to still maybe think about keeping the licensee control. Because what you're saying is once they leave the suite, treatment room, maybe?

DR. EGGLI: This just has to do with the completion of the written directive. It doesn't have anything to do with any post-op complications.

MR. LIETO: Okay.

DR. EGGLI: This is just the written directive.

MR. LIETO: Maybe he --

DR. EGGLI: Who?

MS. TULL: Ron.

CHAIRMAN MALMUD: Ron, Dr. Zelac?

DR. ZELAC: Just for clarification, for Ralph's benefit, particularly. The idea is that it should be possible for the physician that conducted the procedure to complete the written directive at the conclusion of the procedure in terms of how much activity was impacted, etcetera. That's all it is.

MS. TULL: And this wording mimics the current rulemaking that's going on, so it's what's going to be in regulation which we kind of look at the regulations for medical event report, written directives and say let's translate that to microspheres. This is how it translates to microspheres.

MR. LIETO: I'm thinking also just like in a seed implant procedure where we want to keep this analogous to that type of a procedure, would that be the right terminology?

DR. NAG: Yes, because I think initially when we were discussing we said nights in hospital, but now that you have put forward the possibility that the patient may be an in-patient and could be there for a few days in a very few cases, then the post-op, immediate post-op area or post-procedural area would

be acceptable.

MR. LIETO: Okay.

MS. TULL: Is that acceptable? Okay.

DR. THOMADSEN: I would make it post-procedural as post-operative.

DR. NAG: Because some of the patients may not be done in the operating room, in a radiology suite, but you can call a radiology suite an operating suite.

DR. THOMADSEN: You can call my office that, but it doesn't make it one.

CHAIRMAN MALMUD: So Ashley, that would be bullet two, "after administration, but before the patient leaves the post-procedural recovery area, the" --

MS. TULL: I understand you. Replace "operative" with "procedural."

CHAIRMAN MALMUD: Yes, but also the punctuation there is a little -- it's "after administration, but before the patient leaves the post-procedural recovery area," --

DR. THOMADSEN: The colon is fine.

MS. TULL: The colon starts a list.

DR. THOMADSEN: It's a stop which would satisfy grammatically.

CHAIRMAN MALMUD: You'd put a colon there?

DR. THOMADSEN: I think you can.

DR. EGGLI: Yes, because a list follows.

DR. THOMADSEN: Yes, a list follows and this is completing the sentence that begins above, "the written directive shall include" -- pause, because of the colon -- "after administration, but before the patient leaves the post-operative recovery area." Then you've got another stop, the colon.

CHAIRMAN MALMUD: You've got a semi-colon, but that's okay.

(Laughter.)

DR. NAG: That's fine.

MS. TULL: Okay, so it will read, "after administration, but before the patient leaves the post-procedural recovery area:" and everything that goes in the directive.

CHAIRMAN MALMUD: A member of the public, please introduce yourself?

MS. FAIROBENT: Yes, Dr. Malmud, Lynn Fairobent with AAPM.

I just have a question on this paragraph two before you leave it based on this morning's discussion. The way this reads like Ashley just read it, it says that the signature of the AU has to be

obtained before the person leaves the post-procedural area. What is the AU is not on site? You went through this whole discussion where the AU -- it's just under the supervision of. Is this always going to be feasible to do?

CHAIRMAN MALMUD: You raise a good point. Thank you.

DR. THOMADSEN: In high dose rate, we have 24 hours, don't we, to --

MS. TULL: Is that right?

DR. NAG: No, only in the case of an emergency.

CHAIRMAN MALMUD: What is the practical recommendation, Dr. Nag? You participated in the proceeding.

DR. NAG: I participated in the proceeding where the AU would always in the procedure room and was involved always. No problem with that.

CHAIRMAN MALMUD: Mr. Lieto?

MR. LIETO: I have a question for our three rad. onc. members. In a brachytherapy case, is a brachytherapy administration ever one without the AU being present?

DR. NAG: No, it's done by the AU.

MR. LIETO: I know in some facilities I've

heard that the seed implant, sometimes urologists will put the seeds in, but isn't the AU always pretty much shoulder to shoulder or looking over their shoulder in those cases?

DR. NAG: In the places that you have described, the urologist may be putting the needle in, but the seeds are placed by the radiation oncologist, so -- but those -- I would say that the balance to that would be something like the ophthalmologist where obviously the radiation oncologist does not perform surgery on the eye and therefore the ophthalmologist places the radioactive material, but the radiation oncologist is there telling them how much to put there.

MR. LIETO: I guess I'll use that as an analogy.

CHAIRMAN MALMUD: You're on.

DR. EGGLI: I think this addresses the issue of sort of the definition of ready availability of the authorized user. And to me, out of the building or halfway across town really may not rise to the threshold of a ready availability. I can see authorized users two rooms down the hall, then they can amend the written directive before the patient leaves the post-procedural recovery area. If the

authorized user is halfway across town, one could argue that may not meet the ready availability requirement for the authorized user and maybe this regulation, with the guidance in this forum, would encourage the authorized user at least to be readily available on site, if not in the procedure room.

DR. NAG: I wholeheartedly agree with that. I was going to say something similar, that this would cause the authorized user to be at least nearby and yet it will not slow down the procedure because even if the authorized user is not there at the beginning, he would be there some time during the procedure to sign off on the case.

DR. EGGLI: I'm good with this.

CHAIRMAN MALMUD: Any other comments? Dr. Welsh?

DR. WELSH: I agree, that's the way it should be and I support it as written.

MS. TULL: I'm just wondering, one of the manufacturers -- no, yes? I don't mean to put you on the spot.

CHAIRMAN MALMUD: Dr. Putnam, would you care to comment?

DR. PUTNAM: I think an AU should be on site. I agree with everything that's been said, and I

think this would encourage an AU.

MS. TULL: Okay, Riad is shaking his head.

DR. PUTNAM: And I also think that IRs should be AUs.

(Laughter.)

MS. TULL: We will put that on the October agenda.

(Laughter.)

CHAIRMAN MALMUD: Dr. Zelac?

DR. ZELAC: Just one thing, for the record, the post-procedural entries into the written directive are not an amendment. They are completion of the written directive. There is a subtle difference there that has come up already. So I just want to be sure that that's clearly understood.

MS. TULL: Okay, so I think it's okay as written.

CHAIRMAN MALMUD: The wording is okay as written. It does not state that the AU must be physically present, but it assumes so and -- I'm sorry.

MR. LIETO: I was just going to agree with your point and ask that should we be explicit about that?

CHAIRMAN MALMUD: I would leave the

wording as it is, it that's okay with you.

MS. TULL: That's it.

CHAIRMAN MALMUD: Thank you. Having taken the break, we can now move to the next item on the agenda.

Dr. Howe?

DR. HOWE: Does ACMUI agree with all these changes?

CHAIRMAN MALMUD: Yes.

DR. HOWE: Did you vote on them all?

DR. NAG: I think we may have --

MS. TULL: These were all recommendations from last year and so you've already made a recommendation on that. I'm just showing where NRC has implemented them to kind of close the loop and make sure that everyone is okay.

CHAIRMAN MALMUD: Do you want to attest it once again? Is there a motion to attest it?

DR. EGGLI: Move to accept all the changes.

CHAIRMAN MALMUD: Is there a second?

MR. LIETO: Second.

CHAIRMAN MALMUD: Any further discussion?

All in favor?

(Chorus of ayes.)

CHAIRMAN MALMUD: Any opposed? Thank you.

MS. TULL: You'll see a draft.

CHAIRMAN MALMUD: We will clarify that for the record. Thank you.

We'll go to the next item on the agenda which is status of active petitions for rulemaking.

Dennis Rathbun.

MR. RATHBUN: Good morning. Dennis Rathbun, Director of the Division of Intergovernmental Liaison Rulemaking.

And I'm pleased to be here to talk about the status of several of our petitions for rulemaking. I'll ask Ashley if she'll operate the slides for us.

I came here last October and talked to you about petitions then and this is something of an update. So let's just go to the first slide.

The first petition for rulemaking is 35-18, one submitted by Mr. Peter Crane, a former NRC employee. And it dates from September of 2005. Mr. Crane requested that we partially revoke the petition release criteria rule contained in 10 CFRT 35.75 insofar as it allows patients to be released with more than the equivalent of 30 millicuries of iodine-131 in their bodies.

Mr. Crane also asserted that the

regulation was defective on legal grounds because the person petitioning the rule change in 1991 did so at the request and with the assist of the NRC staff.

I'm pleased to report that we've finished our work on this petition. I'm not at liberty to discuss the merits of what our actions are and it's been submitted to the Executive Director of Operations, so consequently it's pending management approval.

Let's go to the next one.

Petition for rulemaking 35-19 from Dr. Stein, a medical oncologist, dated from March of 2006, the action requested was that we establish training and experience requirements for authorized users limited to parenteral administrations requiring written direction of certain radioactive drugs used to treat cancer. My eyes are not quite that good. It's samarium-153, Quadramet, iodine-131, Bexxar, and yttrium-90, Zevalin, and that we recognize the following as adequate training and experience to retain authorized user status for parenteral administration of these drugs. That would be 80 hours of classroom and laboratory training and supervised work experience and written attestation.

The resolution on that one, we have

finished our work, resolved June 14th of 2007 and closed on October 24th of 2007. And published in the Federal Register as noted on your vu-graph there.

Rulemaking, we concluded, was not warranted, that the current regulations established the appropriate amount of training and experience for a physician to become an authorized user for the parenteral administration of unsealed byproduct material including Quadramet, Bexxar and Zevalin.

The last one, petition for rulemaking 35-20 from Dr. Ritenour which was received in September of 2006 and the action requested from Dr. Ritenour was to amend 10 CFR 35.7.57 to recognize that number one, that the medical physicist certified by the ABR and ABMP before October 24, 2005 when part 35, subpart J expired, as grandfathered, whether they were named on an NRC or agreement state license. And secondly, that all diplomates that were certified by the named boards in the former 10 CFR 35, subpart J, for the Radiation Safety Officer, whether they were named on the NRC or agreement state license. That one also, I'm pleased to say we have submitted to the Executive Director for Operations and is pending management approval.

And that concludes the status of where we are and if there are any questions, I'd be pleased to

answer them.

CHAIRMAN MALMUD: Any questions? Dr. Nag?

DR. NAG: I'd just like to know what is the meaning of pending management approval? That means it has been approved by a subcommittee and it's gone further to a formal approval? What does it mean?

MR. RATHBUN: Right, Dr. Nag. We have a petition review board of which I am a member and George Pangburn the Deputy Director of FS&E is the chair of that board. And we have a lawyer representative, previously Chip Cameron, now retired, and now Brad Jones. And Rob Lewis, and previously Jan Schlueter, and we receive input, our advice from a working group who review and analyze a petition request and then we make a determination after a considerable amount of work, really, and debate and discussion and make our own decision or determination and then forward our package, our recommendation through the management, through Dr. Miller as the Director of FS&E and Mr. Virgilio and Deputy Executive Director for Operations to the Executive Director for Operations and with our advice as to what should be done.

In some cases, for instance, the Commission may want to be involved and we may arrange

to have a briefing with the Commissioner's technical assistants and to inform them what we have recommended, but basically that's the process which Mr. Delligatti described in some detail this morning.

It takes time. It takes time. For instance, when we met last October, following that, our Petition Review Board met in December on at least one occasion, I think maybe two, and then the working group constructed their own analysis and brought it back to us. We had a lot of lengthy discourse, discussion with the lawyers, with respect to the adequacy of what we were doing and the advice that they offered, they provided important input to what we do and then we -- this takes a lot of time. Then we send it up through, as I mentioned, the Office Director, the Deputy Executive Director for Operations, and to the EDO. That's where we are on the last one, Dr. Ritenour's petition.

Yes, sir?

MR. LIETO: Are both petitions that are pending management review, the Crane petition and the Ritenour petition, are they both sort of in that same docket state, so to speak?

MR. RATHBUN: Yes.

MR. LIETO: That --

MR. RATHBUN: They're not formerly docketed in the legal sense, but conceptually, you're right. Yes.

MR. LIETO: And you don't have a sense of time frame when they'll be --

MR. RATHBUN: I think it should be imminent. I'm hopeful. I'm sure you know. We have a new EDO who is taking his poster job May 2nd and it would be good if we could get it done before that transition.

MR. LIETO: Is there anything that this Committee can do to shall we say expedite or encourage the process along?

MR. RATHBUN: Well, you're going to meet with the Commission.

(Laughter.)

You'll have your own issues that you want to discuss.

DR. NAG: Is it to be assumed that if it is pending management approval stage you are not allowed to discuss what you really recommended?

MR. RATHBUN: It really wouldn't be appropriate as Mark Delligatti described this morning. There are times, appropriate times to express your views.

MS. TULL: Dr. Malmud, this is Ashley. ACMUI has been sent these documents, so you are aware of what is going up. Okay. I just wanted to clarify that.

MR. RATHBUN: You're at least informed.

DR. EGGLI: I just have one more procedural question. You mentioned a working group. Is that the first stage of the petition review? Is a working group appointed to review?

MR. RATHBUN: Yes. I mean basically, the first real -- as I described last October, the first step really is to go through our Office of Administration and they will take a look at the material and the proposal, request for petition, and make some determination and then -- but the action office for handling the petition is my division on the material side and then there's a parallel activity on the inter-reactor regulation side.

It just takes a lot of time.

CHAIRMAN MALMUD: Thank you. Thank you for your presentation.

MR. RATHBUN: Thank you.

CHAIRMAN MALMUD: I'm going to move on. The next item on the agenda, NARM transition plan-up date.

Mr. White, welcome.

MR. WHITE: Good morning, everybody. Today, I'm going to give you an update from our last meeting in October on the NRC's implementation of the NARM regulations.

The purpose is to provide an update on NRC's effort to implement the requirements of Section 651(e) of the Energy Policy Act of 2005 for certain naturally occurring and accelerator produced radioactive material. The topics that I'll be discussing will be NRC's final regulations, associated guidance in support of the regulations, the transition plan to facilitate an orderly transition of regulatory authority.

The status of the final regulation, hopefully we all know that the regulations passed were published on October 1, 2007 and it became effective on November 30, 2007. The final regulations are responsive to stakeholder comments and incorporate model State standards.

As part of the NARM transition we decided that several of our guidance documents needed to be updated and we actually also developed one new guidance document, NUREG-1556, Volume 21 which is "Program-Specific Guidance About Possession Licenses

for Production of Radioactive Material Using an Accelerator." That guidance was published in October of 2007.

We also revised two of our guidances, NUREG-1556, Volume 13, and NUREG-1556, Volume 9. And NUREG-1556, Volume 13 was published in November of 207 and Volume 9 which was for medical use was published in January of 2008.

There's a 30-day public comment period for each of those guidance documents and we incorporated comments within the guidance as necessary. We also are making minor revisions to other guidance documents and inspection procedures. That's still in progress.

On August 31, the Commission issued a waiver to allow States and individuals to continue their activities involving NARM. And the Commission plans to terminate the wavier in phases. We decided we have three phases.

Once the waiver is terminated, all persons that possess the new byproduct materials in NRC jurisdiction just be in compliance with the new regulations, and will need to apply for a license within six months, apply for a license amendment within six months or apply for a new license within 12 months.

The Commission approved all the governor certifications for all Agreement States, which document that their States have a program for licensing the new byproduct material that is adequate to protect public health and safety and that they will continue to regulate these materials.

Therefore, the waiver has been terminated for all Agreement States.

Transition Plan, we'll get into the phases. We had Phase 1 which was implemented on the date that the rule was implemented. On November 30th, we terminated a waiver for the federal government agencies, federally-recognized Indian Tribes, Delaware, District of Columbia, Puerto Rico, U.S. Virgin Islands, Indiana, Wyoming, and Montana.

We also sent out a Federal Register notice on March 18, 2008 to indicate the Phase 2 states. And Phase 2 will be terminated on September 30, 2008 and I will tell you those states. And then Phase 3 right now we're expecting the waiver will be terminated in the summer of 2009, but no later than August 7, 2009 which is the final waiver termination date.

States that become Agreement States by august 2009 will have their waiver terminated coincident with the effective date of their

Agreements. So we have a couple of states that are possibly looking at agreements and so if they make the August 7th deadline, we will terminate the waiver going to their agreements.

The States and territories that will have their waiver terminated in Phase 2 are Vermont, West Virginia, Missouri, Idaho, South Dakota, Guam and the remaining territories and possessions of the United States.

Therefore, for Phase 3, we'll have Connecticut, Michigan, Alaska, Hawaii, Virginia, and New Jersey, depending on Agreement State status. Right now, it looks like Virginia is going to make the August 7, 2009 deadline. The other state that will be close to the deadline will be New Jersey, but right now we're not sure if they'll make that date and so we're working on internal procedures to try to avoid a whiplash effect.

(Laughter.)

We're still working on how we will do that.

NRC will assume authority for NARM-exempt distribution licenses upon waiver termination. Also upon waiver termination, NRC will assume authority for all Sealed Source and Device evaluations and

registrations for NARM in Agreement States without Sealed Source Device authority and for all non-Agreement States.

We're currently working on another regulatory issue summary which will basically summarize what I'll discuss and we'll also provide some Frequently Asked Questions and Answers that will be helpful to licensees. We'll also provide a Federal Register notice indicating when the third phase will be terminated, six months prior to the date of termination.

And for any current information on the NARM-related activities, you may go to the "NARM Toolbox" at this website.

Any questions?

CHAIRMAN MALMUD: Are there any questions? It appears there are no questions. Thank you, Mr. White, for your presentation.

That will take us to the next item on the agenda and that is the Status and Specialty Board recognition.

That's Cindy Flannery.

MS. FLANNERY: It's a standard item. The recognition status of the listed boards here has remained unchanged since our last meeting in October.

Of these boards listed that have applied for recognition of the certification process, all but three of them are currently recognized and listed on our website. The ABMP, the CBNE, and the CCPM, Canadian College of Physicists in Medicine, review of their applications will continue pending some supplemental information that NRC has requested.

As far as the American Board of Medical Physics, the last communication with them on September 2005 the Certification Board of Nuclear Endocrinology, our last communication with them, conference and email exchange, was June of last year. I think they're still interested in pursuing recognition status.

And the last one listed here, the Canadian College of Physicists and Medicine, they just submitted an application last fall, shortly before the last ACMUI meeting. We requested some additional information and the CCPM is pursuing some changes to their bylaws. They've sent out these proposed changes to their membership via newsletter and they're receiving comments.

The plan is for this organization, this specialty board, to vote on it at their next annual meeting, which will be in June of this year. And after that meeting, the presumption is that they're

going to submit those proposed changes and that supplemental information to the NRC so we can continue the review of their application.

At this time, NRC has not received a copy of those proposed bylaw changes. They have not been submitted. So that covers the three boards that are not yet recognized. As far as the remaining boards that are currently recognized and listed, their status also remains unchanged since the last meeting.

I guess just a comment on the American Board of Radiology, I have received communication from them that they have received requests from diplomates who have received their certification prior to the effective date. They are reviewing their qualifications on a case-by-case basis at the request of the individual. So I've mentioned that at the previous meeting that they have requested this approach and NRC was on board with that and they were actually starting to receive some requests. So right now, the American Board of Radiology is doing that for the diagnostic radiology specialty as well as the radiologic physics.

Another comment is just for awareness. The NRC published an article in the winter 2007 newsletter, FSME newsletter, that was just published

in February of this year and that article, the purpose was to raise awareness to diplomates out there that there are currently boards that are offering that for their diplomates, meaning that they will review the qualifications for those diplomates who got certified prior to the effective date on a case-by-case basis at the request of the individual and if they meet the current NRC training experience requirements, then the Board will revise their certificates, reissue new ones, to distinguish them as diplomates who meet current criteria and that way those applicants can submit their revised certificates for being listed as AUs, AMPs, and so forth.

So that concludes my update on the status of the specialty boards.

CHAIRMAN MALMUD: Thank you. Are there any questions?

Dr. Vetter?

DR. VETTER: Most, if not all, of these boards require diplomates to periodically go through recertification? Maybe we've asked this question before, I don't remember. So if I, for instance, my original certification from the American Board of Health Physics is in 1977, but every four years I have to recertify. So if my recertification comes after

January 1 of 2005, am I now qualified?

MS. FLANNERY: I don't think it works that way, no.

DR. VETTER: Is there anything to prevent that?

MS. FLANNERY: I don't know the answer to that. I don't know if there is other staff that could maybe help out.

CHAIRMAN MALMUD: Ralph?

MR. LIETO: Well, she's looking for an answer. I think there's a question right now, before I ask my question.

DR. HOWE: The criteria for being recognized was that the Board could confirm that all of its diplomates at that date met their requirements in 2002, and because the Board could not meet that standard for earlier dates, people are not recognized before that.

I think in how physics, you're not issued a new certificate, you're issued a recertification medallion and your Board certification date remains the original certification date. So I believe that your date is your date and it does not become a 2005 or 2007 or 2008.

DR. VETTER: But if I do not maintain my

certification, if I do not renew, then I cannot call myself, according to the bylaws of the American Board of Health Physics, I cannot call myself legally a certified health physicist.

DR. HOWE: But for NRC purposes, once you use your board certification to be on a license as an authorized individual, NRC is not concerned whether you keep that board certification up. You went through that pathway because you met the certification requirements that were recognized by NRC at the time you applied to become an individual. So you as an RSO may have used your board certification process many years ago to become the RSO at Mayo Clinic, and you are now an RSO and you use that standing to move to somewhere else as another RSO or to maintain your standing as an RSO.

DR. VETTER: Yes, I'm not concerned about myself, I'm concerned about my assistant RSO, who if I do not show up at work, would become the RSO, interim RSO, but he would have to go through the alternate pathway because his certification is prior to January 1 of 2005, but his recertification is after January 1 of 2005.

DR. HOWE: But one of the criteria for recertification is not that you meet the current

requirements in part 35. There are other criteria.

DR. VETTER: But they're independent.

DR. HOWE: Yes.

DR. VETTER: I'm still not clear on your answer.

DR. HOWE: My answer is that he is board certified on the date he was board certified.

DR. VETTER: That's the way the NRC interprets that.

DR. HOWE: That's the way NRC interprets it. Now if the Board were to come back and tell us that everyone they're recertifying now meets all of our criteria, we would take that into consideration, but the Board has not said that.

DR. VETTER: Have you ever asked who has not said that?

DR. HOWE: The Boards.

CHAIRMAN MALMUD: So then if I understand you correctly, Dr. Howe, if Dr. Vetter's Board were to communicate with the NRC and indicate that it regards the recertification of its individuals as being equivalent to being certified on that date that you would consider that?

DR. HOWE: We would consider it and they would make a statement that said that all of their

members met our current criteria as of the recertification date. We could distinguish those people that met our criteria from those people who did not. We would accept it.

CHAIRMAN MALMUD: Is that clear, Dr. Vetter?

DR. VETTER: Yes, that's helpful. Thank you very much.

CHAIRMAN MALMUD: Thank you. Any other questions, issues?

Mr. Lieto?

MR. LIETO: I have sort of a more generic one. The criteria for the recognition of the boards, is that explicitly laid out some place that's available?

MS. FLANNERY: Yes, the process is listed on our website. I believe it is just one bullet above the link that has this list of the recognized boards.

MR. LIETO: So is that process amenable to revision, the analogy being sort of like the guidance documents that we just labored over, is that the process on how and the criteria for recognition of that board, or any board, I should say.

MS. FLANNERY: I don't know if that question has ever been asked, so I don't know the

answer to that. Revising the process, Ron could probably answer that.

CHAIRMAN MALMUD: Dr. Zelac?

DR. ZELAC: It was a requirement set down by the Commission that there be a process established and in place and referenceable before we moved ahead with the rule in 2002. Excuse me, 2005. And that was accomplished. There was nothing that would preclude reconsideration of the requirements in that document, but I think what you're driving at really relates more to the resolution of the Ritenour petition at the moment, perhaps.

MR. LIETO: Well, I didn't have that in mind, but I guess I was looking for an alternate pathway.

DR. HOWE: This is Dr. Howe. I think it's also important to understand that the requirements that the staff is looking at to determine whether a Board meets the criteria for being recognized by the NRC are clearly stated in the regulations. So it is not an issue of changing guidance to recognize new boards. The criteria are in the regulations and they're in 35.50(a), .51(a), .55(a), .190(a), .290(a), etcetera.

And the process though can be amended, but

not the requirements without rulemaking.

CHAIRMAN MALMUD: Thank you. Other comments?

DR. ZELAC: Dr. Malmud?

CHAIRMAN MALMUD: Dr. Zelac.

DR. ZELAC: The purpose of that whole procedure was to lay out guidelines that would be clearly available and referenceable with respect to what it was that a board needed to do to become, have its processes recognized and what steps it needed to take to accomplish this, what steps it would need to take and would be expected to take once recognized in the future with respect to possible modifications in its certification process and who needed to be notified about that and in what time frame and the possibility of a board losing and the reasons for same, its recognition.

The whole process from beginning to end is laid out there and that's the intent and this has considerable input from our Office of the General Counsel was to make sure that there was something that would stand up to possible challenges.

CHAIRMAN MALMUD: Thank you, Dr. Zelac. Thank you. We'll move on to the next item which is Ashley's closing and then if we may, at the very end

of that just go over for a few minutes of a review that we will be presenting to the Commission.

There really are two topics, but three issues among those three topics.

(Pause.)

MS. TULL: First thing I have is ACMUI had requested the basis for only having one RSO on a license and I have the basis from OGC that I just received in my email, so I made copies. Just give the extras to me whenever they get to the ends, please. It's an internal NRC document. So please do. You can take it with you.

CHAIRMAN MALMUD: Thank you.

MS. TULL: You understand. The next document I'm passing around is the recommendations that you made at this meeting for review. And the last one is the action item.

I guess while those are coming around, do we want to discuss dates for the next meeting? I printed off a calendar and the ASTRO meeting is the 17th and 18th of October which is a Friday, Saturday and this room is available basically any date that we would want in October. ACRS is meeting much earlier in the month, the 1st and the 2nd, so we wouldn't be meeting that early. So I would ask, does the

Committee want a Monday/Tuesday date again? Do you want to try to tag on to the ASTRO meeting, either before or after? It's in Virginia. It's in Arlington, so it's close to the same time.

DR. NAG: What meeting?

MS. FLANNERY: No, I think it's in Boston.

DR. NAG: ASTRO in Boston?

MS. TULL: In Boston in October? I just looked at their website and there's something in Arlington, Virginia in October, the training.

MS. FLANNERY: It's in Boston.

MS. TULL: I just pulled it up on their website yesterday. There's something in Arlington, Virginia in October.

I wouldn't have made it up.

(Laughter.)

DR. NAG: Are you talking about ACRIN?

MS. TULL: A-S-T-R-O.

DR. NAG: Okay. ASTRO meeting is in --

PARTICIPANT: December 19th to the 25th.

MS. TULL: Right, that's on their website, but they also have something in October. If no one is attending it, it's not a problem.

DR. NAG: Don't they usually come up with model, a workshop? The ASTRO meeting is usually a

five-day event and not a two-day event. The two-day event are workshops and other meetings.

MS. TULL: Okay, their website says ASTRO's Transitional Advances in Radiation Oncology and Cancer Imagining is in Arlington, Virginia October 17th and 18th.

DR. NAG: That's usually a small working group.

MS. TULL: Okay, so that doesn't conflict with anyone here?

DR. NAG: I'm not a member of that group.

MS. TULL: Okay, so do you want a Monday/Tuesday meeting? Do you want Tuesday/Wednesday, Wednesday/Thursday? I would propose October 20th and 21st as a Monday/Tuesday.

MS. GILLEY: Can you move it earlier in the month?

DR. VETTER: Yes, 13 and 14?

MS. TULL: The 13th is a holiday, it's a federal holiday.

DR. NAG: Columbus Day.

MS. GILLEY: Can't we move it to different days than Monday/Tuesday then?

Could we do -- not have the 13th as a travel day?

MS. TULL: So the meeting would be the 15th and 16th?

DR. FISHER: I've got a conflict. It's the IRPA meeting in Buenos Aires.

MS. GILLEY: I thought it was the 18th through the 22nd, October 18 through the 22nd.

DR. VETTER: It's the 18th through the 24th or 25th and you've got to leave at least a day early so --

MS. TULL: So the 18th through the 24th, there's a conflict?

MS. GILLEY: Yes.

DR. VETTER: I would say the 17th for sure, maybe even earlier.

DR. NAG: The 14th and 15th would be open then.

DR. THOMADSEN: Fourteenth and 15th would be open.

MS. TULL: That would require travel on a federal holiday, I don't know.

DR. THOMADSEN: The 14th is a Jewish holiday.

MS. TULL: Okay.

DR. THOMADSEN: The 14th and 15th.

MS. GILLEY: What about the week before,

the first week in October?

MS. TULL: It's open. We can do 7th and 8th of October, 28th and 29th or 27th, 28th, 29th, 6th, 7th, 8th.

DR. FISHER: Seventh, eighth?

MS. TULL: Sixth and seventh would be a Monday/Tuesday.

DR. NAG: Sixth is Labor Day.

MS. GILLEY: October.

DR. VETTER: October 6th and 7th.

DR. NAG: Labor Day somewhere else. Labor Day in Australia.

DR. VETTER: Is the 7th and 8th possible?

MS. TULL: Tuesday, Wednesday?

DR. THOMADSEN: The 8th is Rosh Hashanah.

MS. TULL: Okay, we have another holiday on the 8th.

DR. THOMADSEN: October is bad that way.

CHAIRMAN MALMUD: Sixth and seventh, but you're not okay with sixth and seventh?

DR. VETTER: I can make it work. It's just I have to skip out on part of another meeting, third through the fifth.

Would the end of the month work?

MS. TULL: That's what I was going to say,

27th and 28th. Typically, it's the end of October anyway; 27th, 28th Monday, Tuesday. Do you prefer flying on Sundays, not missing work, or would you rather fly on a workday?

DR. NAG: Twenty-eighth, 29th, Tuesday, Wednesday?

CHAIRMAN MALMUD: Monday, Tuesday?

MS. TULL: Okay, 27th and 28th. If for some reason we have a major conflict and that doesn't work, what are the alternate dates, not the week before. Would it be early October, 6th and 7th?

MR. LIETO: Or maybe even later in the week?

MS. TULL: Twenty-ninth and 30th is holidays?

DR. THOMADSEN: No, the 8th.

MR. LIETO: I was saying keep it that same week but just moving it towards the end of the week.

CHAIRMAN MALMUD: Sixth and seventh would be second choice.

MS. TULL: Okay.

CHAIRMAN MALMUD: First choice is the 21st?

MS. TULL: Twenty-seventh, 28th.

CHAIRMAN MALMUD: The first choice is 27

and 28?

MS. TULL: Yes.

DR. NAG: The 29th and 30th would be an alternative.

MS. TULL: I don't know if there was a strong preference, but there was a preference to travel on Sunday, so people are not out of the office. It takes me six to eight hours to get here.

DR. FISHER: For me coming from the West Coast, Sunday travel really helps, because it's a full day.

MS. TULL: Yes. If you have a layover, it makes for a -- you can catch a direct flight.

CHAIRMAN MALMUD: So the first choice is Monday and Tuesday, October the 27th and 28th. And the second choice is Monday, Tuesday, October 6th and 7th.

MS. TULL: Okay, let's cover the recommendations from this meeting. The first one was that NRC should pursue rulemaking to allow more than one RSO on a license. We'll consider this recommendation. You're going to get a big under consideration memo after this meeting.

CHAIRMAN MALMUD: Yes.

MS. TULL: So I'm just going to state them

all and not tell you necessarily fast-forward.

CHAIRMAN MALMUD: Okay.

MS. TULL: For the second one, we would incorporate the 35.600 Subcommittee recommendations for gamma knife Perfexion for rulemaking.

For the third one, NRC staff should revise the abnormal occurrence criteria using Option 4 with amendments. The AO criteria should read "a medical event that results in one, death; or two, a significant impact on patient health that would result in permanent functional damage or a significant adverse health effect that would not have been expected from the normal treatment regimen as determine by an NRC or Agreement State designated consultant physician."

MR. LIETO: I'm just wondering, is there a document?

MS. TULL: I passed them around.

CHAIRMAN MALMUD: You have it.

MS. TULL: There's one that says recommendations and one that says actions.

DR. NAG: We got the action items.

DR. EGGLI: They look alike. You just have to read the label.

(Laughter.)

DR. NAG: I think it's an action item.

MS. FLANNERY: Here's some more action items.

CHAIRMAN MALMUD: Ashley, in this item, I have to poll the other Members of the Committee. When we use the word "normal treatment regimen" it raises a little anxiety in my mind. How about just eliminating the word normal. It's the treatment regimen.

DR. THOMADSEN: Yes, I think that was the intent.

MS. TULL: Okay, Region 1 is shaking their head.

CHAIRMAN MALMUD: Region 1 is what?

MS. TULL: I said they're nodding in agreement. They have no problem with that.

CHAIRMAN MALMUD: Dr. Thomadsen, you agree?

DR. THOMADSEN: I think that was --

CHAIRMAN MALMUD: Drop the word "normal."

MS. TULL: Okay. Any other comments on that one?

Okay, number four, NRC staff should incorporate the three simulated cases approach as stated in the proposed yttrium-90 microsphere brachytherapy guidance. Additionally, NRC staff

should add a statement in the guidance to address the three on-site proctor cases.

So I will create a version of this and send it to ACMUI for comments.

Yes?

DR. EGGLI: There was the issue in that too that the simulated cases had to be hands on for every individual.

MS. TULL: While other people were giving presentations, I was madly typing over there, so I'll use the transcripts for the exact wording of the recommendations. This is just so you have an idea of what I'm going for.

CHAIRMAN MALMUD: Was that your concern too, Ralph?

MR. LIETO: Yes, I'll wait for the official version.

MS. TULL: And you'll see the proposed guidance before it goes --

MR. LIETO: It was just the issue about the amendment to how the amendment process with NRC was going to fit into that guidance.

MS. TULL: That's not going to be dictated in the guidance. It will just be this is the piece you need to be an AU and then here's the after piece.

We don't tell people when to apply or how to --

MR. LIETO: Well, I think they need to understand when they go to the guidance document how they're going to get approved by the NRC. I mean that was the whole issue with the presentation by the vendors is how the new AU is going to get on a non-broad scope license.

MS. TULL: And as the guidance is currently written in your binders, they could get an AU license. It just doesn't say anything about the three proctor cases. NRC was not being prescriptive with that.

MR. LIETO: Well, I still have a very -- I'm very uncomfortable because the licensee that's going to go through this process, I think the NRC organization needs to understand where their various pieces fit into this and if I put in a license amendment to Region 3, okay, and they say well, wait a minute. Okay? Where are the three on-site and where's the three proctored --

MS. TULL: Wouldn't require the three on-site in that top piece.

MR. LIETO: Your guidance documents says that.

MS. TULL: Right.

MR. LIETO: But it's not going to state that to the regions. I mean how are the regions going to know this is how the process works?

MS. TULL: We'll talk to them. We've been talking to them.

MR. LEWIS: Whatever guidance we develop, we'll need to disseminate to our license reviewers.

MS. FLANNERY: I mean the guidance -- I think our path forward here is the guidance to incorporate the motion that was on the table.

MR. LIETO: Right, and the motion incorporated the aspect of the phase when they could apply for a license, what they had to provide for license amendment. It doesn't say that you have to be -- have the three on-site cases to apply an get approved on the license.

MS. TULL: Give me a chance --

MR. LIETO: That's what I was going to say --

MS. TULL: You'll see the guidance document --

MR. LIETO: You're saying that it's not going to be on there. I think that's a real, real serious deficiency in the guidance document.

MS. FLANNERY: It was my understanding that that would be incorporated in there, too. I mean, both parts of the motion.

MS. TULL: Simulated and proctored, separately.

MS. FLANNERY: Right, and ACMUI will have an opportunity to look at this guidance before it goes up on the website.

MR. LIETO: I just, why not just put that statement in there right off the bat?

MS. TULL: Of when the AU can apply?

MR. LIETO: Right, that this is what you need to apply for an initial, in the case of an initial AU where you're not approved, you need this piece first, okay, submit the license amendment, and then you have to provide the notifiable --

MS. TULL: You're an AU when you have three simulated cases. Correct?

MS. FLANNERY: I think what Ralph was saying was what was in the motion, there are two parts to it, but they both get included in the guidance. And what I'm saying is --

MS. TULL: They will be.

MS. FLANNERY: -- I think that's the plan. It's not just going to be that the first part, it's

going to be both parts.

MR. LIETO: Because I would not have made the motion that way if the AU can go walk away with the interpretation, I got those three simulated cases, you know, if I'm not there for the on-site training and so forth.

MS. TULL: Do you have any change to the recommendation then when I say additionally NRC should add a statement in the guidance to address the three on-site proctored cases?

MR. LIETO: The motion stated that. The motion stated that --

MS. TULL: So I won't incorporate it.

MR. LIETO: That there be three on-site cases had to include the team for that after they got the license amendment.

MS. TULL: Is there anything I need to change with this motion?

MR. LIETO: Huh?

MS. TULL: Is there anything I need to change with this motion like my -- I guess I don't understand.

DR. VETTER: When she listens to the transcript, she'll get it.

MR. LIETO: And that's fine.

CHAIRMAN MALMUD: I think, if I may, Ralph, I think what Ralph is saying is that there should be no ambiguity, if possible, and that the statement should incorporate three components. Number one, that there should be three simulated cases, three hands-on simulated cases. Secondly, an application for the authorized users status. And third, to complete it, the three on-site proctored cases.

Is that it, Ralph?

MR. LIETO: Yes.

CHAIRMAN MALMUD: And if that's a concise statement, that somebody wouldn't have to go looking all over the internet to find out how to put the whole thing together. The three steps are there.

Is that what you meant?

MR. LIETO: I mean, they're going to look at this guidance document as sort of being the complete course of action that they need to do. And if you don't say that --

MS. TULL: I think that's our understanding.

CHAIRMAN MALMUD: That's what you were going to do anyway.

MS. McINTOSH: Dr. Malmud, do you just want to restate the motion just to make it explicitly

clear what you're saying? You could do that.

DR. EGGLI: It's crystal clear.

MS. TULL: We're on the same page.

CHAIRMAN MALMUD: Ashley had it. I just want to translate what your concern was.

MS. TULL: Yes, you'll have a chance to see it before it gets published. So if there is something that you want changed or tweaked, it's the guidance document. You'll definitely see it. Just email me. You know I will respond.

(Laughter.)

MR. LIETO: No comment.

CHAIRMAN MALMUD: She can count on you, Ralph.

(Laughter.)

CHAIRMAN MALMUD: Ron, I'm sorry.

DR. ZELAC: I think it's worthwhile to note that the guidance document is intended for two audiences. One are those people who will be applying for use of the material, but the second is also for NRC staff and how to view the application that comes in and how to handle the application that comes in with respect to what's required.

CHAIRMAN MALMUD: Yes.

MS. TULL: Okay, for the last one, except

changes as proposed, this is yttrium-90 microsphere guidance, with one amendment we were substituting the word procedural for operative, so you'll see that change as well.

CHAIRMAN MALMUD: Yes.

MS. TULL: For the action items, NRC staff should provide the basis for the decision to only allow one RSO per license. This will actually be closed now. I just gave you a copy of that basis.

Number two, NRC staff should probably notify ACMUI members in a separate memo when an ACMUI recommendation is not accepted. I have made a note of that and I'll do my best to send you an email when that happens.

NRC staff should set up an NMED account for new Member Mattmuller. This is mainly a note for me. It will get done.

Dr. Vetter, Dr. Fisher, Dr. Thomadsen, and Mr. Lieto should assist NRC staff for the NAS project. I wasn't sure exactly sure how to word this, I wasn't totally involved in the conversation, but that the gist of it, NRC is going to consult with ACMUI. I'll pull something from the transcript to get an official action item there.

Number five, ACMUI should form a

subcommittee to discuss the permanent implant brachytherapy rulemaking which is 35.40 for written directives, and 35.3045 for medical event reporting. Subcommittee includes Dr. Nag, Dr. Welsh, and Dr. Thomadsen. This actually I don't believe passed. There was a vote, so I closed it out. No current subcommittee for this.

The next one, NRC staff should email Dr. Nag separately when the permanent implant brachytherapy proposed rule is published. I'll be sure to send an email to Dr. Nag. It will go to the entire Committee as well. But I'll make sure he sees something separately.

DR. WELSH: Can I ask to be included in that as well?

MS. TULL: Yes, the whole Committee will get it. It will go out on the medical list server, but I'll be sure to send it to ACMUI separately. Does that help? Okay.

The last one, NRC staff should arrange a public full Committee meeting. This will be approximately at the end of July to discuss the permanent implant brachytherapy rulemaking. NRC staff should send ACMUI an e-mail for potential dates. I'll send everyone an email. We'll discuss dates over

email for July. It will be a teleconference.

CHAIRMAN MALMUD: Thank you. That completes the items on the agenda. Now the -- now we're going to regroup elsewhere. It's in Building One, the conference room in Building One, the lower level.

MS. TULL: Correct, it's in the hallway. You don't even check in past the guard. You don't go anywhere on the elevators. It's just in that hall.

CHAIRMAN MALMUD: On the ground level.

MS. TULL: The ground level.

CHAIRMAN MALMUD: And that will be at 1:15 with the meeting at 1:30.

MS. TULL: Correct. Could I suggest maybe that around 1 o'clock or 1:05 that we meet in the lobby where everyone checks in with the security guards at Two White Flint and we could all walk over there and be seated.

CHAIRMAN MALMUD: We can check in here in this building in this lobby and then walk over there as a group. At what time?

MS. TULL: Say 1:05?

CHAIRMAN MALMUD: 1:05, okay. We can do that.

MS. TULL: I'm going to do some set up in

that room at 1 o'clock, and then I'll just come over.

DR. THOMADSEN: Can we leave our stuff in this room?

MS. TULL: Yes.

DR. THOMADSEN: Good.

MS. TULL: Are we coming back to this room?

MS. FLANNERY: We talked about it. It's up to the Committee.

CHAIRMAN MALMUD: It's safe to leave things here.

MS. TULL: Correct. You can leave everything here and I don't know if you want to come back and discuss anything after the Commission meeting.

MR. LIETO: I think what Cindy was referring to was a debriefing after the Commission meeting.

CHAIRMAN MALMUD: Whatever the Committee wants. I don't see the need for it, but if the Committee wants it, we will do it.

MR. LEWIS: I would not leave laptops here. This is an area that can be accessed by the public.

MS. FLANNERY: It's not going to be locked

during lunch.

MS. TULL: Theron can lock the room. You can leave your things here. Theron will lock the room.

CHAIRMAN MALMUD: Before we break up, there will be two discussants at the meeting with the Committee, with the Commission and they are going to be Drs. Eggli and Vetter. Dr. Vetter's issue is the fingerprinting and Dr. Eggli's issue is T & E. And the T & E is going to focus specifically on --

DR. EGGLI: It does two things. One is the issue of competency and the second is the alternate pathway and that's actually really two issues. One is the unintended consequence of forcing -- recognized Board programs to train to the alternate pathway and the second is the nature of the attestation on the true alternate pathway.

CHAIRMAN MALMUD: And our recommendation with regard to correcting the problem about the alternate pathway requirement for the Boards is for --

DR. EGGLI: The people caught in the gap between completion of residency and when they can actually take the Board is to allow these people an authorized user status based on their training directive certification of completion of all training

and experience requirements.

CHAIRMAN MALMUD: Thank you.

DR. EGGLI: And as it turns out what I'm going to mention is Florida has a precedent for this in place already. They actually call it an AU in training, but conceptually it's a similar process, so precedent exists for this in between process with the expectation that these individuals will become Board certified.

CHAIRMAN MALMUD: Thank you. With that, we can adjourn for lunch because we do have a tight schedule for lunch for you.

MS. TULL: Are we coming back here after the meeting?

CHAIRMAN MALMUD: As a group, we're not planning to, unless we decide at the end --

MS. TULL: If you want to leave your name tags here, you can. Unless you want them for the commission meeting.

Okay, I'll collect them as you leave the Commission meeting.

MS. FLANNERY: I don't know where mine is.

(Laughter.)

CHAIRMAN MALMUD: Ashley, I would be remiss if I did not communicate to you the feelings of

the Committee with regard to the amount of work that you've done in preparation and during here. We're all very grateful to you.

MS. TULL: Thank you.

(Whereupon, at 12:15 p.m., the meeting was recessed, to reconvene at 1:05 p.m.)