Official Transcript of Proceedings

NUCLEAR REGULATORY COMMISSION

Title: Advisory Committee on the Medical Uses of Isotopes
OPEN SESSION

Docket Number: (not applicable)

Location: Rockville, Maryland

Date: Tuesday, April 25, 2006

Work Order No.: NRC-984 Pages 1-278

NEAL R. GROSS AND CO., INC.
Court Reporters and Transcribers
1323 Rhode Island Avenue, N.W.
Washington, D.C. 20005
(202) 234-4433

UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

+ + + + +

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

OPEN SESSION

+ + + + +

TUESDAY, APRIL 25, 2006

+ + + + +

The Advisory Committee met at 8:30 a.m. in Balcony B in the Natcher Conference Center, Natcher Building (Building 45), National Institutes of Health, Bethesda, Maryland, LEON S. MALMUD, M.D., Chairman, presiding.

MEMBERS PRESENT:

LEON S. MALMUD, M.D.	Chairman
EDGAR D. BAILEY	Member
DAVID A. DIAMOND, M.D.	Member
DOUGLAS F. EGGLI, M.D.	Member
RALPH P. LIETO	Member
SUBIR NAG, M.D.	Member
SALLY WAGNER SCHWARZ, R.Ph.	Member
ORHAN H. SULEIMAN, Ph.D.	Member
WILLIAM VAN DECKER, M.D.	Member
RICHARD J. VETTER, Ph.D.	Member
JEFFREY F. WILLIAMSON, Ph.D.	Member

SPEAKERS AND PARTICIPATING NRC STAFF:

THOMAS H. ESSIG, Designated Federal Official, NMSS/IMNS/MSIB

CYNTHIA M. FLANNERY, NMSS/IMNS/MSIB

ANGELA McINTOSH, NMSS/IMNS/MSIB

CHARLES MILLER, Ph.D., NMSS/IMNS

ROBERT L. O'CONNELL, NMSS/IMNS/MSIB

I-N-D-E-X

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

(10:44 a.m.)

MR. ESSIG: Okay. As Designated Federal Officer for this meeting, I'm pleased to welcome you to Bethesda for the public meeting of the ACMUI.

My name is Thomas Essig. I am Branch Chief of the Materials Safety and Inspection Branch and have been designated as the federal officer for this Advisory Committee in accordance with 10 CFR Part 7.11.

Present today as the alternate Designated Federal Officer is Cynthia Flannery, Team Leader for Medical Radiation Safety within the Materials Safety and Inspection Branch. Raise your hand, Cindy.

This is an announced meeting of the committee. It is being held in accordance with the rules and regulations of the Federal Advisory Committee Act and the Nuclear Regulatory Commission. The meeting was announced in the April 11, 2006, edition of the Federal Register, Volume 71.

The function of the committee is to advise the staff on issues and questions that arise during medical use of byproduct material. The committee provides counsel to the staff but does not determine or direct the actual decisions of the staff or the

Commission. The NRC solicits the views of the committee and values them very much.

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

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

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

At this point, I would like to introduce the members of the committee that are here today -- Dr. Leon Malmud, Chairman, who is our Health Care Administrator; Dr. David Diamond, Radiation Oncologist; Dr. Subir Nag, Radiation Oncologist; Dr. William Van Decker, Nuclear Cardiologist; Dr. Douglas

Eggli, Nuclear Medicine Physician; Ms. Sally Schwarz, Nuclear Pharmacist; Dr. Richard Vetter, Radiation Safety Officer; Dr. Jeffrey Williamson, Therapy Physicist; Mr. Ralph Lieto, Nuclear Medicine Physicist; Mr. Edgar Bailey, State Representative; and Dr. Orhan Suleiman, the Center for Drug Evaluation and Research. Did I get it right this time, Dr. Suleiman? For the U.S. Food and Drug Administration.

Dr. Robert Schenter, who is our Patient Advocate Representative, will not be attending this meeting due to an illness. Dr. Malmud, as the ACMUI Chairperson, will conduct today's meeting. Following a discussion of each agenda item, the chair, at his option, may entertain comments or questions from members of the public who are participating with us today.

Dr. Malmud?

CHAIRMAN MALMUD: Thank you, Mr. Essig.

The next item on the agenda is the opening remarks of Dr. Miller. Dr. Miller.

DR. MILLER: Thank you, Dr. Malmud. I'd like to welcome both the committee and the members of the public to our spring meeting. The venue is different today. I apologize to anyone who may have had a hard time finding a place, although I would

think that you wouldn't, given the nature of this facility.

One of the things that I've noticed in just looking around is, since the configuration of the room is a little bit different, at various points in the meeting members of the public are recognized by the chair, Dr. Malmud, so that they can provide any comments that they want. In order for those comments to get on the record, they have to use a microphone.

And I don't -- do we have a microphone available, Mohammed, for the members of the public, or -- okay. We'll try to work to get something there.

I don't want to belabor the beginning of the meeting, so I want to get on with turning the meeting back over to Dr. Malmud, the chair, and get to our first topic. So, again, welcome and I appreciate your attendance today.

Thank you.

CHAIRMAN MALMUD: Thank you, Dr. Miller.

The next item on the agenda is the RIS on visitor dose limits to be presented by Dr. Sherbini. Dr. Sherbini will present the draft RIS on rapidly granting exemptions from regulatory dose limits for certain caregivers.

MR. ESSIG: I would just preface Dr.

Sherbini's remarks with the particular presentation that's included in the members' notebooks has evolved over what was there originally, because originally we were going to present an overview of the proposed RIS. And we received some very good comments from Mr. Ralph Lieto, and so we have restructured.

And I would note that he was the only one on the committee -- so I'm going to chastise the rest of you a little bit -- he was the only one on the committee who provided comments on the RIS.

PARTICIPANT: (Inaudible comment from an unmiked location.)

MR. ESSIG: That's not true. He was the only one that I was aware of. I'm sorry.

DR. SHERBINI: We received also from Sally Schwarz.

MR. ESSIG: Okay. All right. And Dr. Vetter also submitted comments?

MEMBER VETTER: If you are not getting all the comments, there is a problem.

MR. ESSIG: Okay.

(Laughter.)

Thank you for calling that to my attention.

For some reason, Mr. Lieto's comments

became the most visible ones. So --

(Laughter.)

MEMBER VETTER: And the by way, I e-mailed Sally the comments I gave to her that didn't get to you.

MR. ESSIG: Okay. I apologize, then, for the general chastisement. I was out of order.

(Laughter.)

PARTICIPANT: You can self-chastise.

MR. ESSIG: Yes, yes.

(Laughter.)

So we have -- because of the comments, we felt it would better serve our interests if we restructured the presentation to focus on the -- give an overview of the RIS and then focus on the issues.

Dr. Sherbini?

DR. SHERBINI: Thank you, Tom.

I will spend just a few minutes giving a background of where this RIS came from, and then concentrate on the comments. The comments were very good, and we know how to address some of them. We don't know how to address the others, and so we'd like your I guess advice on how to resolve these -- the issues that some of these comments raised.

Okay. This whole thing started with the

incident that occurred a couple of years ago at one of the hospitals in which a member of the public received a dose that was higher than the public dose limit. And after analyzing this case and reviewing the circumstances, the staff wrote a paper to the Commission suggesting that maybe people who take care of patients in a hospital situation should not be subject to dose limits.

The Commission liked the idea and approved the idea that we should not put dose limits on caregivers. So the Commission directed us to write guidance on how to do this. They also suggested that rather than leave it open we start with a limit of 20 millisieverts, and then go up if the need arises. Our experience so far suggests that 20 millisieverts should be sufficient for most cases.

But the method is still open, so that if more is needed it can be obtained. So the 20 millisieverts really can be viewed as an administrative limit, if you will, that can be changed as circumstances evolve. We started writing this RIS a few months ago. We have distributed it for review. It's still being reviewed, and the target date to issue this is June of this year. So that's basically the background.

This is one of the comments that we got. We thought when we wrote this that the parallel between the caregiver being exposed to radiation and the patient undergoing treatment is apt. But the comments suggest that it is not a good parallel.

The reasoning behind our thought is that the caregiver is viewed as an extension of the patient's treatment requirements. And so the involvement of the caregiver and the exposure to radiation of the caregiver is viewed as contributing to the patient's well being, and that really is the major justification for allowing a member of the public to receive a fairly high dose, that it benefits the patient. If it does not benefit the patient, then we really would not have any justification.

So I'm not sure if the committee thinks this is not an apt parameter. Sir?

MEMBER WILLIAMSON: Well, I think it does benefit the patient and maybe should say that and just drop the other phrases about the analogy, you know, between the patients actually receiving the treatment and/or diagnostic services to avoid this controversy. I think you can make the point directly without having --

DR. SHERBINI: Okay. That --

MEMBER WILLIAMSON: -- to defend the analogy.

DR. SHERBINI: Okay. We'll make that change, then.

This is an issue that we find very difficult to resolve, and we really need your help in that. How do we handle the situation of pregnant women or minors acting as caregivers who may receive high doses? We don't know how to address this, and we would appreciate some advice on that matter.

I mean, we had originally thought that we would leave it up to the hospital's policy, the individual hospital's policy, to decide whether pregnant women should or should not be exposed, minors should or should not be exposed, but it's unclear what the best approach should be in this case.

CHAIRMAN MALMUD: Dr. Sherbini, is your comment meant to be an open question for discussion?

DR. SHERBINI: Yes, we'd like some ideas of how to address this.

CHAIRMAN MALMUD: Well, may I precipitate the discussion by saying that there should be no exceptions for pregnant women and children, that they should not be caregivers because of the sensitivity of the fetus and a young child to radiation, which is

greater than that of an adult, given the size of the fetus and the developing physiology of the child.

DR. SHERBINI: Would it be acceptable to leave this up to the hospital's policy rather than make it an NRC policy?

CHAIRMAN MALMUD: Dr. Vetter?

MEMBER VETTER: I'd like to differ with the chair. From the standpoint of risk to individuals, we certainly would want to protect pregnant women and minors to much greater extent than we would other adults. But there are two things about this situation that are quite different I think than normal. One is we're looking at an extremely small -- I would predict we're looking at an extremely small number of people in the first place, and those who are pregnant and minors would be even a very small number. So we're looking at rare occurrences, I think.

The second is I think we need to consider what stimulated all of this in the first place, and that was an individual who you could argue is a caregiver or not in the true sense of the word, who wanted to spend time with her dying parent. So are we going to say a pregnant woman and a minor can't do that? I guess I would say that's going a little bit too far.

On the other hand, I think hospitals can take -- there are many, many steps they can take to keep those doses very, very low. But there might -- what I'm hesitant about here is making a black and white kind of a rule here that suggests that you would never allow a pregnant woman or a minor -- a minor to get more than 100 or a pregnant woman to get more than even 500, if we use the occupational limit. We would never allow that.

I think as a matter of policy, I personally think that's going a little bit too far.

CHAIRMAN MALMUD: Dr. Suleiman.

MEMBER SULEIMAN: I pretty much concur with Dr. Vetter's comments. I think -- first, I think an informed consent by the caregiver would maybe address some of the liability issues. Second, professionally, I think there is no reason that the doses can't be kept so low that I would argue very strongly that probably the risk to either a child or a pregnant female would be very, very, very negligible. We don't want to get into a risk discussion here.

CHAIRMAN MALMUD: Okay.

MEMBER SULEIMAN: But I think informed consent and keeping the doses as low as possible would

really ensure the safety. And I think what I have said all along is the caregiver really is not -- is neither an occupational worker or a member of the general public, so they should be treated as such. So --

CHAIRMAN MALMUD: Okay. Thank you, Dr. Suleiman.

The purpose of my initial comment was to stimulate the discussion, which obviously has occurred.

(Laughter.)

The next element of my question would be: to whom shall this responsibility be given? Shall it be the RSO of the institution involved or another party? Dr. Eggli.

MEMBER EGGLI: I think that this certainly needs to be done in consultation with the RSO, and I would actually like to come back to the first question for just a second, which is I think the guidelines that we use in handling accidental exposures of pregnant patients probably apply. And I don't think you'll find anything in any literature anywhere that with exposures in the 10 rem or less range where you'll find any evidence of any long-term adverse fetal outcomes.

So I think that setting an arbitrary limit that's low is not beneficial. But I think I like Orhan's concept of the informed consent, and that -- I think that that should be a combination of the physician responsible for the radiation exposure to the patient, and the radiation safety officer should clearly -- I think should clearly be involved as well.

I don't think it should be just the radiation safety officer. I think the -- that the radiation safety officer probably has no real relationship with the family members, but the treating physician does have a -- in theory should have a relationship with the patient and the family, and that that counseling should come from both the radiation safety officer and the treating physician to put it in a proper perspective.

CHAIRMAN MALMUD: Thank you, Dr. Eggli. How would you address the issue of a dying parent with a minor child? Who would sign the informed consent on behalf of the minor child?

MEMBER EGGLI: I would -- there would -- the likelihood is that if you have a dying parent, there may be yet one surviving parent who could sign that consent for the -- could sign the consent for the minor child. And, in fact, if the dying parent is

still legally competent, they are the guardian of that child.

CHAIRMAN MALMUD: Thank you.

Dr. Nag.

MEMBER NAG: I would like to propose that we separate the minor from the pregnant women, because perhaps, you know, they are -- I don't know about the exact dose limit, but there would be some difference between a pregnant woman and a minor.

The other thing is although the case that brought this on was about a dying parent with -- and the daughter, the same problem would occur on some of the things I need -- you know, I am exposed to when I treat a child and the mother or the -- you know, the parent wants to be taking care of the child even though the child has a radiation implant in them. And that's something that occurs not very frequently but perhaps once a year or so.

CHAIRMAN MALMUD: Other comments? Mr. Lieto.

MEMBER LIETO: Getting back to I think what Dr. Sherbini was asking before, he had I think asked the question: should this be something left up to the individual licensees to determine? I would say probably, yes, that would be what we would want to

recommend. But I think what needs to be included in this document is some guidance addressing that respective point.

I think that the -- that pregnant women and minors as caregivers should be strongly discouraged. The points that, you know, Dr. Vetter -- the circumstances that Dr. Vetter brought up I think need to be emphasized, in that, one, these are going to be very, very uncommon situations. And now we're talking about very extremes of an uncommon situation.

And do we want to try to establish a guidance document where something might come up once in a five-year period or something like that? I think we'd end up making a guidance document that's going to look at almost every possible variation of our imagination. So I think the guidance should be that it's strongly discouraged unless it's in the best interest of the patient as determined by the licensee's authorized users involved with the patient care.

CHAIRMAN MALMUD: Either Dr. Diamond or Dr. Schwarz was next. Dr. Schwarz?

MEMBER SCHWARZ: I disagree with Ralph. I think that being a woman and being able to be pregnant, I mean, certainly if I was faced with a

situation like this I really wouldn't want to be told that this is not possible. I think that certainly to be careful is the way to proceed.

And as far as guidance, maybe it is left up to the hospital. But certainly not that it's strongly discouraged. I mean, it's certainly not going to try to be in that position, but it may occur. And if that would occur, I certainly think that you need to be safe, allow the patient to be safe, but -- excuse me, the caregiver to be safe but not to say that that can't occur.

CHAIRMAN MALMUD: Thank you.

Dr. Diamond.

MEMBER DIAMOND: Yes. I would concur with Ralph's position. I believe that in this regulatory issue summary that there can be language included that this type of exposure, particularly to pregnant women and to minors, is to be strongly discouraged, and would be envisioned only under very exceptional circumstances, and that particularly under these circumstances there should be a discussion between the treating physician, with input from the radiation safety officer, with clear discussion regarding the potential risks.

And perhaps to go and be more specific

would be an example of overregulating, again, given that the number of occurrences expected per year would be less than one, and perhaps maybe one occurrence every fifth or tenth year.

CHAIRMAN MALMUD: Okay. Thank you, Dr. Diamond.

May I just summarize where we are at the moment? It seems as if we've heard four elements discussed. The first one is that it should be the responsibility of the licensee. The second one is that informed consent is an essential element, either by or on behalf of the minor.

The third is that there be safety precautions as part of the process, so that the usual barriers that are constructed -- a lead shield, for example -- for someone who wishes to stay in the room for a prolonged period of time, should be a requirement, as it would be if we were trying to maintain within the existing guidelines.

And the last element was not mentioned, but we did discuss it previously, and that is that there should be contemporaneous notification of the regional NRC office that this event is occurring, since it is a very rare event and would not flood the NRC with unnecessary data, but would keep them posted

of an unusual situation.

Are there other elements, or are there -- are there discussions of any of the elements that I've mentioned? Dr. Diamond?

MEMBER DIAMOND: Yes. Would you also include as a fifth point that the visitor be badged?

CHAIRMAN MALMUD: Okay. Badged. That's a fifth element.

And, Dr. Williamson, I think you had your hand up.

MEMBER WILLIAMSON: Yes. I think one element that was left out of your summary was the concept of while not forbidding minors and pregnant women to be caregivers, the concept of discouraging them.

CHAIRMAN MALMUD: Yes, thank you.

Other comments? Mr. Lieto? Was that your hand? Oh, I'm sorry. Dr. Eggli.

MEMBER EGGLI: Again, I would like to come back to Sally's comment that we have to pay attention to what the measurable risk is for a child or a pregnant woman. And you'll be hard pressed to find any literature that will quantitate any risk at these low levels, even up to 10 or more rem.

And regulating based on absence of

information of harm I think is not a good thing here, so that the strongly discouraging minors and pregnant women I think is an overdraw, that there is no evidence in the literature to support this. This is something that I deal with three or four times a year with patients who are exposed at a time that they did not realize they were pregnant. And what is the risk to the fetus?

If you want to look at the risk in the first 12 weeks, almost all mutations are lethal and the pregnancy aborts. After that, you can -- and there is nothing in the literature that says that 10 rem will do that. Nobody knows what that threshold is, but all early pregnancies, all mutations are lethal.

After that point, there is zero evidence that exposures even greater than 10 rem produce any medical effect in the fetus or in the child as the child grows. So I think strongly discouraging flies in the face of all existing evidence.

CHAIRMAN MALMUD: Okay. Thank you, Dr. Eggli.

Other comments?

(No response.)

Then, may I once again summarize? And I

think I've left a point out, so please add on to my comments if you will. The elements are: number one, that it would be the licensee's responsibility; number two, the licensee would notify the regional NRC of this unusual situation in a contemporaneous fashion; number three, informed consent is an essential element; number four, there would be discouragement of pregnant women and children from participating, but not exclusion as long as they are informed or the responsible guardian of the child is informed; number five, that obviously all safety precautions would be mandated -- lead shielding, distance, etcetera -- to the degree possible.

And is there one that I left out? Dosimetry badges. Okay, that was it. It was the badges.

So there are six elements in this. I think Dr. Williamson has a comment.

MEMBER WILLIAMSON: Some of the elements are common to everybody who is a caregiver, so I don't see why badges should be prescribed. And, you know, I think -- you know, it is made clear there should be some apparatus for monitoring everybody. Also, contemporaneous notification is required for everybody. I don't see why it needs to be

specifically mentioned in this case, since everybody is covered.

CHAIRMAN MALMUD: Okay. If I may, the reason I included contemporaneous notification is that it's the belief of some of the members of the committee that had there been contemporaneous notification with regard to the incident that precipitated this discussion that the outcome might have been different, since notification after the process is not quite the same and does not give the same opportunities for monitoring by the regional office.

MEMBER WILLIAMSON: Dr. Malmud, the whole point of the RIS --

CHAIRMAN MALMUD: Go ahead. Dr. Williamson.

MEMBER WILLIAMSON: I thought the whole point of the RIS was for anybody that is to be a caregiver that violates the 100 millirem rule there has to be notification in advance of the exposure.

CHAIRMAN MALMUD: Okay.

MR. ESSIG: Dr. Malmud, I was just going to inquire, would you consider making that -- your five points in the form of a recommendation that -- would that seem appropriate?

CHAIRMAN MALMUD: Yes. If that would be helpful, I think that in -- in creating --

MR. ESSIG: Or a motion?

CHAIRMAN MALMUD: In creating exceptions, the more clarity there is to the exception, the more likely is adherence to the exception policy. So that's why I included these elements. And if you wish, I will mention them again as a motion. Is that the pleasure of the committee?

In that case, there are -- I'll summarize again. The elements are: number one, that it becomes the responsibility of the licensee; number two, that the licensee will give the regional NRC office contemporaneous notification of this rare exception; number three, informed consent will be required; number four, there will be educated discouragement of pregnant women and children from excessive exposure; number five, that the standard safety precautions will still be in place, despite the fact that we've given exception for the dosimetry; and, number six, that there will be some measure of exposure of the parties.

MEMBER VETTER: What was that last one?

CHAIRMAN MALMUD: Some measurement of dosimetry badges. Badges.

Dr. Vetter asked what the last item was,

and he is correct in asking me to clarify it. That the individuals who are the subject of the exception will wear badges.

MEMBER VETTER: Okay.

CHAIRMAN MALMUD: That's a motion. Is there a second to the motion?

MEMBER VETTER: Second.

CHAIRMAN MALMUD: Dr. Vetter seconds the motion. Any further discussion? Dr. Miller.

DR. MILLER: I would like to further discuss it from a regulator's perspective. One of the points of the motion was prior notification to the NRC, and I guess --

MEMBER DIAMOND: Actually, I believe it was concurrent notification.

DR. MILLER: Okay.

MEMBER DIAMOND: Concurrent.

DR. MILLER: Okay. Fair enough.

CHAIRMAN MALMUD: I used the word "contemporaneous."

DR. MILLER: Okay. But that would still -- that would still mean notification to the NRC that the situation is taking place. And I guess the question I have, Sami, is from a regulator's perspective, would we consider that necessary? Given

the fact that, you know, our regulations provide for certain requirements for when notifications had to be made.

And I'm just putting the question on the table from a burden perspective, and I would be interested in my staff's view from a regulator's perspective in that regard.

DR. SHERBINI: No. We had not initially thought about having the licensee notify us when things like this happen. We were -- basically, once the exception is granted, then the burden is on the licensee to do the right thing without telling us basically, and that's the way it works in some cases that have been -- yes, sir.

MEMBER SULEIMAN: Dr. Suleiman. I'm confused. My perception all along was that the NRC wanted to be notified of this. I, however, agree that if you've got these controls in place it is business as usual, unless there is some overlying, serious, something that is -- scenario that is occurring. But I would -- I would agree. Why would you want to bother? It's just an additional bureaucratic step.

DR. MILLER: I guess to get it clear, Sami, what we would be looking for is, when such a situation presents itself, that the licensee would

seek an exemption?

DR. SHERBINI: Well, the exemption in many cases would be issued to the Department rather than to an individual caregiver. So the Department that handles many cases that require such a situation --

DR. MILLER: Okay.

DR. SHERBINI: -- would have an exemption to expose caregivers when the physician deems it appropriate to do so.

DR. MILLER: So it would be a request and an exemption. It would be a blanket exemption for --

DR. SHERBINI: Yes.

DR. MILLER: -- that licensee, not on a case-specific basis.

DR. SHERBINI: That's right. That's right.

DR. MILLER: So I guess the question that's on the table, then, is: having sought that exemption, and having successfully got it from us, we would be comfortable that they're putting the right steps in place.

DR. SHERBINI: Yes. Yes.

DR. MILLER: And if they're putting the right steps in place, then would there be a need for an individual notification every time a specific case

came up?

DR. SHERBINI: No. There would be inspections to check on the program.

DR. MILLER: Okay.

DR. SHERBINI: But --

DR. MILLER: All right. I think we've heard from our perspective. Now I'd be interested in the committee's reaction.

CHAIRMAN MALMUD: The next question -- the next comment was Mr. Lieto's, and then Dr. Vetter's. Mr. Lieto?

MEMBER LIETO: Yes. I think there is a little disconnect here. Where Dr. Sherbini is coming from is the assumption that the licensee is going to do this in advance, with the understanding this might occur. I think most of us on the committee side are looking at this. This is going to be a rare event.

We don't ever expect it to happen. But when it does, it's going to be something where you may only have hours or less to do anything about it, in terms of notification. And that's where this immediate notification -- I think where Dr. Malmud is coming from. And the example is the incident that initiated all this in 2002, okay, was -- it happened in a matter of hours that same day and included a

holiday.

So what -- you know, in those types of circumstances, and where I think this guidance document needs to come from, is both situations, where - the situation where Dr. Sherbini is coming from where the licensee might be doing a lot of these unusual types of research or therapies and wants to get a preapproved type of authorization. But I think it needs to address the situation that initiated this, which was something that happens, you know, that day or overnight.

CHAIRMAN MALMUD: Mr. Essig.

MR. ESSIG: If I may -- and I'm glad you brought it up, Ralph -- the situation that we're trying to address is the one that is the emergent situation. The one that the licensee anticipates we -- I can give you an example, because it is part of the public record, of the University of Pennsylvania has the license condition -- approval of exposures up to two rem.

And they had identified as -- and I've forgotten the exact treatment modality here, but the parent in this case was the one that would receive up to two rem. We approved that as -- approved our regional office granting that exemption, but that was

something the licensee knew about ahead of time, and just the nature of the situation prevented them from keeping the dose to the parent to 100 millirem.

But that isn't the -- I don't view that as the situation that was the subject of this RIS. The subject of the RIS is the emergent one, where there is -- the licensee finds himself in a situation -- as you noted, the event back in 2002 that triggered all of this was -- it evolved very rapidly, and so I think in this case what we're saying is the Commission has given us the authority to grant an exemption with very little justification for an exposure limit up to two rem for the individual licensee that notifies us that they're in this -- in this situation.

If they need to go beyond that in the judgment of the attending physician, then they certainly -- they certainly can. But we would grant a two rem exemption for that emergent situation with very few questions asked. It is more of a notification -- come into our Operations Center -- which is our 24/7 point of contact, and then we would follow up the next business day with the licensee.

CHAIRMAN MALMUD: Thank you for that clarification, Mr. Essig.

MR. ESSIG: And I might add that we are

going well beyond the point of this particular slide, which was on the doses to pregnant women and minors. I think we've kind of leaped ahead to some of the other points in the other slides, so -- so maybe before we go much further, Sami, if you want to catch us up to where -- Dr. Vetter had his hand up. Has your point been handled yet?

MEMBER VETTER: Well, just very quickly, I think -- maybe I'm the only one that's confused, but I think -- I think this RIS says we must notify the NRC. And, therefore, there is nothing different about what's in his motion. He is just reemphasizing that for a pregnant --

DR. SHERBINI: Maybe I should clarify this. Initially, whether it's a request that is issued -- that is put forward to the NRC long term or an emergency request, in either case the initial contact has to be notification of the NRC that the licensee would like to do this.

If, as Tom said, you have time, then you can submit an exemption request, and, you know, take your time to discuss with the region what you want to do, etcetera. If you don't have time, it's -- if it's an emergency, then the RIS has provisions where you can just call the NRC, say, "I'm going to do this,"

and actually go ahead and do it -- you know, if it's off-hours or whatever.

So either case, there has to be a notification initially to the NRC. If it's a one-time case, then after the notification it goes away. If it's not, then it gets added to the license.

CHAIRMAN MALMUD: Dr. Williamson?

MEMBER WILLIAMSON: Yes. I guess I'm very unclear. I thought this document was applicable in addressing only one-time requests. And every time a patient or their family fell into this situation, a separate emergency request would have to be made.

And now I'm hearing from Dr. Sherbini that actually this is describing -- this is a guide to how to prepare a license amendment to implement a standard variance from the regulations that any patient who comes, you could do this to if they've fulfilled these conditions, and you would not have to advise the NRC on a case-by-case basis. Is that correct?

DR. SHERBINI: Well, you know, the distinction isn't as sharp as it's stated. In either case, you need an exemption from a certain part of the regulation, either case. The difference is really how you're going to go about doing that. If it's an emergency situation, the RIS says that you have some

leeway in doing this in an unusual way.

If you do have time, then you do it the usual way that any exemption is requested. You know, you submit an exemption request from any part of the regulation of the NRC and describe it.

CHAIRMAN MALMUD: Dr. Sherbini -- this is Malmud -- may I ask, how often do you expect this to occur annually in the United States? Once a year? Ten times a year? A hundred times a year? Order of magnitude.

DR. SHERBINI: We estimate that it's less than five times a year.

CHAIRMAN MALMUD: Less than five times a year.

DR. SHERBINI: Yes.

CHAIRMAN MALMUD: That being the case, don't you think that it would be wise for the licensee for a variety of reasons, including the licensee's own interests, not to mention those of the patient and the caregiver, that the NRC be notified that this event is occurring in a timely fashion, meaning when it's necessary?

DR. SHERBINI: Well, it's a requirement. If this event is occurring for the first time, then the licensee is essentially going to violate the

regulations. Right? And, therefore, the NRC needs to be notified.

CHAIRMAN MALMUD: And that's the reason that I made the suggestion. I think it covers all parties well. And though I'm not in favor of excessive regulation, I am concerned that the licensee not put itself in a situation in which it can be criticized for having done something incorrectly --

DR. SHERBINI: Yes, sir.

CHAIRMAN MALMUD: -- and not having notified the NRC that it was going on, so the NRC could have, in its regional office, offered advice as to how to do it correctly, in a timely fashion.

Again, I'm -- my mind is keyed back to the event of 2002, so I'm trying to prevent that. Also, at the same time, human behavior being what it is, it's better that this be an exception. Otherwise, we begin to see exceptions becoming the rule and extending to circumstances that we did not anticipate.

Since this is a rare event -- as you estimate, five times a year or fewer events than that -- it would seem to me, though I'm not the NRC, that this is a burden which the NRC could share with us as providers, as licensees.

Dr. Suleiman. I'm sorry, who was -- okay.

Mr. Bailey.

MEMBER BAILEY: I have to put on my regulator's hat, which I guess is what I'm supposed to do. But I'm struck by the lack of information. We've got one case that we know of. Years ago we used to joke that every time something occurred regulators felt like they had to pass a regulation to prevent that occurring in the future or to make that event legal.

If we go with this exemption, I don't know why every single therapy license wouldn't come in to have an across-the-board exemption. And having done that, I will say, as would -- I hope I don't insult the doctors, but there are some doctors who would greatly abuse such an exemption.

I'm also struck by why we chose -- or why NRC is suggesting two rem when the occupational dose is five rem, and this is probably a one-time occurrence. It's like putting some magic on two rem.

If you're going to make it an exemption, then without much having to be done to exercise it, I don't know why it isn't simply in the regulations, that under certain circumstances it can occur, so that they don't have to come in but put a reporting requirement on it, similar to what you do with

misadministrations. You don't have to get permission to have a misadministration. All you've got to do is report it.

So to me, looking at this situation, we don't even know how many times it occurs. I think it occurs more than we think. It was only brought to your attention. And with the agreement states having 80 percent of the licenses, I think you're going to get a lot of different interpretations on how this can be administered. I think it needs to be very clear what's going to happen here.

CHAIRMAN MALMUD: Thank you, Mr. Bailey.

Dr. Diamond.

MEMBER DIAMOND: I'm actually -- I'm interested in the academic discussion, but I'm actually starting to get a little frustrated. This is getting a little silly. Emergency occurrences of the use of radioisotopes for these purposes should basically never happen, because that's what we're talking about.

We're not talking about the planned administration of therapeutic doses of I-131 to a five-year old child with a pediatric thyroid malignancy which has been planned weeks in advance in which the proper steps can be taken. We're talking

about the emergency exemption request for these exemptions to visitor dose limits. This should almost never happen.

We've been spending a lot of time and a lot of resources talking about one event in 2002. I think we can simply go issue this RIS with some common sense principles. There should be a reporting requirement, so that we can develop an N, the number of occurrences that have occurred in a prospective way. And I think it's time for us to move on.

CHAIRMAN MALMUD: Thank you, Dr. Diamond, for your practical approach.

Dr. Suleiman.

MEMBER SULEIMAN: Well, I was thinking nobody had mentioned reporting, and then Ed and Dr. Diamond both mentioned it. I think it's -- I believe this issue, depending on how you perceive it, is more prevalent than people will admit to. And I think there are a lot of people who receive significant doses and a lot of people who get to visit them.

But unless you define -- have some sort of a cutoff in terms of reporting, now everybody is going to start being monitored or looked at. And so maybe the -- for sake of argument, the 20 millisievert is a good number, above which, you know, they'll say,

"Well, let's report these to the NRC. We had so many caregivers. We actually receive -- you know, estimate to receive this much exposure or dose." Otherwise, you're going to get lots of reports.

And the two was just -- I don't care. You want to use five? You want to use one? I think, again, personally, I feel that anybody who practices good radiation safety should have those doses much lower than that. But out of principle, select a number and require those to be reported to the NRC, you know.

But I think this could be codified or come up with a policy or whatever. But if you don't have some sort of a number above which or below which -- otherwise, you're going to get overwhelmed with a lot of additional, unnecessary reporting criteria. But I do think this is much more prevalent. It's not just the dying patient. Some of these survive. And so I think a lot of people do visit them, and maybe getting more than you suspect.

CHAIRMAN MALMUD: I believe Dr. Eggli was next, and then Dr. Williamson. Dr. Eggli?

MEMBER EGGLI: I actually have two points. One is on your motion, Leon. And actually, we have a motion on the floor, moved and seconded, so this is

the discussion of a motion. I think on your dosimeter I wouldn't use the term "badge," because I think we want to monitor their exposure in real time. I would just use "dosimeter."

And, secondly, I have to agree with Orhan. I recently treated a child for thyroid cancer, and the mother wanted to know why we were placing so many restrictions on her, because the last time the child was treated elsewhere they didn't have any such restrictions about being in the room.

(Laughter.)

So I'm sure Orhan is correct about the issue of the practice. So I think that the concept, both as a standing exemption as the one granted to CHOP, and the concept of the urgent exemption, are both -- are both needed and are valuable, because it's out there and it's happening all the time.

CHAIRMAN MALMUD: Thank you.

Dr. Williamson.

MEMBER WILLIAMSON: Well, I would recommend that this current RIS be restricted to the single use emergency setting that would then, by definition, require, as Dr. Malmud calls it, contemporaneous notification of everything, including the pregnant women and minor children. And you could

ask that that be part of the information that is to be reported if such individuals are involved.

And I think it will be after some period of experience. It will be beyond debate, whether there's a large or small number of cases, and you can proceed to develop a rule accordingly on the basis of some empirical experience.

CHAIRMAN MALMUD: Thank you, Dr. Williamson. That being the case, it would satisfy the concerns of both Mr. Bailey and Dr. Eggli if we kept the motion as it stood, substituting the word "dosimeter" for "dosimetry" or "badge" and suggested that this be on a case-by-case basis.

It would also give the NRC the opportunity to see how many of these cases actually occur nationally, because right now we don't know. And it may be as few as Dr. Sherbini suggests, and, therefore, not terribly burdensome but very informative.

So the motion has been moved and seconded. If it's okay with the group, we'll substitute the word "dosimeter" for "badge" or "dosimetry" and recommend that this be on a case-by-case basis, since it is a rather unusual circumstance to the best of our knowledge.

All in favor of the motion? Oh, call the motion, excuse me. Oh, Dr. Williamson.

MEMBER WILLIAMSON: I'm sorry. I have a question, a point of clarification. I believe your motion is focused exclusively on pregnant women and minor children, and much of the discussion has focused on the general event, which would include adult caregivers. So perhaps you could restate fully the intent of your motion with all the changes.

CHAIRMAN MALMUD: In anticipation of the rest of Dr. Sherbini's presentation, which I'm sure includes the subject that you've raised, may I suggest that the motion be inclusive for all caregivers, including pregnant women and minors, and, therefore, an easily understood, clear policy, with no exceptions, which would allow for this unusual circumstance and which we believe all licensees would be able to understand and apply uniformly.

With that, is there agreement among the committee that that's how it should stand? Seeing no further discussion, we'll move it forward. All in favor?

(Chorus of ayes.)

Any opposed?

(No response.)

Any abstentions?

(No response.)

It is unanimous. Thank you, Dr. Sherbini.

DR. SHERBINI: Thank you, sir. Well, that's it for my presentation.

(Laughter.)

CHAIRMAN MALMUD: Your presentation was succinct and reached its target. Thank you very much.

DR. SHERBINI: Thank you.

CHAIRMAN MALMUD: If we may, we'll move on to the next item on the -- oh, excuse me, Mr. Lieto.

MEMBER LIETO: Yes. I have, well, more of a general statement in that I have a little bit of a problem saying that we're done here, because I have a real question about whether the RIS is really the way to go about sending out guidance to licensees as opposed to my understanding that the old Reg Guides, which are no longer used, but I guess it's the NUREG is the proper terminology for guidance documents.

I think what needs to be developed -- and the draft RIS that we have here is really not a complete guidance document for licensees to follow. And I think as uncommon as these things are going to occur, they're going to go to this Reg Guide and they're going to look for basically a step-by-step

procedure or protocol that needs to be followed, what information needs to be provided, and I don't find that as being this type of a document for providing that.

I think it's going to generate more questions to the licensee. I think what's here is an excellent, you know, effort, but I don't think it's complete. And as I mentioned also, information statements are, I didn't think, regulatory guidance. I may be wrong, but in looking at the way these -- what the definition is for an RIS, that's not what an RIS is defined to do.

And so, again, I don't think licensees are going to look for an information statement as a regulatory guidance document.

CHAIRMAN MALMUD: Thank you, Mr. Lieto. Are you suggesting that it might be helpful for the NRC staff itself to prepare a one page or less document which says that in those rare exceptions when the limits are to be exceeded the following steps shall be taken -- number one, it is the licensee's responsibility; number two, there should be contemporaneous notification of the regional NRC office of the exception; number three, informed consent will be obtained; number four, discussion with

the affected parties will discourage the exposure but not eliminate the exposure for pregnant women and children; number five, that all standard safety precautions for the purposes of reducing radiation exposure will be maintained; and, number six, dosimeter measurements will be obtained, wherever possible, to measure the exposure of the individuals, and that these records will be maintained by the licensee.

How does that sound to you? It's brief, it's readable, and it's understandable. At least I believe it's understandable. That was a question to you.

MEMBER LIETO: My gut reaction is that it's not going to be a complete enough guidance for licensees in light of what is in this information statement. I think there are some issues about real time monitoring and some other things that I think need to be resolved, because what you're suggesting and what's in this information statement, yours is very succinct and of a brief, general nature, but I think licensees are going to want more along the protocol type of a document to follow in being sure that all the bases are covered, and that they're not incomplete.

CHAIRMAN MALMUD: Would you care to give it some thought and come back to us at -- either via e-mail or at a future meeting with some recommendations for what you think would be complete? We've already discussed and moved on the motion, which has been approved. I'm sure the committee would appreciate additional ideas on how to effect this most efficiently.

So do you want to give that some thought, and then draft a memo?

MR. ESSIG: May I --

CHAIRMAN MALMUD: Oh, I'm sorry. Mr. Essig.

MR. ESSIG: I might be able to help with Mr. Lieto's concern. The regulatory issue summary is -- as you know, is one of our several different types of generic communications that the NRC has. We have used the RIS as a vehicle for promulgating short-term guidance where it doesn't require a rather detailed discussion. We've done this in several issues related to occupational radiation protection, and so on.

The preferred long-term approach would be to fold that document into a more traditional guidance document. In the case of the regulatory program for byproduct materials, the chosen guidance documents are

the NUREG 1556 series. And what we could consider as a longer-term solution is taking the guidance from the RIS after maybe some experience with it, deciding whether or not it needed to be amplified or diminished in some way, and then take that experience collectively, sunsetting the RIS and folding it into a NUREG 1556 series, the appropriate one of that serious.

So that would be the -- that would be the longer-term solution. But I believe it's consistent with the purpose of the RIS -- and Angela McIntosh is our generic communications coordinator -- and I believe that this would be a legitimate use of a RIS for promulgating the short-term guidance. Getting it into the public domain quickly is the idea.

The NUREG 1556, to amend one of those, is a rather significant undertaking. And we have done that, but it involves convening a work group of our regional staff, our headquarters staff, and it's a rather -- a long process to do. And so generally we find ourselves having to be rather picky and choosy which ones we -- which ones we tackle, because of the resources that it consumes to update a 1556 series document.

So that would be -- that could be -- so we

have a near-term and a long-term approach, and I think the near -- the RIS would be consistent with the near-term approach, and the NUREG 1556 would be a longer term approach.

CHAIRMAN MALMUD: Thank you, Mr. Essig. If I understood what you said correctly, what you're saying is this is a new process, let's have some experience with it, see what needs to be altered, if anything, and then refine it further if necessary.

MR. ESSIG: Just to clarify, the RIS itself is not a new process. I didn't mean to suggest that. It's just the content of -- this particular subject matter is new, and that we -- it would help us to gain some experience with it, because to -- as Dr. Sherbini noted, we really don't know how many of these are occurring per year.

I mean, one could argue that, well, we had the one in 2002, and to our knowledge that has been the only one. But as members have pointed out, there are probably others that have not come to our attention that have been occurring, nonetheless. So we don't know the true volume of these.

CHAIRMAN MALMUD: Thank you.

I think Dr. Williamson had another comment, then Mr. Bailey. Dr. Williamson?

MEMBER WILLIAMSON: Yes. I just wanted to comment that by supporting Dr. Malmud's proposal I am advocating that these six different points be included, you know, as kind of deliverables of the report, or as conditions that it must meet. I do not accept what I understood his contention to be, that his statement he just made, this very short, brief, terse statement can replace the entire RIS.

I do believe that there is a value served by describing more fully the basis of the situation and a lot of the details. So I am more in agreement with Mr. Lieto on that point.

CHAIRMAN MALMUD: I would only state that my terse summary was not meant to substitute for the RIS, but simply to explain the process.

And I think Mr. Bailey was next.

MEMBER BAILEY: My concern right now is how this document and this process will impact on the agreement states and the 80 percent of radioactive materials licensees in the United States. Whereas this may work well for guidance for NRC, I think this issue needs to be brought up to the agreement states to get some concept, because some states -- I just ran into a state -- in order to grant an exemption, they have to demonstrate that the practice will result in

lower radiation exposure than the regulation itself, which this certainly would not do.

And other states -- for instance, I would say I know at least one state where if you wrote to the Director and said, "Hey, I want to do this," and just said, "Hey, I've got this patient," that would be enough. So I really think this needs to be brought up to those -- to the agreement states and get some input on how this is going to impact them or not.

CHAIRMAN MALMUD: Mr. Essig?

MR. ESSIG: I agree with Mr. Bailey. And, in fact, we have done that. It has probably been two years ago now when the subject was broached during a routine monthly call with the agreement states, and those states who spoke out in favor of -- or that -- after understanding the situation, the approach that we are proposing -- I don't know that we had a RIS in mind even at that -- at that point, but we were thinking in terms of guidance versus rule, those two extremes.

And those who spoke out -- and they were rather vocal during that call -- favored the guidance approach and, hence, not the rulemaking approach. When we undertake a rulemaking, of course, we have to be cognizant of what the potential volume is going to

be of -- and if we don't see -- although the individual issue may have some significance, if the frequency is so low that -- you know, if we're talking less than five per year, then it's -- in many respects it's kind of hard to justify a rulemaking, and that's why we proceed with an exemption to an existing rule.

And so I think we can maybe resurface the idea to the monthly call with the agreement states. A couple years ago when we did that the view was that it should be in the form of guidance rather than a rule.

CHAIRMAN MALMUD: Thank you, Mr. Essig.

May we move on to the next item on the agenda, which is the rulemaking agenda. Mr. Lieto?

MEMBER LIETO: Well, you had made -- posed a question or a charge to me about coming back to the committee.

CHAIRMAN MALMUD: And Mr. Essig said that his staff would assist you with the process.

MEMBER LIETO: Okay. I was going to just say, to close us out, and maybe working with Dr. Sherbini on what has been done so far to come up with something in a precise manner.

CHAIRMAN MALMUD: Thank you very much.

And thank yo, again, Dr. Sherbini. Never

has so much been accomplished with one slide.

(Laughter.)

The next item on the item is the NARM rulemaking, and Lydia Chang of the NRC Commission will be the presenter.

MS. CHANG: Thank you. Again, my name is Lydia Chang. I'm with the Rulemaking Guidance Branch within the NMSS office.

Today I just want to an overview of the NARM rulemaking effort. First, I will briefly describe the Energy Policy Act, talk about the waiver that we have published last year, the rulemaking approach, the strategy, our current schedule, and give you an overall summary of the rule and the implementation consideration, and the next step.

As you know, the Energy Policy Act of 2005 was signed into law on August 8. Within Section 651(e) of the Energy Policy Act, it amends the definition of the byproduct material. It also amends the Section 274(b) of the agreement provision of the Act to include such material with an agreement that NRC might decide to enter with the states.

It also amends Section 81 of the AEA regarding the disposal of the newly-added byproduct material. It does requite NRC to issue a final

regulation within 18 months, which is extremely aggressive. It also allows NRC to grant a time limit waiver.

Within the Act, the definition of "byproduct material" is amended to include certain discrete sources of radium-226, and also material made radioactive by use of the particle accelerator such as accelerator-produced radioactive material and any other discrete sources of naturally-occurring radioactive material other than source material that we determine to pose similar threat in radium.

As part of the working group, we did not find any such isotopes within the NARM that will be included in the last bullet of that byproduct material. So today's talk will only be focused on radium-226 and also the accelerator-produced radioactive material.

The Act also limits the material to only for material produced for commercial, medical, and research activity. So we did not have the whole gamut of NARM. It's still limited somewhat.

The Energy Policy Act allows the Commission to grant the waivers, because the Act does not want the new regulation to impact industry immediately. So, therefore, on August 31st NRC did

publish a waiver, and I have placed a citation over here.

The waiver allows the persons engaged in activity involving NARM to continue with the activity, and also allows the states to continue to regulate the NARM material. As you know, quite a few agreement states already have regulations on their book to regulate such material.

The waiver is effective through August 7, 2006, for import and export. However, the waiver is effective until August 7, 2009, for other activities related to NARM. NRC may terminate the waiver sooner if it is deemed necessary.

Our rulemaking approach is to try to get the other regulators, the agreement states and non-agreement states, early into the process, so we did form a NARM rulemaking working group to working alongside with agreement states to come up with regulations. We also involved various offices from the headquarters, including the state programs, enforcement, OGC. We also involved regional people, so that they can give us the perspective from their day-to-day operations.

And, of course, we included quite a few states within our working group. From the states we

have representatives from the State of Oregon, Texas, Florida, and a non-agreement state, Michigan. We also include a state representative in our Steering Committee, so, therefore, all the decisions were made with the agreement states.

We also try to get the stakeholder involved within the whole process. We had a public meeting in November of last year. We also met with individual federal agencies, including FDA, EPA, NRC -- I mean, EPA and DOE, Department of Homeland Security, and a whole bunch of other folks, to try to understand their concerns.

We also included background documentation within our rulemaking website, at least keeping -- to keep the public informed about the rulemaking process. As I said, we had a roundtable public meeting back in November of last year, and here is just a summary. Ralph and Sally both attended the meeting, so they could probably share a lot more with you guys than I.

Here is the citation for the rulemaking website we created back in November of last year, and we also published availability notification. Right now, the address is -- it's kind of unique, since it has not been published in the Federal Register. Right now, it's filed under the other rulemaking manual.

Once it's published, then it will be filed under the proposed rule manual.

Again, the Energy Policy Act requires NRC to come up with the final rule within 18 months. It does require NRC to consult with the states, and also other stakeholders. They do want us to cooperate with the states and use the model state standards to the maximum extent practicable, and consider their potential impact on the availability of radiopharmaceuticals to physicians and patients.

In doing so, our strategy is to try to minimize adding new stuff. In our opinion, the accelerator-produced radionuclides are very similar to reactor-produced radionuclides. Therefore, they should be treated very similar to our existing regulatory framework. So that's our starting point.

We also look at the suggested state regulation, which is developed by CRCPD, which also includes NARM and other types of radioactive material. So we try to use that as the standard, since, you know, we do have 50 states, and the regulation might vary form state to state. But SSR does provide a very good, concise, and consolidated state position on NARM rulemaking, so we use that as our second thing to supplement the things that we don't have in our

existing regulation.

Since NRC has never regulated cyclotron before, we also kept in mind that Energy Policy Act does limit NRC authority to radionuclides produced for medical, commercial, and research activity.

We kind of evaluated, how should we regulate the material that is produced from accelerator, and we actually proposed to the Commission that we should regulate all materials, both intentionally produced and not intentionally produced, such as activated material, only from the accelerators that is designed to produce radioactive material for medical, commercial, and research activities.

If the accelerator does not produce material for its intentional purpose, then we do not wish to regulate them. An example of those kind of accelerators are linacs for radiation treatment, so that's -- that's like a very big decision that we have made early on and proposed to our Commission.

We also added some minor provisions to supplement the SSRs. We developed a specific requirement for radium-226. It has not -- we understand there is a lot of different kind of material out there that contains radium sources, but there are really no structured approach on how to

regulate them. So we did propose some approach for that.

We provide certain grandfather provisions for certain products, and also certain individuals. We also try to recognize FDA's and state programs, so we don't have to reinvent the wheel. We also try to increase inflexibilities within the regulation, so that we would minimize the impact on radiopharmaceutical industries.

The current status -- on January 3rd, we sent a draft proposed rule to both the states and ACMUI for an advance review. We did receive comments from them, and was considered and incorporated into the current draft that was forwarded to the Commission March 27th. And we've issued a SECY paper.

We did make the draft document available to the public, even though the Commission has not voted on it, and the provisions might change based on the Commission's decision. But we do want to make it available to the public, so that it can take a look, and also to allow extra time.

The final rule is required by the statute to be published on February 7, 2007.

Right now, I'm just going to summarize the type of changes we have included in the proposed rule.

We amended the definition, such as authorized nuclear pharmacist -- I forgot to the bring the byproduct -- oh, there is the byproduct material. That was a big one, you know, change the definition of byproduct material. But I just noticed I put it in alphabetical list instead, so we did redefine authorized user, authorized nuclear pharmacist, byproduct material, low-level radioactive waste, and waste.

We also added similar definitions within the regulations. A couple of them is actually direct adaption from the SSRs.

We also come up with a new definition of discrete source, as required by the EP -- Energy Policy Act. We kind of struggled with the definition quite a bit, and it has gone through several iterations during the drafting of such definition. I guess our primary purpose is that we only want to regulate material that's only designed for medical, commercial, and research activities.

And we also do not want to regulate diffused material. So in -- you know, when you put those two concepts in mind, this is a definition that we, along with several federal agencies, has come up with.

We have defined a source -- a source with

physical properties which is separate and distinct from radiation present in nature, and in which the radionuclide concentration has been increased by human process with the intent that the concentrated material will be used for its radiological property.

I guess the last two words are extremely important for the intent to use for radiological properties, because we do not wish to regulate T-norms, such as fertilizers or fly ash, from power generation -- from powerplants of such.

Some of the general provisions we recognized during general licenses -- a lot of those general licenses are already within the regulations, so we are basically adding radium to certain provisions within that, and also adding cobalt. We added non-radionuclides to the existing provision. In Schedule B, we added 13 radionuclides and have listed over here.

We also added radium to Schedule C, which is the emergency plan requirement. I very much doubt that it would have any impact on the medical community.

As for the radium source, we are proposing to have a general license approach. Since we are not certain of how -- how much material is out there and

what type of material, and the concentration of the radium within those materials, we are trying to do something like a graded approach.

Right now, we are proposing to use a general license for certain antiques, luminescence items that's stored in aircraft. And then, we put some kind of numerical numbers for less than 100 items that's not stored in aircraft, or 50 luminescence items that's not stored in timepieces, and other products containing radionuclides less than one microcurie.

And the reason that we want to use this general license approach in exemptions is because it still provides certain protection. It does require that -- the licensee to notify NRC for possible damages. It does require the -- it does require the licensee to dispose of it accordingly, and also prohibit any abandonment or export of such material.

And whenever we need information in a written request, they need to respond to us, so that we can address the general license more appropriately in the future.

As for the medical use, in our opinion, the non-PET radionuclide drugs -- it's really no different than radionuclides produced in reactors.

Therefore, there are no rule text change that's needed. For PET radionuclides, we only make some minor changes in Part 32 and Part 35. We do want to recognize FDA registration -- the register of the PET facilities by FDA or the states.

We are allowing non-commercial distribution between medical use, which is -- to us which is kind of important, because that would actually minimize the impact from radiopharmaceutical to be available to patients and to physicians.

And we are going to regulate all radionuclides production operations under Part 30 as possession and under Part 32 as distribution. We are including grandfather provisions for certain individuals, so that any authorized user that -- any authorized users that are currently recognized by the agreement state will continue to be recognized.

Some of the implementation strategy that we have proposed within the draft rule is to allow 60-day effective day from the publication of the final rule for federal facilities. For other individuals, since the waiver will still be in effect, the effective date will be depending on when the waiver terminated.

We are including special provisions that

has never been included in the past. In the past, NRC has used enforcement discretions. But for this situation, since we believe that a lot of individuals already have the NARM material in hand, we want to allow them to have specific authority to continue to use material, provided that they continue to use the material safely and comply with other regulations. So we did make a special provision in that aspect.

We are requiring the licensee to submit amendments if they already have the NARM material, to submit within six months from the effective day, or within six months from the day of the waiver termination. For any new license applications, such as cyclotron production operations, we want them to submit new license application within a year from the effective day, or within a year from the waiver termination.

NRC does plan to terminate the waiver sooner. Once we publish a final rule, we will terminate the waiver for federal facilities and Indian tribes. And then, agreement state termination will depend on when the agreement is updated and when the agreement states submit their certification.

For non-agreement states, we are planning to do probably in three batches, depending on the

state's intent to enter into agreement, or whether the state has any NARM regulations or not. We are planning to publish all those -- I mean, publish all those in the Federal Register.

The transition plan is required within Energy Policy Act, so NRC is -- it's preparing the transition plan right now, and the transition plan -- is planning to publish the plan sometimes I guess early next year when the final rule is proposed.

Again, the waiver will be terminated in stages, and it will be elaborated within the transition plan, and it will also be published in the Federal Register.

The waiver -- if we do not terminate the waiver earlier, then the waiver will automatically expire on August 7, 2009.

The next step -- the Commission paper was submitted to the Commission late March, so it's waiting for the Commission to make a decision. I understand that the Commission is planning to have a Commission briefing on May 15th, so perhaps a decision would not be made until after the Commission briefing.

Once the Commission gives us directions, then we will revise the proposed rule, and then publish in the Federal Register for 45 comment period.

And we are planning to have a public meeting during the public comment period.

That concludes my presentation.

CHAIRMAN MALMUD: Thank you, Ms. Chang. Are there -- that was great information. Are there any questions or comments? Dr. Williamson.

MEMBER WILLIAMSON: Could you please explain the second-to-the-last bullet on slide 4. Produced, extracted, or converted after extraction, before, on, or after August 8, 2005.

(Laughter.)

I'm having some -- I'm sure it means something, but I'm having --

MS. CHANG: Right.

MEMBER WILLIAMSON: -- difficulty inferring the intent.

MS. CHANG: Right. Actually, this is the language directly from the Energy Policy Act. The Congress' intent is to regulate all materials, regardless when it's produced. And the reason we include the word "on" -- I mean, "before, on, or after" is basically for legal purposes, so that we can regulate them. It's all materials.

CHAIRMAN MALMUD: Thank you.

Any other questions or comments?

MEMBER NAG: Yes.

CHAIRMAN MALMUD: Dr. Nag.

MEMBER NAG: Yes. I think I might be very stupid, but overall I felt this document really hard to understand. The language is such that it is very hard for me to follow and understand. But maybe that's because I'm very stupid.

CHAIRMAN MALMUD: I speak for the committee when I assure you that you are not stupid, and the document is difficult but not impossible. And it is a bit bureaucratic; however, it is addressing a number of regulatory issues which we as physicians might regard as being bureaucratic from our clinical perspective, but it is a document which explains things in detail, perhaps too excess but in detail.

But let me assure you that we all have a sense of frustration in tackling a document like this. And we do not challenge your intellect.

MS. CHANG: Let me just try to elaborate. Actually, the Federal Register -- it is somewhat cumbersome to review because of the structure. It's a rulemaking process. So the structure of the Federal Register, usually we have a lot of supplemental information that describes all the issues that we have contemplated, and how we come to the proposal.

And then, there's also a whole bunch of boilerplate language that's required by other statutory requirements, and then we have the rule text change. So I would suggest if you want to have better understanding of the document, you might want to start with the Commission paper, because that's more, you know, written for average people to understand. And it doesn't have all those legalese stuff, and doesn't have all those rule text type of language.

And another thing I would suggest is to just go back -- go to the back of the Federal Register where have all the rule text change proposal, just focus on Part 35 portion. That will probably help you to understand what type of changes that we are recommending.

CHAIRMAN MALMUD: Dr. Diamond.

MEMBER DIAMOND: Yes. From the medical perspective, the greatest impact, of course, will be on PET radionuclides. So looking at slide number 15, when you're discussing the -- when you're adding the 13 NARM radionuclides to Schedule B, exempt quantities, can you -- since I don't have Schedule B in front of me, can you give us a sense of what these exempt quantities are, how they will impact upon the clinical use of PET, and what about the nuclides that

you do not list on that slide which are also routinely used for PET imaging?

MS. CHANG: Yes. Actually, the 13 NARM radionuclides was added based on SSRs. As you know, with, you know, a year and a half of statutory timeline to come up with the final rule is extremely difficult. The Schedule B table, it's actually for exempt quantities. It lists the concentration below which -- I don't know, I think I might need other people to help me with that.

Donna-Beth might be able to help you elaborate, you know, the specific radionuclides exempt quantities.

CHAIRMAN MALMUD: Dr. Howe, I see you walking up to the microphone. We would appreciate your input as well.

Thank you.

DR. HOWE: I think one of the points that you have to keep in mind is that for exempt quantities and exempt concentrations, these materials are not allowed to be used on human beings. They're not allowed to be put into products that are ingested, put on people, or in any cosmetics or other products.

So the exempt quantities and exempt concentrations are outside of the medical arena as far

as your patient treatment goes. They are quantities that you may be able to use for laboratory-type tests or for quantification of materials.

MEMBER DIAMOND: So if I understand you correctly, Donna-Beth, this particular bullet point does not have any applicability to the routine clinical use of PET radionuclides, nor to the use of PET nuclides that are currently being studied in humans for new diagnostic or therapeutic purposes.

DR. HOWE: That's correct. Part 35 is the only section in which you can use radioactive materials on or in human beings. And the Part 35 already has regulations that permit research for medical use licensees, and that would be 35.6. And that just requires informed consent and institutional review board reviews. Or if you are under research that is already approved or funded by another federal agency, then that federal agency's requirements come in.

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

Are there other questions or comments? Dr. Williamson?

MEMBER WILLIAMSON: Well, it's just a very narrow technical question on slide 17. It says non-

PET radionuclides in drugs, no rule changes needed. So there is no non-reactor byproduct material that requires special mention in Tables B or C or anything like that? I'm quite surprised at the conclusion, although I'm not a nuclear engineer.

DR. HOWE: What we found was that our current regulations are written in such a way that for -- especially for medical use. Just redefining the material as byproduct was all that was needed for the regulations themselves. We did think that the PET production, the PET radionuclides, were a special feature, and so we did add some things to allow for non-commercial distribution of PET radionuclides between medical use licensees.

But for the most part, the regulations, as they stand, adding the new material into the definition of "byproduct," there was no need to change the words.

CHAIRMAN MALMUD: Thank you, Dr. Howe.

Dr. Van Decker.

MEMBER VAN DECKER: Thank you, Dr. Malmud.

I can assure you, Dr. Nag, that having grown up in north Jersey my ability sometimes to understand language is much worse than anyone else's.

(Laughter.)

Just a couple of questions. This public meeting I assume, therefore, is going to occur within the next month. Is that kind of --

MS. CHANG: It all depends on when the Commission approves the publication of the proposed rule. Once the proposal is published --

MEMBER VAN DECKER: So hopefully fairly soon. I was just getting a sense for that. Okay.

MS. CHANG: Yes. Once it's published, then we will put out announcements.

MEMBER VAN DECKER: Okay. The second question: can you elaborate a little bit for me on the last bullet on slide 17, what that summary was meant to mean?

MS. CHANG: Okay. That means any authorized users within agreement state or non-agreement state that's currently only using the NARM material and no other non-NARM material under NRC jurisdiction, which means that we have not been involved in the past. We do want to recognize these individuals, so that they will continue to be authorized users.

MEMBER VAN DECKER: Oh, okay.

MS. CHANG: Does that make sense?

MEMBER VAN DECKER: Actually, yes.

(Laughter.)

MS. CHANG: Okay. Good.

CHAIRMAN MALMUD: Thank you.

Dr. Diamond.

MEMBER DIAMOND: That was my question. Thank you.

CHAIRMAN MALMUD: Dr. Diamond's question was the same as Dr. Van Decker's. Both have been adequately answered by Ms. Chang.

Mr. Lieto.

MEMBER LIETO: I have a sort of more general question in terms of the whole rulemaking. Are things pretty much on schedule as far as staff was planning with this rulemaking process? And if the rule -- if the Commission delays or, I mean, I should say if they publish it when you expect them to, is that still going to -- is that going to keep things on your timetable? And if not, are there any plans to address possibly not meeting this 18-month timeline?

MS. CHANG: Based on our preliminary schedule that was shared with the public back in November, we were hoping that we can publish the proposed rule by the end of this month. Of course, the Commission has not made any decision, so that doesn't look likely. Therefore, there is some

schedule slippage.

Right now, we have not evaluated whether that will impact our final publication of the final rule. Once we make that determination, it's most likely that we will ask the Commission for an extension.

CHAIRMAN MALMUD: Thank you.

Dr. Miller.

DR. MILLER: Yes. I'd also like to point out that the Commission has scheduled a meeting with various stakeholders on the Energy Policy Act, scheduled for the 15th of May. I don't know if the Commission will vote on the proposed rule prior to that meeting or not. But as Lydia has pointed out, once the Commission has voted, then we'll have a better perspective on whether or not we can meet the date.

We've been trying to march as hard as we can to try to meet the date. They put in a plug for the team that did this. They worked many, many long hours. There were periods where they were in here on weekends until 3:00 or 4:00 in the morning trying to meet these deadlines. It was an extremely ambitious schedule.

We had to work very closely with the

agreement states, because obviously the agreement states and the non-agreement states have been regulating this material for a long time. We have not, so their insights are extremely important.

So we're doing the best we can, Ralph, and we'll have a better handle on it once the Commission has ruled on the proposed rule.

CHAIRMAN MALMUD: Thank you, Dr. Miller.

The next comment is that of Dr. Vetter, and then a member of the public. Dr. Vetter.

MEMBER VETTER: A question. Is it safe to assume that for medical use purposes that this new regulation has minimal or no impact on agreement states?

MS. CHANG: That's correct. That's a fair assumption, since agreement states are already regulating NARM material right now.

CHAIRMAN MALMUD: We have a member of the public. Would you please introduce yourself before your question or comment? Thank you.

MS. FAIROBENT: Yes. Lynne Fairobent with the American Association of Physicists and Medicine. I'm very confused over slide 18. On slide 18, the first thing it says is that there is an effective date of the rule 60 days from the date of publication.

That I understand.

Then, it says that license amendments or new applications don't need to be submitted until an additional six months or a year after that effective date. Isn't that, in fact, the effective date? This wording is just very different than I've seen from any regulation. I mean, is what you're saying that a license amendment basically would be, let's see, eight months from the date of publication, which would be the effective date for the license amendment?

I guess I'm confused over what happens between the effective date and that first six-month period, if you need a license amendment and the effective date and a year later. I've just not seen the wording like this before for effective dates and publication dates. I wonder if you could clarify.

MS. CHANG: Sure. If you can think about different individuals in different states, agreement states and non-agreement states, and also federal facilities, we are trying to impose different kinds of dates on different group of people, regardless -- I mean, based on the waiver.

You kind of have to separate the effective day. The effective day and the waiver are kind of related to each other. We have an effective day, but

the waiver is still in effect. Therefore, the effective day means nothing.

DR. HOWE: Lynne, let me try to clarify a little bit. This is a very unique rule in which we have material that is already being used safely and under regulations by many different people out there in agreement states and non-agreement states. One thing we didn't want to do was to stop the use of that material.

So we did something very interesting. We put an authorization in the regulations that permits people to continue to use the material, but holds them responsible to meeting all of the requirements in 19, 20, 30, all the appropriate parts of the regulation that would apply to this new byproduct material, provided that they, if they need to, submit an amendment request within six months, if they already have an NRC license; or, if they don't have an NRC license, then submit a new application within a year.

So the intent is to bridge that period of time in which people would need to get an official document from the NRC. We are holding them responsible for the regulations, i.e. reporting requirements, reporting medical events, reporting overexposures, reporting loss of material, during that

timeframe, but we're not going to hold them and issue them citations for not having a license at that point.

MS. FAIROBENT: My point is I know what I think the intent was. I don't think it's written clearly enough. And if I am a licensee with a PET facility in the State of Missouri, I have no clue what date I need to submit my brand-new license application to NRC. It appears to me that it's one year plus 60 days from the date of publication.

I think it would be easier to state it in that manner than to say one year from the effective date, which is 60 days from the date of publication. It may be actually easier to follow when there are actually calendar dates in there, but I think it's very unclear to the licensees or potential licensees at this point as it's written.

MS. CHANG: Yes. Actually, once the final rule is published, it would actually have the actual day within the Federal Register, and also within the regulation.

CHAIRMAN MALMUD: So, Lydia, are you saying that once it's published, then the final date will be known.

MS. CHANG: Right. The Federal Register will automatically insert the dates.

CHAIRMAN MALMUD: So the ambiguity will be gone at that point.

MS. CHANG: Right.

CHAIRMAN MALMUD: Thank you.

Is that helpful?

MS. FAIROBENT: We'll see.

(Laughter.)

CHAIRMAN MALMUD: Thank you.

Dr. Suleiman.

MEMBER SULEIMAN: Just a question, some numbers. Do you have any idea, or do you have an estimate of how many facilities are going to require a new license? That is, those facilities that are probably currently under non -- or not within agreement states that have PET facilities.

DR. HOWE: We did some estimates to try to come up with burden for OMB and for regulatory purposes. We think maybe about five percent of the current number of licensees that we have might be a ballpark number for new individuals who will need licenses.

We think most people that are licensed, either in NRC states or in agreement states, are already using radioactive material, and, therefore, already have a license. But there might be some

people that are, for one reason or another, only using this material and are not licensed at this point.

MEMBER SULEIMAN: So five percent is what absolute number?

DR. HOWE: We have about 4,000 NRC licensees, and so five percent of that. It's not a very large number.

CHAIRMAN MALMUD: Dr. Miller.

DR. MILLER: If I can further complicate matters, there's another aspect of this also in that non-agreement states who are currently regulating it may be pushed with this regulation to finally come in and want to become an agreement state. We've got so indication from a couple of states.

So along with this, we would also have a possibility of a non-agreement state applying for agreement state status, having that review take place, and if that review were completed prior to the -- you know, the expiration of the waivers, well, then, they wouldn't need an NRC license. They would simply come under the new agreement state agreement.

CHAIRMAN MALMUD: Thank you.

Are there other comments? Mr. Bailey.

MEMBER BAILEY: Lydia, just for clarification, if you had a stand-alone PET facility

operating now -- and we'll use Missouri since it seems to be the state of choice today -- who does not currently have an NRC license, under the suggested -- or under the proposed regulations, regardless of whether or not the practicing physician, RSO, pharmacist, met the requirements in the regs for byproduct material, they would be deemed to be qualified under the new license?

MS. CHANG: They would need to apply for a new license for the production, but individuals were deemed qualified, yes.

MEMBER BAILEY: Yes.

MS. CHANG: Am I correct, Donna-Beth?

DR. HOWE: That's part of our grandfathering process. We are adding to the definitions of authorized user and authorized nuclear pharmacist, that if you were a physician who was using only NARM material then you would be considered -- during the effective date of the waiver, then you would be considered an authorized user or an authorized nuclear pharmacist. And so that would cover over for the commercial PET centers also.

CHAIRMAN MALMUD: Mr. Bailey has a followup.

MEMBER BAILEY: Yes. You said NARM

material, but if there is one of those people out there that's still using radium-226, they would also be grandfathered to continue using radium-226?

DR. HOWE: That's correct.

CHAIRMAN MALMUD: Thank you. And now we know why Missouri is called the Show Me State.

(Laughter.)

Dr. Schwarz.

MEMBER SCHWARZ: Since I am the individual that comes from the State of Missouri, it is a wonderful state. But, for example, which is a real example, we are a broad scope license. We have a PET production facility, and now we'll have to apply, I'm assuming, for a license.

Do you know exactly what will be involved in terms of submission of this license for the PET facility? We have three cyclotrons, to add to the problem.

DR. HOWE: If your PET facility is in the business of commercial distribution, then --

MEMBER SCHWARZ: It is not.

DR. HOWE: It is, then, for non-commercial distribution?

MEMBER SCHWARZ: That's correct.

DR. HOWE: Then, we are permitting non-

commercial distribution under Part 30 and Part 35, if you don't need a 32 license. And so it would -- it would be simply adding the radiation safety program that would be associated with that PET production facility to your license.

MEMBER SCHWARZ: And if we then --

MS. CHANG: They don't have a license, because they are non-agreements.

DR. HOWE: Well, her facility has an NRC license. And so you would just amend your -- so you would be going for an amendment.

MEMBER SCHWARZ: Just an amendment.

CHAIRMAN MALMUD: Does that clarify the issue for you, Dr. Schwarz?

MEMBER SCHWARZ: And then, if we were to become a distributor, we would need an additional license, Part 30.

DR. HOWE: That's correct. You would need a 3272 medical distribution license.

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

There's another comment from a member of the public. Would you please introduce yourself before your comment?

MR. BROWN: Roy Brown with CORAR. I'm not

sure I really understand the answers here, because the question posed by Ed Bailey really said -- let's take Missouri. That's a great example. In Missouri, now I can operate a PET facility with a cyclotron distributed commercially without an NRC license, and without a state license, because the State of Missouri register does not list -- does not issue a license.

So if I have -- I really don't have an authorized user now that's approved on a license. I have what I consider an authorized user, but it's not on a license. So would they still be grandfathered?

DR. HOWE: What we've done is we've revised the definition for an authorized user. Now, in this particular case, you're talking about a pharmacy. And so the authorized user is really the authorized nuclear pharmacist.

MR. BROWN: Well, yes, but since they don't have an NRC license and don't have a State of Missouri license, they --

DR. HOWE: Right.

MR. BROWN: Yes, they're qualified, but they're not on a license.

DR. HOWE: If you are talking an authorized nuclear -- a nuclear pharmacist, then we have written into our grandfathering procedures, if

you are a nuclear pharmacist and you are dealing only with the material that are now under the byproduct, that you would be grandfathered, and you would be considered.

And the licensee, just as when we developed the nuclear pharmacy rule back in 1994, we allowed pharmacies to designate their own authorized nuclear pharmacist if they met certain grandfathering criteria. We've added that into 3272.

MR. BROWN: No, that's wonderful. I really, really like the grandfathering. I just thought you had to be tied to a license to take advantage of it.

DR. HOWE: No, you do not.

MR. BROWN: Okay. Great. Thank you.

MS. CHANG: And I guess one clarification is that for the authorized user we're allowing them to use notification instead of license amendment as part of the grandfather approach.

DR. HOWE: Yes, and there is also the notification provision for the authorized nuclear pharmacist that meets the criteria.

Now, I'm not sure how Missouri -- we'll address it in Missouri, because we do have -- for commercial distribution you have to be registered with

FDA, whatever that means, or you have to be registered with the state. And so I don't know if the states register the PET facilities as pharmaceutical production facilities or not. So we may have to do some tweaking on that part.

CHAIRMAN MALMUD: Thank you, Dr. Howe.

I will turn the podium over to -- oh, excuse me. Dr. Schwarz?

MEMBER SCHWARZ: In the State of Missouri, I believe that the nuclear pharmacies are all registered as pharmacies in the State of Missouri. So that would be the traditional nuclear pharmacies. The PET facilities are managed in several different -- well, two different ways. One is, as a nuclear pharmacy, they are authorized or registered as a state pharmacy, or they're registered as manufacturers which distribute to a nuclear pharmacy.

DR. HOWE: I think at this point we've got flexible enough wording in 3272 to capture both of those, but we'll look carefully.

CHAIRMAN MALMUD: Thank you.

Are there other comments? If not, I will turn the podium back to Mr. Essig for a moment, who will tell us about the next hour.

MR. ESSIG: Lunch.

(Laughter.)

CHAIRMAN MALMUD: Thank you. We have been informed. We'll rejoin at 1:30.

MR. ESSIG: And I believe there is adequate lunch facilities here.

CHAIRMAN MALMUD: Yes. Out the doors and to your left.

MR. ESSIG: To the left?

CHAIRMAN MALMUD: Yes.

MR. ESSIG: Okay.

CHAIRMAN MALMUD: Thank you.

(Whereupon, at 12:35 p.m., the proceedings in the foregoing matter recessed for lunch until 1:36 p.m.)

CHAIRMAN MALMUD: If I may, I'll call the meeting back to order. And the first item on the agenda will be presented by Roy Brown with CORAR assessment of the new NRC draft rulemaking to implement the Energy Policy Act.

This is an open session and we invite Mr. Brown to begin.

MR. BROWN: Thank you. Let me start off by thanking the ACMUI for allowing me to speak to you. I know you have a very, very full agenda. And I really appreciate the time you have given me to

present our initial thoughts on the rulemaking.

Let me also start off by commending the NRC staff. They have done a tremendous amount of work in a short period of time. We actually believe that the 18-month time table on this rulemaking is not very generous and the staff has done an incredible amount of work.

Also, it has been very, very helpful that the NRC released the NRC SECY paper. It allowed us to get a chance to review the draft rulemaking before it gets published in the Federal Register. It just gives us a little bit more time to digest everything that is in there. So we really appreciate that. And we would encourage that in the future. I know this is a special circumstance.

I'm going to skip this slide. I think most of you know who CORAR is. I'll just briefly say CORAR is a North American Trade Association for the manufacturers and distributors if radionuclides and radiopharmaceuticals. Most of the major manufacturers of these products are members of CORAR. So we are definitely a stakeholder in this whole process.

We have had a chance to review this draft rule now but these are only our initial thoughts. We really need to spend some more time on really digging

into this in more detail and determining what kind of impact this is going to have on the industry.

Let me talk about some of the positive aspects of the rulemaking first. First of all, we think that the NRC's classification of accelerators into three different categories is a very wise decision. We agree with this interpretation. We think that the proton therapy machines, those machines that are not designed to produce material and not being used for that purpose, we don't think there is any reason for the NRC to get involved with those. But what we do, CORAR has long supported NRC getting jurisdiction over the machines that do actually produce products.

So we agree with the NRC's classification of these accelerators into three categories. And then writing rulemaking to cover two of those three categories.

Also, we agree with the NRC's regulatory policy on uniform regulation, regardless of method of production. They talk about this in some length in the rulemaking. A good example is cobalt-57 which for years now has been -- you can produce cobalt-57 either in a reactor or in a cyclotron. We are glad NRC recognizes they are not going to make any distinction

of how this material gets produced. It will be regulated the same way.

So we strongly agree with that philosophy. We feel it is the best way to deal with these radionuclides.

Also, we had a little bit of a discussion on this a few minutes ago about grandfathering. We very much agree and very much appreciate the NRC's effort to grandfather in previously qualified, authorized users, or authorized nuclear pharmacists and RSO.

It was also very helpful this morning to get clarification that even if someone isn't an authorized user or an authorized nuclear pharmacist on a previous registration but not on the license, they too would be grandfathered in. So we think this is very important. We think this is a big step forward. It will dramatically help the rulemaking.

A couple more positive aspects. The way we read this draft rulemaking is looking at Part 30, looking at the emergency planning and the decommissioning funding in Part 30, we don't think those would be triggered by small PET facilities in the draft regulations.

Looking at the criteria under Part 30,

they don't meet the half life or the quantity designations to require emergency planning or decommissioning funding so we agree with this interpretation. Once again, we think this is a wise move on the NRC's part and we support this.

And lastly, the last positive aspect of the rulemaking, before I get into the negative ones, is the NRC's waiver that runs through 2009. Once again, this will allow seamless practice of nuclear medicine and seamless production of these NARM radiopharmaceuticals until all the dust settles on this new rulemaking and it is implemented with a new set of licenses and license amendments.

So we think this waiver is a very wise way to go. We think this will create really a seamless effect in the practice of nuclear medicine.

Okay, you knew this was coming. Some of the negative aspects, some of the concerns we have with the draft rulemaking. CORAR's big concern all along has been the lack of uniformity in the agreement states. And we don't think that the draft rulemaking has done much to address that.

And we recognize a lot of this problem is really not the NRC's problem. It is really an issue with the organization of agreement states and the

CRCPD. Although we are very strong supporters of the SSRs, the suggested state regulations, these are really not implemented uniformly among the states.

One of the major problems we have is the first bullet point here. In the past, we've had a great deal of difficulty getting new NARM radiopharmaceuticals approved in the agreement states. Some states don't actually go in and do the approval to review a new radiopharmaceutical. And we have some cases where it has been six, nine, ten, eleven months before a new NARM radiopharmaceutical will actually get approved in all 50 states and be able to be used in all 50 states.

So we really don't see anything in the new rulemaking that will make that any easier. We were hoping with some higher levels of compatibility, that may bridge us a little bit and create more uniformity. But we don't see anything there.

Also, we had raised before -- the second bullet point -- there are some state-specific product approval and labeling requirements. Some states require special labeling and special approval for products to be used in those states. Once again, this refers back to the level of compatibility and frankly we see a lot of the levels of compatibility we would

like to see higher in the draft rule.

The third bullet point here, sealed sources and device registries. These are handled differently by different states. The NRC, obviously, does it uniformly. But the NRC does not do it in the same manner as states do. And not all the states handle it the same way. So there is quite a discrepancy still here.

And we don't think the draft rule really addresses this. And once again, we know this is not NRC's jurisdiction but we were asking and pleading for NRC's help to try to get more uniformity through this rulemaking.

And lastly, all these kind of point to tho last bullet point, the level of compatibility we would like to see it higher, Category B in all new areas and even in some of the existing rules to promote more uniformity.

A couple more concerns, even though the NRC held a very, very productive workshop back in November that CORAR participated in and quite a few people in this room participated in, regrettably the regulated community really had no interaction with the steering committee, the NMSS, EPA, Energy Policy Act Task Force, or the NARM working group.

It would have been nice to have some interaction with that group. We know there was a rulemaking being written. But it would have been nice to work out some of these issues, some of the concerns we have with those groups.

Another concern we have is the new fee structure in Part 170. We are afraid this is going to negatively impact some of the small facilities located now in non-agreement states which will now, the future, be under NRC's jurisdiction. In the past they have very, very low fees or in some cases, no fees. In some cases, you know, a five-dollar registration fee in non-agreement states. And now they are going to be subject to pretty heavy NRC fees for license amendments, new license, and license inspections. So we are concerned about the impact on small licensees.

Some suggestions on what to do with the draft rulemaking. Once again, we would like to see a higher level of compatibility for both the new regulations and the existing regulations that are on the books for use of radionuclides in medicine.

We would also like to see some clarification on how NRC intends to regulate incidentally-produced materials on accelerators. The NRC really addressed in their preamble to the

rulemaking. They said they are going to regulate not only the material that you planned to make but the material you don't plan to make, things like zinc-65, europium-152, and -154 in the concrete wells surrounding the bunker.

There is really nothing in the rulemaking that talks any more about how NRC plans to regulate this. We realize this may take place in the guidance document but we really haven't seen ay guidance document or don't have any indication of what guidance docs will be out there when the rule is finalized. So that would -- any of that information would be helpful.

And lastly, although the NRC -- I'm sorry -- although the NRC promoted the use of CRCPD, suggested state regulations, we would like to see strict adherence to them to communicate greater uniformity. And once again, we realize that this is not completely an NRC problem. This is really a problem with the states but we will be making a similar plea to CRCPD and the organization of agreement states.

That concludes my comments. Once again, thank you very much for the opportunity to come speak to you this afternoon. And I think we have a few

minutes for questions maybe? Okay -- wait a minute, I'm sorry. I have one more slide here. I'm sorry about that.

One more suggestion we had is we are encouraging the NRC to take a look at exempting low energy PET cyclotrons. Some of the low energy PET cyclotrons, and once again, I'm talking here about cyclotrons that are less than 11 MeV or less. These are typically self-shielded. And as a result, there is not a high neutron field generated outside the cyclotron. So there is not a lot of neuron activation in the room surrounding the cyclotron.

So we think there may be some opportunity to there may be some opportunity here to summarily exempt certain cyclotrons like 11 MeV or less from some of the regulations. And lastly, CORAR would like to see at least one more workshop -- and it was nice to see this morning that, in fact, NRC does have one planned after the rulemaking is published. Now I'm done, thank you.

CHAIRMAN MALMUD: Thank you, Mr. Brown.

Are there any questions or comments for Mr. Brown?

Mr. Lieto?

MEMBER LIETO: Mr. Brown, could you

clarify in your -- I don't know which slide it is, but under the concerns that you are -- I guess the second bullet there where it says there is no plan to get NARM radiopharmaceuticals into the states faster than the current cumbersome process.

Are you saying that each individual state has to approve the accelerator-produced materials now? And that this rulemaking process would not solve that?

MR. BROWN: Yes, that's right. Each one of the states has their own process. And some of the states, some of the more progressive states they just say hey, does it have FDA approval? If it does, send us a copy of that, send us a copy of the package insert and a copy of the labels. You are good to go.

Other states say well, we have to review it and approve it, look at the radiation shielding, look at the labeling. And jump through several hoops before we can allow it in our state.

And let me just give you a short story here. A couple of -- not the last NARM product that was approved but I think two NARM products ago that was approved, the state in which this NARM product was manufactured, refused to review it and approve it for the manufacturer.

So the manufacturer -- that state said

well, go to an adjoining state. And as long as you have an adjoining state, and that is a state that touches the state the manufacturer was in, as long as you go to an adjoining state and get them to approve it, then we will approve it.

While this company went to all four of the adjoining states to the state where is it was manufacturer, three of the four said no, we're not going to do that. One of the four said we will approve it but you have to get another state to review. And then we will review it. Then the third state will approve it.

So you had to go through three state approvals o get it approved in the state you were producing it in. And it is that kind of silliness that we are trying to avoid.

MEMBER LIETO: Because it would seem like in Part 35, isn't there a specific phraseology that says that if it is an FDA approved --

MR. BROWN: For all byproduct material, yes.

MEMBER LIETO: Right. Well, this would now fall under that definition. So I think that would solve this problem wouldn't it?

MR. BROWN: I don't know. I think we are

still going to have a problem with some states wanting more information and wanting specific approval. And right now we have states requiring more than other states do.

And I don't see that changing unless the NRC can do something about making it a higher level of compatibility to say, you know, enough of that silliness. If one state approves it, you all should approve it. Like I said, that's what we are looking for is some help from NRC.

CHAIRMAN MALMUD: Mr. Bailey?

MEMBER BAILEY: Mr. Brown, are you talking about specifically non-agreement states or are you including agreement states and non-agreement states?

MR. BROWN: Some of the problem -- most of the problem is with non-agreement states. They are generally the source of the problem. But in some cases, agreement states are problems, too.

Yes, the one thing that will occur, and without having any level of compatibility associated with it is that the problem will go away or should go away in the non-agreement states because those states will no longer have authority to regulate their radioactive material.

Now I know in the past on some of the PET

facilities, the question -- when we got back to the argument of is this a pharmacy or is this a manufacturer, under the pharmacy laws, you could get all kind of differences. But once you go under the manufacturer and have FDA approval, I don't see that that should really be a problem. Maybe I have more confidence than perhaps you do, but I don't think in general agreement states want to argue about things that are already approved by somebody, whether it be NRC or FDA or, for that matter, another state. But this could be a problem. I'm personally not familiar with people doing things except -- particularly when we were looking at some of the new modalities.

And I think the problem in many cases was just lack of information about them. And under this new system, I don't see that those kinds of things will occur nearly as much as they have in the past.

I agree on the non-agreement states, I think the problem will go away because they will now be NRC states, if you will. But two of those three states I mentioned in the example were agreement states. And said, well, you will have to get somebody else to approve it. And then we will approve it kind of thing.

And, you know, if NRC could come up with

some leadership and say well, we will approve it. And then all the agreement states will say well, if NRC has approved it, after it has FDA approval, then all the agreement states will approve it. That would be wonderful. Does that make sense?

MEMBER BAILEY: Yes, it makes a lot of sense. And I'm just assuming that that will happen. Whereas you have these materials that were out there in never, never land as far as federal government was concerned before, I can understand and I know it occurs that some agreement states don't want to review things or don't feel that they have the staff or the time and they are not getting paid to do that or for whatever reason, it occurred in the sealed source and device registry where NRC actually said if you don't want to do them, then give it back to us.

Some states decided they we would retain the right to do the sealed source and device review. But as far as I know, once they are approved by -- and appear in the sealed source and device registry, everybody accepts them with very little change to them. So I think that is where we are going on these pharmaceuticals. I think the real problem before was hey, they are new. And somebody needs to review them. But hey, not me.

MR. BROWN: Yes, the manufacturers don't have a problem. We're glad to have anybody review it. We just don't want multiple approvals that take, you know, ten months to get them all from all the states.

CHAIRMAN MALMUD: Thank you.

MR. BROWN: Thank you.

CHAIRMAN MALMUD: We will now move on to the next agenda item which is Part 35 Training and Experience, the Status of Board Applications. It looks as if the presenter will be Cindy Flannery with Donna-Beth Howe and Ron Zelac. And the NRC staff will present that status of applications submitted for recognition by the various specialty boards.

MS. FLANNERY: Good afternoon. I'm just going to be providing a status on specialty board recognition and updates since the ACMUI meeting last October. And this first slide here just gives a definition of some terms that are used on the categories in the next slide for the recognition of specialty boards.

Approved means that the board has met NRC's criteria. Their certification process has met NRC's criteria and they have been notified via letter that they are recognized and they post it on the NRC's website.

Under review means that additional information was requested of the specialty boards by NRC. And that supplemental information has been received and is currently under review.

And awaiting input means that that additional information has not yet been received from the board.

And this table just lists the nine boards that have submitted applications for recognition of their certification process. Six of those nine boards are currently recognized. And a couple of the boards here, namely the American Board of Radiology and the American Osteopathic Board of Radiology have specialties. And so in the case of the American Board of Radiology, the specialties are in various stages of the review process. But right now the radiation oncology specialty is currently recognized.

And this last slide is just a copy of the website where the specialty boards are listed and the sections of the regulations that they are currently recognized under.

And that concludes my presentation. And we can open it up for discussion at this time.

CHAIRMAN MALMUD: Dr. Williamson?

MEMBER WILLIAMSON: Yes, can you explain

why the American Board of Radiology is approved for 490 and 690 only from January 2007 forward? What is wrong with the certifications issued before that date?

MS. FLANNERY: Yes, in the cases of future dates, the boards have had to make changes to their certification process to meet NRC's criteria. And in this particular case, they had to distinguish candidates who have received their work experience under AU and have met NRC's criteria from those who have not. And namely that is for under 390, it is required to obtain work experience under an authorized user. And they had to make changes to their certificate by putting the words AU eligible above the seal of the certificate. And that will go into effect in June of 2007.

MEMBER WILLIAMSON: So the sole problem was that the head of the residency program was not an authorized user? Can you explain in more detail what the problem was say for 490 which is brachytherapy?

MS. FLANNERY: You mean the program director?

MEMBER WILLIAMSON: Yes, I don't understand. So --

MS. FLANNERY: It is not always the case that the program director is an authorized user. So

in the case of -- if they are involved in the case experience, for example, in 390, the case experience say, for example, the three administrations of iodine-131 just as an example, the person who would be attesting to that case experience may not be an authorized user. It could be a program director became the case experience, it is not required that that attestation be -- the boards are not required to include that as part of their program. That is up to the individual.

MEMBER WILLIAMSON: Let's see if I -- I'm still confused. I'm sorry. Can you explain more clearly why radiation oncologist who has gone through an approved residency and presumably done brachytherapy under an authorized user by the laws of the state or the NRC regulations, why their board certification doesn't not count towards becoming an authorized user?

MS. FLANNERY: How the application was submitted is just put all the 390, 490, and 690 all together. And didn't separate them. Does that answer your question? I'm sorry.

MEMBER WILLIAMSON: No, it does not. So for 490 -- which is 400 -- 35 400, which is brachytherapy --

MS. FLANNERY: Right.

MEMBER WILLIAMSON: -- if I understand, you are concerned that there are some diplomats of the American Board of Radiology that never had brachytherapy training? Never had case experience with brachytherapy? And the reason you reject all board certificates before 2007 is because you think the American Board of Radiology was not adequately tracking that? I'm really not clear what you are saying.

MS. FLANNERY: In the example I was giving before, I was referring to 390.

MEMBER WILLIAMSON: Yes. I'm talking about 400. My last three questions have been about 400.

MS. FLANNERY: Okay. As far as the application, the 480, 690, and 390 were just all put together. The application did not separate them. So somebody who is certified in radiation oncology would meet all three of those criteria, in 390, 490, and 690. And they weren't separated.

And so the board had put -- I guess requested that as an effective date.

MEMBER WILLIAMSON: What do you mean was not separated? What was not separated? Why whom?

MS. FLANNERY: The Board submitted the application for 390, 490, and 690 all together. And the 390 criteria could not be met until June of 2007.

CHAIRMAN MALMUD: Dr. Vetter was next. And then Dr. Diamond.

MEMBER VETTER: Several of these boards have recertification requirements so I'll just pick mine. I'm certified by the American Board of Health Physics. And every four years I need to get recertified. So if I am recertified after January 1 of 2006, am I qualified under this rule?

MS. FLANNERY: Under --

MEMBER VETTER: This says certification after June -- January 1 of 2006 for training for radiation safety officer.

MS. FLANNERY: No.

MEMBER VETTER: And if the answer is no, which I anticipated it would be, what can the board do to rectify that? In fact, if you look at my experience or the experience of the physicists who work for me, they all far exceed -- because of their current experience, they far exceed the requirements but they took the boards before January 1 of 2006. So shouldn't these boards be able to rectify that in the sense of recognizing the experience that these

individuals now have?

MS. FLANNERY: The board could, on a case-by-case basis, on behalf of the individual say that the individual has met the criteria. But not for an entire year unless they looked at all the individuals who have received their certification in that year. That's the only way it could be done.

Or if the board is willing to do it, they could conduct that review on a base-by-case basis.

MEMBER WILLIAMSON: All right. Under the current structure, that makes sense to me that one of my physicists who has 20 years experience doing about everything you can do in medical health physics and is certified by the American Board of Health Physics previously but now under my supervision has worked with HDR and gamma knife and you know, you name it, they have worked with it, on a case-by-case basis, that individual, it seems to me, should be able to get approved under this process, as long as the board has established with you a procedure whereby they would individually examine that person's record as part of their recertification process. Does that make sense? Am I making myself clear?

MS. FLANNERY: Yes. The American Board of Health Physics, for example, had to make some changes

to meet the criteria. And the effective date in this case would be January 1, 2006. The only other option if the Board is not able to review it on a case-by-case basis, would be for that individual to get recognized by the alternate pathway, which is submitting documentation for the training and the experience.

MEMBER WILLIAMSON: Just one more brief question. Is the mechanism currently in place for boards to do that? Or is this something that they would have to propose to the NRC? Because it seems to me there are plenty of -- I think the same thing would hold true of other boards, too. There are lots of people out there who are currently qualified under the way that the boards are currently defied -- that is you define the requirements for each board. They evaluate the candidates.

These candidates who were certified years ago and now have all of this experience working under an authorized user or an RSO or medical physicists, if they were to take the boards today, they would qualify. The fact of the matter is they took it a long time ago. And it is only because they took it a long time ago that they don't qualify.

So if there is a mechanism for the boards

to individually review and approve those individuals when they go in to get recertified, it seems to me it would make a lot of sense. But I don't know if that currently exists, if that opportunity exists, or do we have to create a new mechanism or how do we look at that?

MS. FLANNERY: I don't know of any boards who are currently doing that. But the NRC would recognize that if the board could speak on their behalf to say that they meet NRC's criteria, that that individual meets NRC's criteria. But I don't -- I can't speak for the boards and I don't know that any -- we are willing to do that at this point.

DR. BETH-HOWE: I did the American Board of Nuclear Medicine. And in their application, they had to change some of their criteria to make it clear that they would meet. But what they also believed was that most of their candidates in previous years would meet the criteria even though those criteria were not the criteria listed in previous years.

So they have essentially agreed that they will go back to individuals that are not authorized users, reevaluate what their criteria was and if they, in fact, did meet our existing criteria today, they would modify their certificate to put the designation

that is on their certificates now that indicate that they are eligible to be authorized users. And part of their problem was that they have individuals that take examination that are not trained in the U.S. and, therefore, their training isn't under an authorized user.

But they have committed to going back and reviewing individual criteria to see if they meet our existing criteria today. And so they will go back and retrospectively add that to their certificate.

I don't think we have had any other boards that have agreed to do that. We did talk to the American Board of Health Physics and they were offered the opportunity to do the same thing but they haven't come back to us with that.

CHAIRMAN MALMUD: Dr. Diamond?

MEMBER DIAMOND: So Cynthia, tell me what will happen to the radiation oncology trainees who are expecting to become Board certified by the American Board of Radiology and Radiation Oncology in June 2006.

MS. FLANNERY: The option for these diplomats would be to apply for authorized user status under the alternate pathway which is the training and experience pathway.

CHAIRMAN MALMUD: Does that answer your question Dr. Diamond?

MEMBER DIAMOND: It answers it. It doesn't make me very happy.

CHAIRMAN MALMUD: Could you explain why it doesn't make you happy?

MEMBER DIAMOND: Because my understanding is that the diplomats who are anticipating -- those who are expecting to become diplomats in June 2006 by virtue of their training programs, having been modified to meet the new regulations as enumerated, should have already met all those criteria. And I guess your point is you do not think that those criteria have been met. Is that correct? I'm trying got specifically tease out what is special about these 2006 diplomats that is causing the problem in radiation oncology and what are we going to do with these 200 individuals in June 2006 when they are hoping to get jobs which is right around the corner.

MS. FLANNERY: The ABR has had to make changes to their certification process in order to meet NRC's criteria. And the date that was applied by the ABR was they could make those changes in the next round, which is June of 2007. And so really the only other option would be the training, experience pathway

or unless as I mentioned earlier, if the board is willing on a case-by-case basis and on behalf of the individual to state that the individual has met NRC's criteria, those are the only two options.

MEMBER WILLIAMSON: In your communications with the American Board of Radiology, in which they made these comments to you, was it clear to all parties that there was going to be this mess two months from now? I'm just -- I'm the pragmatic guy on the panel. And, you know, these doctors are expecting to get jobs. And you are telling me that from now until -- they are expecting to start those jobs on July 1st, 2006. They are going to be able to go thorough this paperwork to become authorized users for all of these uses?

MS. FLANNERY: I don't think I could answer that question for the board at this time.

CHAIRMAN MALMUD: This is Dr. Malmud. When we discussed this issue over the past several years, we were concerned that the NRC process was essentially imposing upon the boards criteria for board certification by requiring that the boards train the residents for the alternate pathway since, by definition, a certain percentage of residents would not pass the boards. And, therefore, would require

the alternate pathway to be authorized users.

Or would take the boards at such a time that was delayed and, therefore, could not be authorized users by virtue of the boards not yet having board certification. Now I don't recall the precise outcome of that discussion except our concern about it. But I worked on the assumption that for those who did not pass the boards or who had not taken the boards and therefore could not use the board pathway to certification that if their training supervisor certified that they had the requisite experience required under the alternate pathway, that they could be authorized users.

Am I correct so far? So that the answer to that was an affirmative nod from the three persons giving this session.

So, therefore, the question boils down, Dr. Diamond, to whether or not in their training they received the training requirements of the alternate pathway.

The training requirements of the alternate pathway, I assumed -- and this is an assumption and not a fact -- were being met by the American Board of Radiology but yet though they were being met, they were not being documented in a fashion up to that

point which would necessarily be adequate for the successor to the training program should the individual leave and the training program director no longer be there.

And that our concern was for the future. But that the current training program directors, who would have just graduated or these individuals who are now going to enter practice could certify truthfully that these individuals had received the requisite training under the alternate pathway.

It's a long way of saying that my assumption was we would not interfere with the ability of these young physicians who just finished their board certification training but not yet sat for the boards to practice and become authorized users if their training program directors would simply certify correctly and honestly that these individuals had received the training requirements according to the alternate pathway.

Am I okay so far? Okay. Is that a problem? Do you think that will present a problem Dr. Diamond, Dr. Nag for those who are finishing radiation oncology training?

MEMBER DIAMOND: I can't speak for a program director. I think that the logic that you

spell out I follow. I think it boiled down to the fact that the letter communicating to NRC from ABR indicated that they would be able to certify that all of their programs would meet all the enumerated requirements in 2007 as opposed to this 2006 cycle.

An I would hope that the training programs, having access to all these enumerator requirements for some period of time would have already modified their training to meet all of the criteria for the alternate pathway. So I would hope that there will be no problem in that these preceptors can correctly and honestly certify that those points have been made.

But it is going to generate a lot of consternation. So do you have any thoughts on this?

MEMBER NAG: I think there will be a period where you will have to use the alternate pathway. But I think the specialty board to place all the requirement by 2007 so that one year we will have a problem.

MEMBER DIAMOND: So Subir, since you are closer to the academic centers than I am, do you think that the training programs have instituted the required changes to their training programs so that the diplomats in 2006 will, in fact, have met all of

the criteria of the alternate pathway? And that their preceptors can correctly and honestly attest?

MEMBER NAG: Yes.

MEMBER DIAMOND: So that this may be a non-issue?

MEMBER NAG: Yes, I have seen at least our training program and a few others, I don't know about all -- but they do have all the NRC -- so they will have to go through the alternate pathway.

MEMBER DIAMOND: Okay -- so maybe I made too much of an issue over a technical point that is actually moot. I hope that you are correct.

CHAIRMAN MALMUD: If I may, Dr. Diamond, it is not a moot issue in that if the program director certifies that the individual not yet board certified has met the T&E requirements under the alternate pathway, that will be reviewed on an individual case-by-case basis. And the additional workload falls to the NRC staff for this transition of about a year or so.

MEMBER DIAMOND: And also not only the additional workload but also remembering that from a pragmatic point of view, many of these individuals are going to be moving and applying for jobs and trying to buy their first homes and so forth.

And if you don't have an authorized user designation, let's say you are in a non-agreement state, you can't work. You don't work, you don't get paid. There is going to be -- this is a very short time horizon. And I'm just wondering -- there is not a representative of the American Board of Radiology here today. But I'm wondering if the trainees that are getting ready to graduate are aware of this specific issue.

CHAIRMAN MALMUD: If I may, I can't speak for the trainees but I think Dr. Zelac has a comment which probably relates back to a discussion we had some months ago. Dr. Zelac?

DR. ZELAC: Well, actually I wanted to address the specific point that Dr. Diamond just raised. These newly completed residents now seeking their first positions can certainly go to institutions where there is an authorized user and for the time that it takes for their application to be reviewed before they can also be added to the license as authorized users, they can certainly act and perform their functions under the supervision of an existing authorized user. The rules allow for that.

MEMBER DIAMOND: Right. I think the main issue is individuals who are entering small clinics in

non-agreement states I think is the key issue at hand.

DR. ZELAC: If there is no existing authorized user at the facility, yes. That would be a difficulty. And there would be some time required for them first to complete their application and submit it and clearly some time required for the review of the application. But on the review side, it ought to be quick because all of their information is basically current.

MEMBER NAG: Another practical point and that is when you finish you education and you are in a job, at that point you are not board certified. So you do have that one year or so from the time you finish your licensing until the time you are board certified.

CHAIRMAN MALMUD: You are, of course, correct, Dr. Nag, and that is the issue that we were concerned about for those who had finished training but were not yet board certified. And that is why we discussed the fact that the training programs will have to train to the level of the alternate pathway or their graduates, the trainees upon completion of training, may have a problem in becoming authorized users if they have not had the requisite experience.

And though I am not a program director any

longer, it is obvious to me from the behavior of the residents in our program, that they are fully aware of the changes that are occurring and have rushed back to me for certification that they, for example, in radiology, that they had the requisite experience in the use of iodine-131 for the treatment of thyroid cancer and hypothyroidism. So our resident group is aware of it.

And how aware the other residents are throughout the country, I'm not sure. But the new guidelines were published as of October of `05, as I recall. And, therefore, they was adequate notice in addition, the leadership of the American Board of Radiology was aware of it. And has discussed it. And it has been discussed also at the AUR. So I suspect that most residents in radiology are hustling around.

What is happening in radiation oncology, I can't address since I have no familiarity with it all.

Dr. Williamson?

MEMBER WILLIAMSON: Well, I guess I am concerned that many of the previous diplomats of the American Board of Radiology and Radiation Oncology will not be able to meet the alternate pathway requirements. The alternate pathway requirements were

intentionally made more prescriptive and burdensome than the requirements for board eligibility. For example, enumerating the number of hours of didactic training versus practical training. In addition, the sections 400, 600, 300 -- 400 and 600, excuse me, specify that the 500 hours must be spent with specific modalities such as HDR or gamma stereotactic or cobalt-60 teletherapy.

So I would say a diplomat who was maybe treating lung cancer -- a diplomat of 1995 who is treating lung cancer for seven years or some long period of time and wanted to switch to neuro would not be able to become an authorized user of gamma stereotactic without presumably going back and having 500 hours of additional training.

Whereas if the application would have been approved without this date qualification, there would be no problem. So I think it is more also than just an impact on individual practitioners. There is a serious shortage of radiation oncologists and medical physicists in the country, estimated to be of the order of 20 percent.

CHAIRMAN MALMUD: Would you care to comment on that issue Dr. Zelac or Dr. Howe?

DR. ZELAC: Dr. Williamson is quite

correct in terms of the alternate pathway requirements being more prescriptive than those under the board certification pathway. If for no other reason that the hours of didactic classroom and laboratory are specified under the alternate pathway where it is not under the board certification pathway. In terms of what type of experience an individual gets in fulfilling their qualification for the total hours, it really depends on the modalities that they are interested in.

They are going to be getting their training and work experience in one of them. And presumably -- or at least one, and it is in at least that one that they will be seeking their authorization, not for the others. It is not that they have to get it in all three, for example.

MEMBER WILLIAMSON: The question was, if I can be permitted a follow is someone who has an older board certificate whose training program included only manual brachytherapy now in 2007 moves to a small institution where they have to be in charge of HDR brachytherapy, what do they do?

PARTICIPANT: Well, clearly they would be qualified to do the manual brachytherapy and would seek authorization under 400, meaning they have met

the qualifications under 490. In terms of 690, before they could be qualified, meaning authorized to do that type of work and they haven't done it before, you should get additional training. That's reasonable.

CHAIRMAN MALMUD: Wouldn't they also require credentialing by the institution at which they are going to practice this new modality for themselves? And wouldn't the credentialing require some experience? That question is addressed to Dr. Williamson.

MEMBER WILLIAMSON: Well, I imagine so but the issue is with board certification, this retraining is left to the discretion of the physician who is presumed to be a professional and able to develop a self-directed training program as is necessary to move to a new modality.

Now it will be prescribed -- the criteria aren't clear whereas if the board certification prior to 2007 were accepted, the person to change fields would only have to show the additional technical and safety training which is required of all AUs regardless of which pathway they use.

CHAIRMAN MALMUD: Dr. Eggli?

MEMBER EGGLI: For training requirements for diplomats of the American Board of Nuclear

Medicine, I think their training program is long enough and robust enough that they have no problem. However for diplomats of the American Board of Radiology, particularly for those who are graduating in 2006, it is a real scramble to get in the 80 hours of classroom and didactic by the time they graduate.

And there may be a whole bunch of 2006 diplomats of the American Board of Radiology who could functionally be disenfranchised because there is just not enough time left in their residency between when -- well, between when ABR understood what the regulation was and was actually going into effect and time left to implement it.

So I think there are going to be a whole bunch of people who are graduating this year who are diplomats of the American Board of Radiology who may well turn out to be disenfranchised because there is just not enough time to -- not to get the 700 hours in because that has been understood. But to get the 80 hours of classroom and laboratory experience into their curriculum before they graduate, I think there is a real serious challenge for those diplomats.

CHAIRMAN MALMUD: Dr. Howe:

DR. BETH-HOWE: Just kind of a word of warning. When you are thinking about credentialing,

not all of these authorized users are going into facilities that do credentialing. They may be going into private practice. d so credentialing in not something that you can fall back on all of the time.

CHAIRMAN MALMUD: You are correct. That's a good point. Thank you.

It sounds as if there may be an opportunity for some entrepreneurial physicists in the field to rev up a course or two for those graduates of training programs who have not met the training requirements by June of `06.

Dr. Eggli?

MEMBER EGGLI: It actually turns out several entrepreneurial folk are doing that and offering web-based interactive training. However, for most of our residents, the cost of that is prohibitive.

CHAIRMAN MALMUD: Thank you.

MEMBER EGGLI: It is up to 8,000 dollars per individual.

CHAIRMAN MALMUD: Sounds as if they need some competition with a lower-priced product of equal quality of course.

Dr. Zelac?

DR. ZELAC: If I can add just a couple

more words to the question that Dr. Williamson had raised before. The individual who was previously certified, who has been authorized using brachytherapy, implant brachytherapy, and now goes to a facility at which they wanted to do HDR, for example.

The qualifications that they would have had to have met for board certification initially when they got it would have included the same requirements in terms of the three-year residency that exist both in 490 and in 690. So if they were qualified under 490, they would meet most of the qualifications under 690 as it is written today.

The one thing that was added intentionally on the advice of this advisory committee was that such individuals who now wanted to get into a new modality would have to receive specific training in that new modality under an appropriate person before they could get approval to do it.

But the length of the training is not specified. It is simply some additional training which is felt to be appropriate be it from the manufacturer, be it from an involved physicist, be it from an involved authorized user. Wherever the source of the training was, it had to cover certain things

which are enumerated in the very last section of 690.

And I'll quote, "has received training in device operation, safety procedures, and clinical use for the types of use for which the authorization is sought." And then it tells how this training requirement can be satisfied.

So this person, in fact, is not going to have to spend years or go through a laborious process in order to, if you will, extend their existing authorization to cover the new modality in 690.

CHAIRMAN MALMUD: Thank you, Dr. Zelac. Is that Dr. Eggli's -- no, I'm sorry. I keep confusing your arms.

(Laughter.)

CHAIRMAN MALMUD: Mr. Lieto?

MEMBER LIETO: I guess I'm am still a little bit bothered and confused about the status of diplomats before the dates here. Let's say, for example, and this is, I guess, maybe to carry on with what Dr. Vetter started, say an RSO that was American Board of Health Physics certified in 2004 or a nuclear medicine physician applying for 190 who is approved in 2004.

Their board certifications, according to this, even though they met the NRC requirements at

that time to be an authorized user or an RSO, because of this magic date, those criteria and credentials are no longer good enough to be an RSO or an authorized user simply because of that effective date of the rules.

And I guess I'm trying to understand how we are supposed to explain this to those diplomats.

DR. BETH-HOWE: Your supposition is correct. The problem is that our regulation didn't come into effect until 2005. And so there may have been changes between what the boards approved in 2002 versus what the boards -- not approved but what the boards were seeking for their candidates prior to the candidates that are listed here on our website.

In some cases, the boards -- like the American Board of Nuclear Medicine -- they have gone back and they have made a commitment that they will review the criteria for their individuals to see if they meet our existing criteria. And if so, they will give them a new certificate.

But you have to keep in mind that one reason there are dates here is because the boards had to make changes to their acceptance criteria of individuals to sit for the board to meet our criteria. So some of the people in those earlier dates don't

meet our criteria. Some of the people in the previous dates do.

MEMBER LIETO: But --

DR. BETH-HOWE: And the NRC decided that we -- when they did the rule in 2002, they did not grandfather the boards. They said the boards will have to be reviewed from this point forward.

MEMBER LIETO: But the understanding was that those diplomats would have been AUs or RSOs under the rules that were in effect at that time. If they were able to be an authorized user or an RSO at that time, they met NRC criteria up until that date.

How can you say that after that date because you changed the rules that they are no longer allowed to become an authorized user or an RSO?

DR. BETH-HOWE: That's what changing our rules did. It changed the criteria.

MEMBER LIETO: But you can't change the rules and then say everybody before hand who met the criteria are no longer acceptable. And that's the point I'm trying to make. You are kind of saying that you are going to hold people accountable for what has changed in the future as to what the criteria under which they got certified when that certification was perfectly acceptable.

DR. ZELAC: Consider this, if the individual who was trained previously had been active and had applied to become authorized, they certainly would have met the criteria and been authorized at that point in time because their training comported with the requirements at that time.

That same individual who chose or did not apply to become authorized at that point in time and waited, now the criteria are different. The criteria that they have to meet now are not the same as they were previously. And that doesn't guarantee that the training and experience or certification that they got previously is going to meet the current criteria.

The holdover, of course, was Subpart J -

MEMBER LIETO: But the problem, Ron --

DR. ZELAC: -- until it disappeared.

MEMBER LIETO: The RSO is a classic example. It is your requirement that you can only have one RSO on the license. I think if it was up to us, we would have multiples on the license.

DR. ZELAC: Well, we're not talking about people that were grandfathered, because clearly, people that had made their application --

MEMBER LIETO: But they couldn't.

DR. ZELAC: But the people that had been

authorized and were named on licenses were grandfathered over. Those people that, for whatever reason, had not been named on a license at the time of the transition and then chose to apply later have to meet the new criteria. Otherwise, we'll never make a change.

MEMBER LIETO: But that's my whole point. The NRC set up the process that wouldn't allow these people to be named.

DR. ZELAC: The Commission, when it reviewed the change in training and experience requirements, said specifically that all the boards that had been previously recognized would have to be re-evaluated so that it was clear that the criteria being required of their candidates by those boards would meet the current criteria. This was the decision of the Commission, not staff. The date at which a board's process for examining their candidates is effective, as indicated on what's on the website, is what the board tells us. We don't tell the board well, we think it was effective as of such and such a time. The board says here are the -- okay, our criteria now meet your's. Fine. And these same criteria were in effect for the last ten years, so anybody from 1996 forward is good. And we'll say

fine, that's great. So 1996 will appear on the website.

CHAIRMAN MALMUD: Mr. Bailey.

MEMBER BAILEY: If I read this correctly, there's not a certified health physicist in the United States or Canada who meets the requirements to be an RSO today. They cannot go by the first pathway. Is that correct? Because none of them have been certified since January 1, 2006. However, all of the requirements listed for this certifying board have been in place for more than 20 years. Dr. Vetter and I have both served on the American Board of Health Physics. All of these requirements have been met for a long time.

There has been created a pathway where a certified health physicist has to have six years experience, but if I decide to go to a tech school and take four three-hour courses and work for a year, I can be an RSO. So what that, in effect, does; why would some facility go out and hire a Dr. Vetter when they could hire someone as their RSO who only has maybe not even an associate degree and one year's experience. This is an inadvertent thing, I think, that happened, but it's not a good thing.

DR. BETH-HOWE: When we reviewed the

American Board of Health Physics to see what their criteria were, their criteria didn't match our criteria with respect to certain degree programs. And also, I believe some of them didn't require - I think maybe they didn't require a Bachelor's Degree or something.

MEMBER BAILEY: The American Board of Health Physics has required a Bachelor's Degree since about 1990, at the very latest, that it's been required. They're in the same subjects. They're six years of experience necessary, and I'll give an example of some really strange thing that can happen. Because I chose not to work in a hospital, I'll have to go back and take those 12 semester hours and work under somebody before I can be an RSO in a hospital. I could have very easily maybe gone to work in a hospital, but I didn't.

DR. BETH-HOWE: But the Board criteria were not the same as the current criteria. And when the board came in, they have not to-date been able to say we meet the NRC criteria from 1990 forward. They have that option, but they haven't gone back and reviewed.

MEMBER BAILEY: I was in on some of those early discussions with the board, and there was a

requirement in there at that time that the experience part of it had to be hospital-based to be an RSO. And it was true that the American Board of Health Physics did not have specific questions every single year on medical health physics, although I'd be hard-pressed to find a year they didn't. But as it came out in the regs, what the boards had to meet, they certainly have met. Now if they need to go back and say hey, we want to make it retroactive to when we required a Bachelor's Degree, would that be an easy thing for them to do?

DR. BETH-HOWE: Other boards have done that.

MEMBER BAILEY: So that's a yes.

DR. BETH-HOWE: That's a yes.

MEMBER BAILEY: Okay. Thank you.

DR. ZELAC: If I could add one comment; what Dr. Vetter had been suggesting before, that as a service to its diplomats, a particular board could choose to examine the qualifications that a particular person had submitted when they sought to become certified and see if those qualifications match the current requirements. Clearly, a letter from the board that said that this person's certification matches your current requirements should be adequate.

I don't know any reason why it wouldn't be adequate for that person to become authorized based on that as their training and experience credential. But again, that's a decision on the part of the board to do as a service to its diplomats.

Now I have discussed this with some of the ABHP current members, and they were reasonably agreeable to this being something that a board ought to be doing, and in that case, would be willing to do.

CHAIRMAN MALMUD: Thank you, Dr. Zelac. That certainly delivers a message, which would be useful to those diplomats of that board, and would be in the hands of that board's leadership. Thank you. I think Dr. Williamson had another comment.

MEMBER WILLIAMSON: Can you update the ACMUI on the status of applications for authorized medical physicists?

MS. FLANNERY: We are discussing this because there are two different boards that have applied, and we're discussing which one. As far as the American Board of Radiology, right now we are waiting for some information that we have requested. And then as far as the ABMP, we're waiting for information from that board, as well. So we can't continue the review process until that supplemental

information has been supplied to us.

CHAIRMAN MALMUD: Thank you. Does that answer your question, Dr. Williamson?

MEMBER WILLIAMSON: Well, in a manner of speaking, I suppose. It's a formal answer.

CHAIRMAN MALMUD: Thank you. Are there any other questions or comments regarding this subject for these three presenters? If not, thank you very much. We'll move on to the next item on the agenda. Dr. Zelac.

DR. ZELAC: Dr. Sherbini had, as you well know, only presented a couple of slides on what was a very involved and lengthy topic. I've got more slides on what should be a very simple, and straightforward, and easy matter to handle. I think we'll be able to get through this one hopefully quite quickly.

There was a rule change for authorized users seeking RSO status, and I want to just review it with you to be sure that you are aware of it. It's understandable as to what was done, the rationale behind why it was done is a little more involved, but let's go and see where we get to.

In order to become an RSO under current NRC requirements and regulations, in Part 10 CFR 35.50, Training for Radiation Safety Officer, one has

to satisfy three separate requirements. First is having general training and experience. Second is having training specific to RSO responsibilities that will be undertaken. And third is the submission of an RSO attestation of qualifications from a preceptor.

The first point, the general T&E for RSO responsibilities - I've listed there on the slide the different pathways that one can follow in order to satisfy those training and experience requirements. The first, and I'll just leave off the 35.50 - (a)(1) is essentially the health physics certification pathway; (a)(2) is the diagnostic medical physics physicist certification pathway; (b) is the alternate pathway, which can be followed, of course, by anyone; (c)(1) is the pathway for therapeutic medical physicists who are not named as authorized medical physicists on license. For example, a facility at which the physicist is doing implant brachytherapy only, not doing HDR, not doing Gamma Knife, not doing teletherapy; so, therefore, they're not named on the license as an authorized medical physicist, because those are the only things, except for Strontium-90 source calibration, for which an authorized medical physicist is required. So (c)(1) is the pathway for certified therapeutic medical physicists who are not

essentially named on a license as an AMP. And the last pathway, (c)(2), is for authorized individuals, the authorized user, the authorized nuclear pharmacist, the authorized medical physicist. Again, different pathways for training and experience.

You'll notice that the last requirement listed on the slide is the preceptor RSO attestation of qualifications. And I simply want to go into that now for a moment. The basis for this requirement - the Staff Requirements Memorandum, SRM, for the proposed rule on medical use of byproduct material recognition of specialty boards had the following two statements in it.

"In addition, the Commission has approved the recommendation of the Advisory Committee concerning the preceptor statement." And here's the meat - "A preceptor statement is required from individuals, regardless of the training pathway chosen." So a preceptor statement would be required for individuals going down the (a)(1) pathway, the (a)(2) pathway, the (b) pathway, the (c)(1) pathway, or the (c)(2) pathway. Regardless of what pathway of training and experience you sought RSO status, you would have to supply a preceptor statement. And you'll notice I included those that were authorized

users, authorized medical physicists, and authorized nuclear pharmacists. Dick.

MEMBER VETTER: If I may ask a quick question while you're on that subject; you need a preceptor statement from whom? So if the authorized user wants to be the RSO, who provides the preceptor statement for the RSO portion?

DR. ZELAC: The preceptor statement has to come from an RSO. And, specifically, I'll pull it out and we'll see what the exact wording is. This is Section 35.50(d), the preceptor requirement. "Has obtained written attestation signed by a preceptor RSO that the individual has satisfactorily completed the requirements in Paragraph E, which we'll get to in a minute, and in Paragraphs" - and then the different T&E pathways are named. "And has achieved a level of radiation safety knowledge sufficient to function independently as an RSO for a medical use licensee." So that's the preceptor has to attest to, and the person who has to do it is a preceptor RSO. Does that mean at the same facility? No. It does mean a preceptor, someone who is named on a license, an NRC license as an RSO, or the way we operate, it could be named on agreement state license as an RSO and still qualify.

MEMBER VETTER: So, hypothetically, if an authorized user at an academic medical center, so they had their own RSO, moved to a private practice and wanted to be the RSO at that private practice, he needs to get a preceptor statement from the authorized user from that academic medical center?

DR. ZELAC: No, he needs to get a preceptor statement from the RSO at that academic medical center.

MEMBER VETTER: I'm sorry, that's what I meant. From the RSO --

DR. ZELAC: Or from any RSO.

MEMBER VETTER: All right. But he has not been practicing under that RSO. He's been an authorized user there.

DR. ZELAC: He or she has been at that facility working with materials, and presumably, has demonstrated their ability through that work experience to not only use the materials, but use them in a safe manner, which respects all the requirements to do that. If the RSO is willing to attest to that, and Section E, which we haven't gotten to yet, and the RSO thinks that this person should be able to handle the RSO responsibilities at their other new facility, they would sign it. If they don't on any one of those

counts, they won't, and the person has to seek their attestation somewhere else, or fill in the blanks in terms of the requirements that the preceptor RSO designated hasn't felt that they satisfied yet, by getting additional training, for example.

The current rule, or the rule that was current until recently, meaning in January, had a problem in interpretation. It listed the various training and experience pathways, (a)(1), (a)(2), (b), and (c)(3), but it didn't list (c)(2). That meant - (c)(2), again, is for the authorized individuals. That meant that an authorized user, for example, who wanted to be named as the RSO, would also have to satisfy the training and experience requirements in one of the other pathways. This wasn't by design. When the rule was put together, it was thought perfectly obvious that there shouldn't have to be an attestation to the fact that this person was an authorized user, for example, because that clearly appeared on a license already. Why does somebody have to attest to that when it's already documented? But our counsel told us that if (c)(2), that particular pathway wasn't there, wasn't named explicitly in the rule language, that the authorized individual seeking to become the RSO would have to meet the

qualifications for one of the other pathways, as well as being an authorized individual already.

The fix, simply, as I said, this was a very simple thing, the fix was simply to add (c)(2) to the list of training and experience pathways in the preceptor Section D. So what I had read before, which says - and, again, this is the preceptor requirement - "Has obtained written attestation signed by a preceptor RSO that the individual has satisfactorily completed the requirements in Paragraph E", which we'll get to in a minute, and in Paragraphs" - and then it had the listings of the various sections, we added (c)(2) to that section. So that meant, in turn, that when a preceptor RSO now provided the attestation, what were they attesting to? First, that the individual is authorized on the licensee's NRC license as an AMP, ANP, or AU. Secondly, that the individual has completed the specific RSO training described in 35.50(e), which we'll get to in a minute. And finally, the overall statement of qualification that the individual "has achieved a level of radiation safety knowledge sufficient to function independently as an RSO for a medical use licensee."

So that was the fix, and so just to finish up the tale, so to speak, let me show you specifically

what is required in terms of the specific RSO training. We already went through this in terms of the added training for the authorized user under 690, but this is what the requirement for added training is for the RSO.

And this is simply quoting from the requirement for added training that appears in 35.50(e), "Training in the radiation safety regulatory issues and emergency procedures or the types of use for which a licensee seeks approval. This can be satisfied by completing training that is supervised by an RSO, an AMP, an ANP, or AU, as appropriate, who is authorized for the types of use for which the licensee is seeking approval." So it's pretty straightforward, it's pretty direct, it's pretty pragmatic in terms of what this added requirement is that an AU has to fulfill before they can, in fact, become the RSO, and have a preceptor sign-off, essentially, that they are qualified to do so.

Anything further that we want to cover on this issue?

CHAIRMAN MALMUD: Are there any questions, comments, or discussion for Dr. Zelac? I see none. Any from the public? Oh, Dr. Vetter.

MEMBER VETTER: I'm still kind of thinking

about this. Well, the example I had used before is a real one, where I received a telephone call from a physicist from an academic medical center, an authorized user had moved from that center to a private practice, and they needed an RSO. And under the old rules, he qualified as an RSO. They sent the package in to Region I, Region I said he did not qualify as an RSO under these rules, so the AU went back to the academic medical center to get the RSO to sign a preceptor statement, and the RSO said you didn't practice under me; and, therefore, I will not sign the preceptor statement.

Now I don't know what -- you said there may be some alternative mechanisms for obtaining the appropriate training and get certified, not certified, have an RSO attest to this individual's competence to do radiation safety. And I don't know if this is a big problem or not, but here's an individual who is practicing nuclear medicine in an academic medical center. True, he wasn't working for the RSO, or working under the RSO or anything. But like you said earlier, obviously, he's been working safely for many years, but the RSO there was uncomfortable signing a preceptor statement saying this authorized user would be a good RSO because he didn't work directly with

him, so it sort of left him in a lurch, and I don't know what the answer to that is.

DR. ZELAC: So the RSO wasn't sufficiently familiar with this person's qualifications?

MEMBER VETTER: I don't know any of the individual. All I know is the RSO would not sign because the authorized user didn't practice under the RSO. In other words, the RSO didn't supervise the authorized user in a radiation safety capacity; and, therefore, he would not attest to his ability to be an RSO.

DR. ZELAC: If the RSO had any knowledge of the authorized user's competence or experience, I think he was probably going beyond what he or she should have in terms of refusal. Again, if they felt that this person -- if they couldn't sign a preceptor statement, attestation because they believed that this person had not had any specific training, they may have had a lot of work experience, but they didn't have any specific training relative to RSO responsibilities, one would expect that a reasonable working relationship, they could have gotten something done in short order and satisfied, if you will, the RSO.

The alternative was for this person to

seek some specific training under an authorized whomever for the type of work for which they wish to be the RSO, and get that person, if it happened to be an RSO, to sign, or the RSO at that facility to sign the preceptor statement. There are pathways, and that's the point, that the additional requirement for training is not onerous in terms of fulfilling it, even if the person hasn't necessarily done everything that they might need to serve as the RSO; if they haven't had that as part of their work experience as an authorized something else, they can easily get it.

CHAIRMAN MALMUD: Dr. Eggli.

MEMBER EGGLI: I actually had a similar sort of phone call. I don't know if it was the same individuals, but it was the same situation. And I think the comment I would like to make is that authorized individuals in the new environment are awfully protective of what they put their signature on, because essentially, the new regulations make those authorized individuals liable, in a sense, for that signature on that piece of paper. Maybe it's always been that way, but I think there's a new heightened sense of not just responsibility, but liability for signing as an authorized individual when you sign somebody's preceptor statement. And I can

understand the health physicist's reluctance, the RSO's reluctance to sign that statement because, essentially, the person didn't work for them, they didn't supervise them, the experience they had wasn't under the supervision of that individual. And if you want to get real rigid about the interpretation of the regulation, you shouldn't be writing a preceptor for that individual. And I think there's a whole new heightened sense of both responsibility and liability associated with an authorized individual putting their name on a preceptor statement. And I think that's going to be one of the consequences of the regulation.

DR. ZELAC: Recognize that in this case for an RSO, it has to be a preceptor RSO who makes the signature on the attestation. For authorized users, in general, you're right, it could be another authorized user signing the preceptor statement. But in this case, it's the RSO, an RSOs have always had that, if you will, liability hanging over their heads, or at least for the recent past in the last couple of decades, have had that thought in mind, or should have had that thought in mind before they sign or do anything.

CHAIRMAN MALMUD: Dr. Williamson, then Mr. Lieto.

MEMBER WILLIAMSON: I believe I'm familiar with this case, as well, and I don't believe that the RSO took issue with the adequacy of the training of the individual, but simply did not participate in it, and felt uncomfortable attesting to the fact that the individual was able to independently practice, because this person had no direct knowledge of this person's capability functioning under those circumstances.

The way the regulation is written, it's more global. It doesn't ask you to examine the CV of the person and determine whether this person has adequate credentials. It asks you to attest to the independent ability. And I emphasize, I think this is a rather daunting task or duty set forth for us for our colleagues, regardless of what kind of authorized person we might be; especially when you consider the chilling impact of, I think, some of our earlier deliberations today.

MEMBER LIETO: Well, I guess Jeff stole a little bit of my thunder there, but I think what Ron was talking about in terms of the RSO's attestation; this is something entirely new. Physicians in the past have been signing preceptors for other authorized users via the alternate pathway for many years, but for RSOs, AMPs, nuclear pharmacists, they've not had

to do this before. And so there's not any sort of guidelines out there as to okay, what do I need to look at before -- if I did not provide that training, what do I need to look at before I can make an attestation in good faith that this person can function? Is it a CV review, do you quiz previous employers, or do you just sit down with the guy and get a gut feeling as to I think this guy knows what he's talking about? And there's just not really any good, shall we say, guidelines out there, and it's all new.

DR. ZELAC: The one comment I'd make is that in the case -- the RSO is particularly difficult because you've got an RSO who is attesting for an authorized something else, user, medical physicist, nuclear pharmacist. It's not as if it's an authorized user attesting for a potential authorized user, or an authorized medical physicist attesting for a potential another authorized medical physicist, so this is kind of a hybrid situation, if you will, and I understand that there can be difficulties with that type of an arrangement.

To my knowledge, we haven't had responses from the regions who, of course, are having to handle on a day-to-day basis a great volume of difficulties

in this regard, but that doesn't mean that things are not happening that simply don't get that far because somebody won't attest.

MEMBER BAILEY: What I hear you saying is what we used to call brother-in-lawing it. And I really hope you're not going the direction you're talking about, because I know in at least two states that I've worked for, we have turned back preceptor statements because the individual did not have experience working with that person, and this was for Aus. We insisted that they have someone who had direct knowledge of that individual's capabilities and so forth. You cannot hire a new cardiologist, if you have private practice, and be the AU or do the preceptor statement for that AU. And I think you'll find that is not uncommon in many states, so we're going to have two different systems, where one, if you can get somebody to sign the paper, you're in. The other one where they're really still going to be questioning whether the individual signing the preceptor statement even knows the individual.

DR. ZELAC: Dr. Malmud, if I can comment. When the current training and experience rules were being formulated, one thing that was considered was the fact that the person who might provide the

attestation may not necessarily have been the one under whom the training was actually provided. That doesn't mean that the person signing the attestation would be unfamiliar with the qualifications of the person for whom they were signing, but they would not necessarily have to have been the supervisor for the work experience, or for that matter, for the classroom and laboratory training that had been accumulated by this person. And it was for that reason that the preceptor definition which exists now in 35.2 includes the work "verify", so such a person who was going to serve as the preceptor could look at documentation and credentialing, and whatever else provided by the applicant, and decide on their own if they felt comfortable enough with that information, plus their personal knowledge, hopefully have such thing, of the person in order to sign the attestation. So yes, in one sense, if there are states which are specifically requiring that the training be provided by the person signing the attestation, or the work experience be accumulated under the person signing the attestation, NRC requirements are different.

MEMBER SULEIMAN: Perhaps either some guidance or some examples that spell out a little bit more specifically prescriptively attestation

preceptor. Until you've worked with somebody or worked under somebody, or had somebody work for you directly and see their work, I mean, there's a real disconnect sometimes.

DR. ZELAC: I understand, but this gets to the point of someone signing something, essentially, without having the appropriate knowledge to do so, whether we intent, or malevolent nature, whatever it is. And Dr. Eggli made this point before, there's a lot at stake when you're putting your name on a document.

MEMBER SULEIMAN: But if it isn't standardized someway, somehow, you're going to have tremendous inconsistency among different regions and different facilities. I mean, that's my concern. Is there anything that would help level the playing field in terms of the attestors, and the preceptors, and so on, without having different interpretations by different people based on their personality or experience?

DR. ZELAC: I can't speak to it directly because I don't remember, but I can tell you that the NUREG 15.56 Volume 9, which is Medical Use, was updated at the time that the training and experience rule was coming into effect, so that they would both

be available at the same time. Whether that specific point that you have raised has been included in terms of providing some specific guidance to preceptors, I can't say, but 15.56-9 will undergo some changes in the future, in the not distant future, and perhaps something like that would be appropriate.

CHAIRMAN MALMUD: Dr. Vetter.

MEMBER VETTER: That may be difficult because I'm sure there are some academic medical centers where the RSO does not get to know every resident, simply can't. They're huge programs, and even if the RSO is providing some lectures and that person is sitting there listening, on the basis of some lectures, what can you tell, or the person sitting there listening, what can you tell? They stayed awake.

DR. ZELAC: Well, the other thing, too, is that what you're describing, the residents typically would not be named on the license as authorized users. Am I correct?

MEMBER VETTER: I'm sorry, let me clarify. I'm thinking when the resident has completed training, and they want to take a package of paperwork with them, including a preceptor statement from their authorized user that they practiced under and the RSO

because they're going into a small practice. And the RSO may not even know who that person is. Now what kind of guidance are you going to write for that RSO?

DR. ZELAC: Well, one could say that the RSO could look to the authorized user who is signing the preceptor statement for that intention. And if you're satisfied that this person seems to be functioning satisfactorily, I will be, too.

MEMBER VETTER: Actually, that's what I had in mind. If this come to me and I have to sign, the authorized user is going to send me a letter saying the same thing. So I'm going to depend on the authorized user's evaluation and judgment of that individual.

DR. ZELAC: Right.

CHAIRMAN MALMUD: Who was next? Dr. Williamson.

MEMBER WILLIAMSON: Yes. I guess regarding the compatibility in the agreement states versus non-agreement states, isn't this level of Compatibility B - wouldn't the agreement states be forced to accept the same interpretation as NRC?

DR. ZELAC: Mr. Bailey is shaking his head no, and I think he's reflecting the point of view of many of those persons who are associated with

agreement state programs. However, the training and experience that became effective in October of 2005 has a compatibility level of B for training and experience.

MEMBER BAILEY: But not for definitions.

DR. ZELAC: But not for definitions, so we have some issues to resolve.

CHAIRMAN MALMUD: I have a question, and that is as follows. Beginning with this year, June of `06, it would sound to me as if the wise thing to do is to provide each trainee upon his or her completion of training, with several statements, one with regard to being an authorized user, one with regard to being an RSO, if that's what they're interested in or have trained in, as well as their diploma having completed their residency. So in leaving a program, one should have at least three documents, and perhaps with respect to therapy, a fourth document.

DR. ZELAC: That sounds like a very appropriate approach for those that are involved with training programs.

CHAIRMAN MALMUD: So that for those of us in training programs, we should be using the belt and suspenders approach, meaning give them everything you think they may need to keep their pants up, not

knowing what's coming along. How do we spread that word quickly, for at least those who are finishing now moving forward? Is this actually a recommendation? And should we be the ones making the recommendation? How is the information to be transmitted? It's almost as if we're doing a disservice to training somebody, allowing him or her to complete the training, and not giving the documentation they might require in the event that we drop dead and can no longer certify that they received the direct training experience with us that they had.

MEMBER NAG: I think they may be a good idea, but the thing is, what we review, like all the program, just like the board, and tell the individual in a practical problem you may wish to discuss this with your training programs.

CHAIRMAN MALMUD: Thank you, Dr. Nag. But I'm still concerned about those who are finishing training this year and who will finish training next year. When I separated from the Air Force, they told me that there was a document that I might need some day, and I should keep a copy of it. And lo and behold, I required it this year, some 30-some years after having completed my term in the Air Force. And I have saved that document, there it was. I pulled it

out, xeroxed it, and sent it off. I suspect that we would be very wise to protect those whom we are training by suggesting that they leave with certain documents. And it would be very useful if we sitting here today can decide what those documents should be.

A physician finishing training, whether a radiation oncologist, a radiologist, or nuclear physician, would require board certification. That's the target, that's the goal. And what other documents should that individual be prepared to have in the event that he or she may need them in the distant or near future? What would you recommend?

DR. ZELAC: Well, recognize with respect to the board certifications that on the request of the boards the requirement for them to receive from their candidates a certification was removed, and that requirement for an attestation under the new terminology was placed on the individual who is applying to become authorized. So with respect to the board's involvement, that's probably not the way to go, because they've begged off, essentially, from getting involved with anything relating specifically to the kind of attestation being required by NRC or agreement states, presumably.

CHAIRMAN MALMUD: I agree with you, Ron.

In addition, the individual may be one of those small minority that never achieves board certification.

DR. ZELAC: Right.

CHAIRMAN MALMUD: So we really have to satisfy the alternate pathway. Now let's assume that the trainees are finishing and must satisfy the alternate pathway in addition to the board certification, if they're able to achieve it. What documents should we really be recommending that those individuals carry with them and keep in a safe place into the future?

DR. ZELAC: Well, again, you're addressing and rightfully so, those people that are in training programs right now, those people are finishing up their training programs very soon.

CHAIRMAN MALMUD: Correct.

DR. ZELAC: If those people are going to seek in the near future authorized status, or RSO status, or both, they will need, of course, the attestations that are covered in the various sections, and they should have an easy pathway to getting them because everything that they have accumulated in the way of training and experience is recent. However, if those same individuals finishing now should decide that they are not going to seek the status for five

years or their circumstances are such that they don't, what would they need? They'd need exactly the same documents, except it would be easier to get them now than to go back five years from now and try to obtain the same attestations from the same people. If you're an authorized user in one of the categories for authorized use, it's the attestation from an authorized user in the same category. If it's an authorized medical physicist, it's an attestation from an authorized medical physicist. If it's for an authorized nuclear pharmacist, again, it's an attestation from an authorized nuclear pharmacist, and if you're seeking RSO status, it's a preceptor statement, an attestation from preceptor RSO.

CHAIRMAN MALMUD: Now the first three are clear. Let's go to the last one, the statement from the RSO. What would the RSO have required of the radiology resident in order to give the radiology resident an attestation of RSO status? Since numerically the largest number of trainees each year is made up of radiologists, what should that individual carry with him or with her from the RSO in the event that that individual would become the RSO at a small hospital or clinic in a remote area, in addition to practicing radiology?

DR. ZELAC: The individual seeking RSO status has to follow one of the pathways that exists in the current rule in order to satisfy the training and experience requirements. This person that you're speaking of, the person is becoming an authorized user, for example, will have gone through the appropriate training and experience requirements to become an authorized user. That's fine. And they will be presumably applying for a license -- to be named on a license, to be authorized on a license. If that's the case, they would probably be following the authorized user pathway. They're not going to be following the health physics certification pathway. That wasn't the way they came, the training that they've had, nor would they be following either one of the medical physicist certification pathways, either diagnostic or therapeutic. So those are out, and not to be considered. What's left is the alternate pathway, and its specific requirements, so you could have someone attest to the fact that they've fulfilled those specific requirements listed in the alternate pathway, or if they were already named on a license, or expected to be named on a license as an authorized user - follow what we were just discussing, which is the (c)(2) pathway for authorized individuals, that

the individual is named on a license as one of these authorized persons, and they've had the specific training in Section E, which we went over, and this is a value judgment on the part of the preceptor that they are qualified to be the RSO for what they wish to be responsible for.

CHAIRMAN MALMUD: Okay. Thank you. I believe we have -- oh, Dick, and then we have a member of the public.

MEMBER VETTER: Okay. Just one quick question. Does the letter of attestation have an expiration date on it?

DR. ZELAC: That has not come up. I see no reason why it would have to have any stale dating associated with it.

DR. BETH-HOWE: The training and experience.

DR. ZELAC: That's another issue, but that has to do with meeting the qualifications of the current rule in terms of becoming authorized to begin with. The training and experience has to be within the past seven years.

DR. BETH-HOWE: The comment was that the recent training and experience would take place, so if you had an attestation that was, say, 25 years old and

you hadn't practiced for 25 years, we would probably look for something more recent as an attestation.

DR. ZELAC: Yes.

CHAIRMAN MALMUD: Thank you, Dr. Howe. We do have a member of the public who's been waiting to speak. Would you please introduce yourself and then make your presentation. Thank you.

MR. WHITE: Thank you. I'm Gerald White, and I'm representing the American Association of Physicists in Medicine. And I have yet some additional comments to make on the training and experience issues, as applies to medical physicists. And you have a written statement in front of you, which is much more complete than the brief talk I'm going to give today.

I do want to say that AAPM understands the Commissioners' desire for a change in the board recognition process, and we understand that it was the Commissioners' desire not to provide a mechanism by which the boards were grandfathered. But we do not believe that the Commissioners had in mind the lack or creating a class of previous diplomats who were unable to use their certificates to become qualified in the future.

We believe that it's been clear in the

recent months that the regulatory language and application process for the boards has been seriously flawed. The process is going on very slowly, and that has impacted the ability of the people to become recognized on licenses.

In the printed material you have some statements, one from Commissioner Merrifield, where he notes that the existing specialty boards, although did not meet -- they've met the intent of the required training, even if they did not meet the exact wording in the regulations. I've also quoted from an NRC statement that says, "If an individual holds certification from a board for which the NRC or agreement state withdraws recognition, the certification will be considered valid if it was granted during the time interval that the board certification process was recognized." The AAPM would like the Committee to consider that spirit in applying this process to medical physicists who were previously certified.

I note that the process impacts medical physicists more profoundly than other specialties. Unlike authorized users, the status of authorized medical physicists is a recent construct, so the opportunities for grandfathering were limited. In

addition, you've already heard, and I'll say again, radiation safety officers, there is but one in an institution, so the opportunity for a medical physicist who had been practicing even for a great many years to become a radiation safety officer, was limited. Dr. Zelac referred to people who had waited until it was too late to apply; but, in fact, for medical physicists, it's not that we were dithering in the brew pub or the lab, the opportunities just did not exist. The entities or the singularity RSO position places undue burdens on the grandfather process for us.

I'll also note there's been much discussion about alternate pathways. Alternate pathways, while it is theoretically possible, can be very difficult to achieve for AMPs and RSOs whose training occurred a number of years ago for reasons that have been previously discussed. And also, it should not be necessary for an individual who has previously been qualified or had a board certification that was recognized by the NRC to have to create the alternative pathway documentation which can be burdensome.

I also note that as Dr. Diamond mentioned, this is going to create a classification of

individuals, practitioners who will be "difficult to license". We'll find it that they'll be at a competitive disadvantage with their peers. I also note that this status will follow, for recent diplomats, will follow for their entire careers. Dr. Diamond raised the issue of the ABR diplomats in therapeutic radiation oncology. That's not an issue that just applies to these folks in the first year or two when they get their first license. They will be on the alternative pathway qualification route, I believe, for their entire career, so every time they change jobs, they're going to have to re-justify their license or status. So we're asking the NRC staff to take whatever steps are necessary to see that previous diplomats of ABR and ABMP boards are recognized without the construct of effective date. The effective date construct had never been seriously discussed in all the years that this topic has come up at the ACMUI, and we think it's an unnecessary impediment.

Lastly, we note in the document that you have that many agreement states have come to a set of successful procedures that will overcome these obstacles, and we would like the NRC to follow their lead and create procedures whereby authorized medical

physicists and RSOs can be named based on previously existing board certification, not grandfathering the boards, but recognizing previously approved certificates.

CHAIRMAN MALMUD: Thank you, Dr. White. Any discussion? So concisely, you are asking that the individuals be grandfathered, not the board itself, but the individuals. Is that correct?

DR. WHITE: Yes. And we're asking that it be done in a practical fashion. We've heard a lot of suggestions here today about case-by-case review by various boards. That sort of thing is just practically impossible. There are probably a thousand diplomats in physics of the American Board of Radiology, and their situation needs to be addressed as a group, I think.

CHAIRMAN MALMUD: Do you have a suggestion for how that might be achieved?

DR. WHITE: I don't. And I had thought about making suggestions, but I think the first goal is to get an agreement that a problem exists, and it needs to be solved. What I'm hearing today is that a problem doesn't really exist, and there are a great many work-arounds by which one can be certified. And I think that both of those things are false. The

problem exists, and there are no easy solutions.

What states have done, is issued an additional time, and states have additional years to adopt these changes. And during that additional time, physicists can apply for these RSO and authorized medical physicists positions under the old rules. The problem we have in the NRC world is that the old rules expired before the new boards were approved, and that's unique in the NRC formalism. And I think it's an error.

CHAIRMAN MALMUD: Thank you. Mr. Lieto.

MEMBER LIETO: Well, I guess I would -- maybe the statement that Mr. White presented here about a possible, I don't want to say fix, but maybe at least for previous diplomats the statement that in the NRC document about procedures, that if an individual holds certification from a board for which the NRC or agreement state withdraws recognition, the certification will be considered valid if it was granted during the time that the board certification process was recognized. And to me, it looks like a way around the problem and concern that we've been expressing repeatedly with previous diplomats being recognized.

CHAIRMAN MALMUD: Dr. Williamson.

MEMBER WILLIAMSON: Well, I think the full story is not in. We don't -- the NRC staff is very tight-lipped on what's going on about the AMP certification. But I think what has happened to radiation oncologists suggests we are on the verge of an unmitigated disaster with board certification, round two. If I point out some history; we went to the Commission three years ago complaining basically, what a disaster the new Part 35 Training and Experience requirements were, that it was going to cause chaos, shortages, all sorts of problems because previously well-accepted and qualified boards will no longer be accepted as default credentials, and everybody will have to go through the alternative pathway. This was accepted and the Staff Requirements Memorandum came out that we were to try again. And here we are. I think we're on the verge of having to admit we've failed the community again.

CHAIRMAN MALMUD: May I ask a question of the group; and that is, who is opposed to granting continuing privileges to those who already have them? What constituency is arguing against continuing the certification of the individuals who already are certified? Who has spoken against it? Who has concerns that something untoward will happen to a

patient as a result of continuing certification for those who already have it? Has anyone? Dr. Holahan.

DR. HOLAHAN: The problem is, as has been said, they weren't previously listed on a license, so I think that's the problem that we were trying to fix, because only authorized medical physicists who are listed on licenses were teletherapy physicists. There was no other authorized medical physicist prior to this new rule that was specified on a license.

CHAIRMAN MALMUD: Mr. Lieto.

MEMBER LIETO: Well, I'd like to say, the problem is even worse than that because only a minority of the states were even teletherapy physicists listed, and those were only the non-agreement states. Most agreement states did not even list them, so even though there had been in the process of NRC regulations that teletherapy physicists be listed on NRC licenses, the agreement states were under no obligation, and many of them did not list physicists on their agreement state licenses. And I can tell you from personal experience, these are problems in getting an AMP approved now that that has generated.

CHAIRMAN MALMUD: If I may, I'll restate my question. Other than the issue of bookkeeping,

documentation, of having been on a previous license, what risk to the public do we perceive in continuing the licensure of those who have been practicing? What risk is there? What evidence is there that a single patient has been harmed by such an individual, whose license will be essentially revoked with this new regulation? Is there anyone who is aware of any single instance in which a patient has been harmed? Dr. Nag.

MEMBER NAG: No. I mean, I was going to say something else. I was going to say that one possibility that the Subpart J that expired October of 2005, one possible fix is that Subpart J be extended until this new board certification takes over in June of 2007, so that between October of 2005 through June of 2007, the regulation of Subpart J be continued. That might be a possible solution.

CHAIRMAN MALMUD: Dr. Nag, does that solve the problem or delay resolving it?

MEMBER NAG: It will solve the problem because the problem now is what is happening the graduates who are graduating in 2006 June, or some people graduate in late 2006, so it will solve those.

CHAIRMAN MALMUD: Is that the only problem, though? Mr. White, is that the only problem,

those who are graduating in `06, or will graduate in `07?

MR. WHITE: No, it's not.

CHAIRMAN MALMUD: Would you please restate what you perceive the problem to be?

MR. WHITE: Well, let me answer the question, if I may, why that doesn't solve the problem. For radiation safety officers, you still have the issue that there is but one RSO in a facility in most states; although, in some states they have things called associate or assistant RSOs. And I can tell you that we have 12 of them on our license just to avoid this problem. But it also affects people who are in the pipeline for RSO, and the existing RSO doesn't want to step aside just to have a junior person named to get on the license.

If the extension period lasted long enough so that practicing medical physicists could get on a license as an AMP, if the construct existed long enough, that would ameliorate the problem. It would still put us in the same position as some of the Rad Oncs having to constantly justify your alternate pathway if you fail to get on a license in time, if you were the procrastinator that Dr. Zelac described. So I think then you have a paperwork burden with no

benefit to the public, but it would certainly be a better situation than what we have now. It's not a solution.

CHAIRMAN MALMUD: So that the answer to my question is that Dr. Nag's suggestion would give time for those who need to address any perceived deficiencies to do so by `07.

MEMBER NAG: I was meaning for the radiation oncologists. I was not addressing the RSO problem. The solution I was giving was for radiation oncology, and I think that would solve the problem for the radiation oncology.

CHAIRMAN MALMUD: Would that solve the problem for the radiation oncology community as a whole, or only for those who are finishing training in `06 or '07, Dr. Nag?

MEMBER NAG: I think it should solve the overall radiation oncology problem.

CHAIRMAN MALMUD: Thanks. Dr. Diamond, would you agree that that would solve the radiation oncology problem for `06 and `07, which is the only problem that you see with this change of interpretation of regulations?

MEMBER DIAMOND: I'm sorry. I was just outside. I didn't --

CHAIRMAN MALMUD: All right. Dr. Nag suggested that the problem with regard to the radiation oncologist specialty could be resolved if - is it Subpart J - were extended to October of `07; therefore, allowing those who are currently in the pipeline or who will be completing their training by `07, to meet the new criteria; and, therefore, not preventing them from practicing without restrictions.

MEMBER DIAMOND: Since I'm the pragmatic guy, I asked myself how many people are being affected? Once again, it's my impression that the only individuals being affected will be those individuals finishing their training programs in 2006, who will be operating in clinics where there is not an authorized user, and who desire to use manual brachytherapy, 35.390 uses, and so forth. I think the easiest solution is just to let them know right now that they need to go and have complete and thorough documentation that they have met all the relevant criteria to which they've been trained, and not go through a process of trying to extend Subpart J.

CHAIRMAN MALMUD: Dr. Williamson, do you have a third opinion?

MEMBER WILLIAMSON: I do, indeed. Yes, I am reviewing 35.690, and respond to a previous comment

of Dr. Zelac's, that 35.400 training would satisfy the 35.600 requirement. Well, anyway, I think it's incorrect. It specifies here that, "The structured educational program has to contain 500 hours of work experience under the supervision of an authorized user who meets the requirements in 35.690 or before October 2005, 35.960, at a medical institution involving" - and then it lists all sorts of things you have to do that are specific to the devices regulated by 35.600. So no, I don't think any old ordinary radiation oncology residency would satisfy this requirement via the alternative pathway. So I think there's a second group of individuals that is older diplomats who wish to switch from the modalities they were trained in to Gamma Stereotactic, or HDR, as it appears in their institution, and they would be in trouble because they do not have this 500 hours under the supervision of somebody who was 35.690 AU, or had the devices at the time at the institution.

MEMBER DIAMOND: Excuse me, Jeff. If my understanding is correct, you're saying that you have a substantial concern because you're concerned about the authorized user prior to October 2005, who is now changing his or her practice to take on a new modality use, such as a 690 use for gamma stereotactic, and

your feeling is that according to the letter of the law, that would entail 500 hours of such experience, as opposed to just going through the specific vendor training, which is designed to be flexible. And I'm confused, because I thought Dr. Zelac specifically spoke to that point and held a different opinion.

MEMBER WILLIAMSON: Yes. I am disagreeing with Dr. Zelac. I think his point is true of those who qualify for AU via the certification pathway only.

CHAIRMAN MALMUD: Is Dr. Zelac still here?

DR. ZELAC: Oh, yes.

CHAIRMAN MALMUD: Ron, your name is being dragged about. Would you please clarify what you said so that you can reassure Dr. Williamson of your position.

MEMBER DIAMOND: Just tell us, is Dr. Diamond right, or Dr. Williamson right.

DR. ZELAC: My comments were clearly at the podium in response to questions without taking the trouble to look specifically at what was listed in the requirements. If Dr. Williamson indicates that that it wouldn't be fulfilled, I'm inclined to say that perhaps the wording suggests that. On the other hand, an authorized user for radiation oncology, it seems reasonable, and I'd like to be able to look more

carefully, it seems reasonable that such a person would be able to add a modality without having to acquire that much additional experience. I reserve comment until I've had a chance to take a look specifically. But since I have the microphone, if I can make on additional comment in response to part of what Mr. White had said. Is that okay?

CHAIRMAN MALMUD: Please do, Dr. Zelac.

DR. ZELAC: The example was given of someone who would become a radiation oncology authorized user via the alternate pathway, having to reassemble all of this information time after time as they move from one institution to another. Once they're named on a license as an authorized user, they can use that as their credential towards being named as an authorized user on another license. They do not have to recreate the entire background. Their authorized status becomes their document of verification, or it should, to go from one licensee to another.

There are exceptions. I know that we, for example, at NRC will accept authorized status from an agreement state; whereas, some of the agreement states anyway will not accept NRC authorized status in order to name an individual as authorized in their

jurisdictions.

DR. BETH-HOWE: Ron, I don't think the regs say that, though, explicitly.

DR. ZELAC: Say what?

CHAIRMAN MALMUD: Someone made a comment that I couldn't hear, and did not introduce --

MS. FAIROBENT: Dr. Malmud, Lynne Fairobent, AAPM, also. I don't believe that the regulations specifically say that if you come in under the alternate pathway and you get on one license, and you move to another, it will be recognized. I think that that's something that is open. I think it was clearly the intent that that would happen, but I don't think it specifically is documented in that manner.

CHAIRMAN MALMUD: Dr. Howe, do you --

DR. ZELAC: We are in disagreement, because I am sure that a person in an NRC state who achieved authorized status on one license can use that listing as an authorized individual to do exactly the same work at another licensee's facility.

CHAIRMAN MALMUD: Dr. Howe.

DR. BETH-HOWE: This is Dr. Howe. And that's included in the definition in 35.2 of an authorized user. The definition is that you meet the requirements for the alternate pathway, or that you

are already listed on a license for that use. And it pertains also to the medical physicist, and the nuclear pharmacist, so it is in regulation, and it is across the board for NRC.

CHAIRMAN MALMUD: Thank you, Dr. Howe. Having heard the reassurances of both Dr. Howe and Dr. Zelac regarding this issue, is there any more concern about it? Good. Oh, there is concern. You know, I was -- in my former role as the Dean and Vice President of a university, I worked more with lawyers than with physicians. And the one thing the lawyers taught me was that when you've won a battle, be quiet. Anything you say from there on will only damage your position. Now you have two highly respected members of the NRC staff, Dr. Howe and Dr. Zelac, who have assured you - are you sure you want to continue this discussion, and to what goal? Mr. Lieto.

MEMBER LIETO: I will restate my point in that I don't dispute their claims about the authorized users. I do dispute that that occurs for the physicists. Physicists are not named on licenses in most agreement states, so that transfer does not occur because they aren't named. I will concede the fact that if they are named on an NRC license, that that is usually accepted by the agreement state, but that does

not mean that they will be named on that agreement state license.

CHAIRMAN MALMUD: Thank you for that information. Now I think that Dr. Eggli was next.

MEMBER EGGLI: And my comment comes back to Subir's, because although I represent Organized Nuclear Medicine, there is an orphan child who isn't sitting at this table, which is diagnostic radiology, and somebody has to speak for diagnostic radiology. And there is an analogy to the Social Security's notch babies, which were people who were born between 1917 and 1922 who have reduced benefits for their whole life just because they happened to be born during that time. And so that the 2006 graduates of radiology programs are going to be notch babies who are potentially disenfranchised. Extending Subpart J until the American Board of Radiology meets all of the requirements would take care of that subgroup, the same as it would take care of the subgroup that Subir was talking about. And, again, the issue is documenting not the 700 hours, but documenting the 80 hours of classroom and didactic, which is required for alternate pathway, but not required for the board certification pathway, so we've changed rules midstream. And I'm used to this, because I spent 10

years in the Army, they always changed rules midstream on me. As a matter of fact, I went in with an obligation of two years, four months, and twelve days, and because they changed rules so often, it took me ten years to pay back that obligation, so I understand changing rules midstream. But we have a group of potentially disenfranchised people, and they are the rat in the snake's belly. This year, 1,600 graduates will happen. The vast majority of them will go into private practice. There are 125 academic medical centers in this country, and based on statistics published by the Association of Chairs of Academic Radiology Departments, there are at least six job openings in each of the 125 academic medical centers which can't be filled. And with 1,600 graduates every year, that tells you how few go into academic medicine every year, so all of these people are going out into private practice. So out of that 1,600, probably all but 100, and probably all but 50 will be affected by this change where their programs are going to have trouble documenting the alternate pathway for them. Extending Subpart J until the board is clearly in compliance with the letter of the law, as opposed to the spirit of the law, would avoid this potential catastrophe for 1,500 people.

CHAIRMAN MALMUD: Now having heard this discussion which it's true, I recognize it's going overtime, but it's very important. Having heard the discussion - oh, okay. I was going to suggest, is there anyone here who would not support a motion that with respect to radiation oncology and radiology, that we recommend in the strongest terms that Subpart J be extended through October of `07? Dr. Miller.

DR. MILLER: Seeking the wisdom of your earlier counsel about dealing with lawyers, I'd like to point out before you enter such a motion, that it's not a simple matter of extending Subpart J. Subpart J has expired last October. Since Subpart J has expired, it's not like we did a year and a half ago or two years ago, where we simply sought approval from the Commission to extend it. What we are basically dealing with then, is promulgating a new rule, since there is no Subpart J that currently exists as a federal regulation. The time that it would take to do that may be longer than the time that's going to be needed to get to 2007. That's my professional opinion.

CHAIRMAN MALMUD: Do you have an opinion regarding a means of resolving this difficulty?

DR. MILLER: It was stated earlier, I

think, in one of the comments of a member of the public that the agreement states seem to have some solution that would work around this. All I can offer at this point in time is to try to entertain the agreements states and the CRCPD to see if there's something we can do to resolve the dilemma. I think from my perspective, and I think from Dr. Holahan's perspective, we recognize that this is a dilemma, especially for medical physicists. And especially in light of the fact that through no fault of their own, they weren't named on licenses. And it seems to be from the evidence that was presented today, that there's a large number that are in that situation. And correct me if I'm misspeaking, but I think the concern would be that they would be disenfranchised, so we need to think about a practical solution.

I don't think the staff has an answer to that question today, and I think that's something I need to ask my staff to try to work on. And I would commit to try to engage the states to see if we can come up with a practical solution.

MEMBER DIAMOND: Dr. Diamond. Since it was I who brought up this issue forty-five minutes or an hour ago when I asked a question regarding the June 2007 issue, I think to summarize, I don't think

additional rulemaking to satisfy this conundrum is going to be practical. I'm disappointed that the ABR was not able to go and make its necessary or requisite modifications to address those diplomats finishing in June 2006, so again the question is, for those individuals who are going specifically to non-agreement states and who will be working in clinics where there's not an authorized user working in conjunction with them, what can be done? I don't have an answer today. There may be some training programs where the diplomats will be able to honestly document that they have met all of the enumerated requirements. There may be other trainees that won't be able to do that. I think we need to go and engage the American Board of Radiology and have a discussion with them. I don't think it can be solved here at this venue.

CHAIRMAN MALMUD: Dr. Williamson. I believe Mr. Bailey had his hand up first, then Dr. Williamson. Mr. Bailey. Is that okay with you?

MEMBER WILLIAMSON: Yes, of course.

MEMBER BAILEY: The question of agreement states not adding physicists to the license - I think about a year ago, I sent some data because CRCPD was meeting at the same time, or whatever. That sort of few the attention of the agreement states to what was

going to be happening, and I think many of the agreement states in their responses at that time indicated that they were going to start doing it. And I know in California we did go in and add some.

The remedy, I think, that's been mentioned, and so I'm hoping that that's not as big a problem now, and I'd be happy to query them again to see what the status is. Another issue that was brought up was that the agreement states seemed to be able to work around this problem. And I think part of that is because the agreement states haven't adopted these regulations yet. They had three years from the time, and certainly, we're now in what year, point 8 or something of that three-year period on T&E. So in the meantime, we're waiting for the next shoe to drop in the continuing sage of T&E and NRC.

The other thing, and I would just throw it out, and I may get something thrown at me, is that it seems to me that there is a process for an exemption to a regulation. And I don't see why these people could not apply for an exemption to those requirements for an authorized user. And if NRC had a bent toward doing that, they could, I would think, certainly grant that exemption for an individual person.

And the last point, and I'll shut up, is

that someone did mention that some agreement states have been adding assistant RSOs for years, or at least for some time. I know in California we basically said that if you had a large facility, you must have at least one assistant RSO, because we felt that those facilities that were operating 24/7 could not possibly have coverage, particularly during vacations and so forth, so at least in California, a lot of the licenses did have assistant RSOs on them, which I presume, although I guess I should ask, would be accepted as an RSO.

CHAIRMAN MALMUD: Thank you. Dr. Zelac and Dr. Williamson. Dr. Zelac's comments may address your concern, Dr. Williamson, so if I may, I'll ask Dr. Zelac to make his comments first.

DR. ZELAC: Thank you. Two things. First, with respect to medical physicists and being named on licenses, and being able to essentially grandfather as the agreement states change their requirements. It was, and Mr. Bailey is correct, approximately a year ago that discussions on this issue were raised. And there were several suggestions that were offered at that time to the agreement states for them to alleviate potential problems down the road. The first of those was that as licenses were

being written or amended, that at that point in time the medical physicist be named on the license. Another was that some states have created lists of qualified experts in various fields, and the state could essentially take action to recognize all of those individuals en masse in a group as the equivalent of being listed on a license, because the whole purpose of having such list was that such individuals, when named by a potential licensee as their physicist, would be automatically accepted, whether they were named on the license or not. So there were various suggestions that had been made over a year ago, or perhaps a year ago, for the agreement states to work towards alleviating what could be a large problem when their regulations finally come into agreement with our's. That was the first point. And if you'll indulge me, I'll just finish up.

With respect to what Dr. Williamson was questioning on my earlier statement, my statement, I think, holds. I am not retracting it, primarily because the example that he had given and was discussing was for an individual who had been previously certified in radiation oncology, and had been practicing and named on a license. Now such an individual then would only have to consider, if you

will, the certification pathway. And for both 490 and for 690, the certification pathway requirements are the same. There are no differences. The examination typically would cover both brachytherapy and devices, so the person who had been previously certified would have had some testing on devices, as well as on source use. They would have gone through the same three-year residency program, and on that basis, being qualified to 490 would mean that they could become qualified under 690 for one of the devices that are covered in 690, as long as they had the additional training covered in Section C, which is the additional section.

MEMBER WILLIAMSON: That would make sense if the board certification were accepted as a pathway for authorized usership at that time. But by hypothesis and, indeed, fact, that is not so. The individual is recognized as an authorized user for brachytherapy say in 1995 by virtue of a regulation which is no longer on the books and not recognized as having any implications for grandfathering today. It is now stated that board certification only after January 1st, 2007 is relevant.

DR. ZELAC: But my point was, just to reiterate, that the individual who is named already on a license, they got there by board certification,

that's fine. But they're already named on the license. We're talking about extending their scope of usage to include a new modality, and for that they should only need additional training.

MEMBER WILLIAMSON: That's 35.57, but it says only for the same kind of use.

MEMBER NAG: I suggest we move on, because this -- I don't think we're going to end this any time soon.

CHAIRMAN MALMUD: Thank you, Dr. Nag.

MEMBER WILLIAMSON: But that's not the one I wish to make. That was a response to comment on one of my earlier. My comment is, I think we should ask for an audience before the Commission and air this whole problem. It may well be that we might just have to admit failure.

MEMBER DIAMOND: Leon, I still think that we should engage in formal communication with the American Board of Radiology so that we can go and best define the nature and the scope of this alleged difficulty.

CHAIRMAN MALMUD: I'm not certain which of the difficulties you're referring to. It seems to me that we've listed three difficulties. One is, the radiation oncologists who are finishing training, and

their need to be authorized users without having to get passed the boards. Therefore, they would have to have satisfied the T&E requirements under the alternate pathway. Some will not have done that.

The second one is the radiology residents who will be finishing with the same problem. The third is the issue of physicists, whether they receive their physics training under the ABR or another route, and what their status is. And it looks as if, in terms of crises, the crisis that may be the largest of all requiring individual attention is the issue of the physicists who, in a sense, are being disenfranchised.

MEMBER DIAMOND: If I may respond to your first two points.

CHAIRMAN MALMUD: Yes.

MEMBER DIAMOND: I think that we need to send two letters to the American Board of Radiology asking how they, as a board, suggest addressing the issue, firstly, of radiation oncology trainees who will be completing in June 2006, who desire to practice 390, 490, 690 uses in non-agreement states in clinics where there's not an authorized user. Ask them how they've decided to address the problem, and then repeat a similar letter to the American Board of Radiology specifically for diagnostic medicine, how

will the issue of trainees finishing in June 2006 who wish to practice 390 uses, who may not be able to document the 80 hours that Dr. Eggli has discussed, what solution is proposed, again practicing in non-agreement states where there's not an authorized user also practicing.

CHAIRMAN MALMUD: On those two issues, who has been communicating with these two boards, who in the NRC? To whom are the ABR - who are they writing to, and who's responding to them?

MS. FLANNERY: That would be.

CHAIRMAN MALMUD: Okay. So do you think that it would be worthwhile drafting two such letters?

MS. FLANNERY: Yes. As I mentioned before, the reason why it has a future date of June 2007 is because the ABR Radiation Oncology specialty could not meet the criteria in 390. So we could possibly go to the board and see if that was the case for 490 and 690, that would be a possibility, and contacting the board that way.

CHAIRMAN MALMUD: Would that satisfy your suggestion, Dr. Diamond?

MEMBER DIAMOND: I think it would be an extraordinarily useful exercise to contact the board and ask the specific question that I outlined a few

moments ago, and ask how they suggest solving the problem. And perhaps, in the interim since you've last had communication with the board, perhaps they've been able to submit additional information or data that would allay some of our concerns regarding the 490 and 690 uses, at a minimum.

CHAIRMAN MALMUD: All right. So you are suggesting two such letters be drafted, one of the American Board of Radiology, one to the American Board of Radiation Oncology.

MEMBER DIAMOND: No, no. American Board of Radiology with respect to radiation oncology, and a second to the American Board of Radiology with respect to diagnostic --

CHAIRMAN MALMUD: Diagnostic radiology. Ralph, Mr. Lieto, you have a comment about that?

MEMBER LIETO: Just a question for Cynthia. Does the ABR understand, or I should say do they recognize that what they've put forth so far will disenfranchise previous diplomats? Do they understand that, or are they just kind of looking at the future and trying to address a future issue?

MS. FLANNERY: I think that was a question that Dr. Diamond had asked earlier, and I don't know the answer to that. I'm sorry.

MEMBER DIAMOND: Ralph, I bet that when they were issuing this material in response to the staff's questions, someone probably neglected this specific issue that was highlighted and brought to our attention an hour ago, as the start of our conversation. Just a guess.

CHAIRMAN MALMUD: Well, it certainly is a worthwhile effort to get those two letters off as quickly as possible, if you're in agreement that those can be written.

PARTICIPANT: Dr. Malmud, I think Dr. Diamond is suggesting letters written from the ACMUI, not necessarily the staff. Is that correct, Dr. Diamond?

MEMBER DIAMOND: I did not specify. Perhaps it would be best for Ms. Flannery to be the author of the letters since she has the ongoing communication. The ACMUI does not have the ongoing line of communication with the ABR. Although, certainly, we as individuals could contact them.

CHAIRMAN MALMUD: Dr. Miller.

DR. MILLER: May I offer a practical solution?

CHAIRMAN MALMUD: Please do.

DR. MILLER: Would it be acceptable to the

ACMUI for the NRC staff to send such a letter, but note in the letter at the recommendation of ACMUI we are sending you this letter? I think that would satisfy all concerns.

CHAIRMAN MALMUD: That would satisfy us. Thank you. Could that letter go out soon?

MS. FLANNERY: I don't see a problem with that.

CHAIRMAN MALMUD: Okay. So we'll assume that that letter will go out to the ABR with regard to radiation oncology and diagnostic radiology. All right. So that begins to address two of the issues. The third issue remains, and that is the concern about the status of the physicists. Dr. Miller.

DR. MILLER: Yes. Dr. Holahan has raised an interesting point. There seems to be a lot of interest in getting a letter out quickly, but then the question becomes does the ACMUI want to review the letter before it goes out to assure that its recommendations are accurately reflected so that we're not back at a table later saying that the staff mischaracterized what your intentions would be.

CHAIRMAN MALMUD: Dr. Vetter says that Malmud could review it, and Malmud would be happy to review it with Dr. Diamond, since it was his

suggestion. We could do that very quickly as soon as the letter is drafted.

MS. FLANNERY: Okay.

DR. MILLER: Thank you.

CHAIRMAN MALMUD: That takes us to the other issue, which is of concern, and that is the status of physicists. What we do not wish to do is be a part of a process which disenfranchises people who are currently practicing, and puts patients at risk for not having adequate physicists to manage the clinical operations. Nobody in this room wishes to be a part of such a process, whether they are ACMUI, the public, or I'm sure the staff of the NRC, so how do we resolve this? Does anyone have a constructive suggestion, rather than replaying the problem? Let the record show we're met with silence so far. I think a member of the public has something to contribute. That's Mr. White.

MR. WHITE: I'm not sure I have a definitive suggestion on the spur of the moment, but I'd first like to recognize that there appears to be general agreement that there is a problem that needs to be solved. And secondly, I heard two potential suggestions, each of which I'm sure have difficulties associated with them. One is something analogous to

an extension of Subpart J, which brings with it a lot of rulemaking overhead, although from the point of the American Association of Physicists in Medicine, that's overhead that would accrue to the NRC and staff, rather than to our organization and our members, so it's not quite as objectionable on this side of the microphone as the other. But there are some temporal difficulties with that.

The other is some discussion of an exemption process, or some sort of interim - I'm not sure in the regulatory world how that might happen. And then the third is maybe a further review of what some states have done in this regard; although, I will say in the states that I'm familiar with, those changes have been done in the rulemaking space, which is much easier in the state world oftentimes than in the federal world. But I think if there is a general agreement that there's a problem that needs to be solved, we can find some way to do it. I'm just not sure that it's this afternoon.

CHAIRMAN MALMUD: I think that we've reached an agreement that there's a problem. We've also been told that we cannot resurrect Part J, and that it is not Lazarus, and we don't have that power, so that that's not a viable solution. Therefore,

other means of solving the problem need to be brought forth in order not to interrupt the quality of healthcare. It's also been my experience with this Committee within the last year that the NRC staff, Dr. Howe, Dr. Zelac, have, in a sense, been more charitable toward a variance and an exemption for a physicist practicing offshore if I remember correctly than the staff was, than the ACMUI was. So I wonder if, in fact, we should be turning back to the wisdom of Drs. Howe and Zelac, and asking them if they have a solution proposed, since they were more understanding of the special needs of the physicist than this Committee was last time I recall the subject coming forward. Dr. Howe, I'm putting you on the spot.

DR. BETH-HOWE: I don't think I have a solution now. I think one of the things that we need to think about is how big is the problem, because we've now had essentially authorized medical physicists, at least in NRC states, for the last - since 2002, and they're only recognized for HDR units and Gamma Knife units. And so, I don't think -- and we're looking at a larger number of Gamma Knife units, but certainly not a huge number of Gamma Knife units, so I'm not sure we have as much of a problem with the

Gamma Knife. And I'm not so sure on the HDR. We haven't recognized an authorized medical physicist for the manual brachytherapy, which I think is probably a larger program, so we don't have a problem for authorized medical physicists for the manual brachytherapy, so I think one of the things we'd have to answer is how big a problem is it, first. And I'm not sure we know that answer right now.

CHAIRMAN MALMUD: Would you recommend that we wait and see, and then deal with it on a case-by-case basis as it arises?

DR. BETH-HOWE: I think we certainly have more flexibility to do that than any other path, because I don't think there would be that many exemptions that we would be considering.

CHAIRMAN MALMUD: Thank you. Mr. Lieto, Dr. Williamson, this relates to physicists. Are the two of you agreeable to see what happens, and then let NRC staff deal with it on a case-by-case basis, as it arises?

MEMBER WILLIAMSON: I think we could maybe make it known to the regulated community that if troubles like this do come up, that the NRC does have a mechanism to grant variances from T&E rules, as you pointed out before and some of us were not very

charitable, I guess, to all the requesters, but perhaps we could turn over a new leaf and even a large batch of cases like this could be reviewed expeditiously, and a decision rendered, or enough precedents set that the staff would feel comfortable running an exemption process even without our assistance in each case.

CHAIRMAN MALMUD: Rather than promising a solution, could you communicate that the NRC will investigate a solution in order to address the issue?

MEMBER WILLIAMSON: I would just say, I think maybe this is the best idea. And I think the representatives of the AAPM maybe have heard that there is a mechanism for submitting petitions to this body. Is that correct?

DR. HOLAHAN: I'd be cautious -- well, are you saying petitions for rulemaking, or --

MEMBER WILLIAMSON: No, petitions for granting an exemption or variance from the written language of the T&E requirement.

DR. HOLAHAN: Then it's an application. I'd just like to clarify, it's an application.

MEMBER WILLIAMSON: But an individual licensee can make such an application. It does not have to be approved by the region to come to

headquarters, does it?

CHAIRMAN MALMUD: Dr. Howe.

DR. BETH-HOWE: Yes, it would have to come to headquarters. I wanted to make another point, and I think it's something we may not be focusing on right now; and that is that there are several mechanisms to become an authorized medical physicist. One of them is being recognized as an authorized medical physicist by a broad scope license. That's independent of whether the state puts the individual on a limited specific license, and I would think that most of your authorized medical physicists, because of the HDR units and the Gamma Knife units, which is what we're recognizing them for, are probably broad scope licensees. And so, if the broad scope licensee recognize them as an authorized medical physicist, then they would be recognized under NRC's definition of an authorized medical physicist.

CHAIRMAN MALMUD: Mr. Lieto.

DR. BETH-HOWE: Also, an MML permitee.

MEMBER LIETO: I would really strongly take issue with your comment that most of the HDR work is at broad scope licenses. HDR is replacing manual brachytherapy in just leaps and bounds in community hospitals. There are some community hospitals setting

up mobile services. It's the exact opposite of the case that most HDR is done in broad scope licenses. I think my guess would be that -- not guess, my strong belief is that it's the exact opposite.

CHAIRMAN MALMUD: Well, then we will wait and see as each individual case arises, and NRC staff has the opportunity to see the scope of the problem and to work out a mechanism for dealing with it. It looks as if that's the best we're able to come up with today.

MR. ESSIG: Dr. Malmud, Mr. White and Dr. Zelac are waiting.

CHAIRMAN MALMUD: Oh, excuse me. Mr. White.

MR. WHITE: Thank you. I'd just like to suggest that the process you describe would be eagerly embraced by the AAPM if we were able to see some set of criteria by which the exemption requests would be judged; that is, if there were some sort of formal or informal guidance to the staff that physicists could look at and feel confident or not confident.

Secondly, I'll point out that this solves only the problem of authorized medical physicists. The problem of RSO remains, and it will remain an issue for about 25 years until physicists who are

certified prior to 2006 retire, so we still need some way to people who are certified prior, assuming that the ABR gains status with a date of 2006, we're still going to have a cadre of physicists who are going to go on for a quarter of a century who need to have this issue resolved, and I'm not sure how to do that. If it's the exemption process, perhaps we should talk about that, but we need to look at both RSO and AMP.

CHAIRMAN MALMUD: Thank you for clarifying the long-term issue, as well. And we will ask NRC staff to look at that latter problem, since we do not seem, as the ACMUI, to have the ability to resolve it, except to offer advice if a solution is proposed to us. Dr. Zelac.

DR. ZELAC: Just some quick observations on the problem. We've been in the new training and experience rule for five months, which is relatively short time. However, within that five months, the number of cases which have come up which have required exemption request consideration have been virtually zero with respect to physicists. Very few physicists have been coming forth whose credentials didn't match the current requirements, and had to have an exemption request considered.

The second thing is that with respect to

Mr. White's comments about having some idea what the guidelines would be, this is one of the suggestions that I had actually made to the American Board of Health Physics through one of its members, that a person essentially serve as a test case and apply for an exemption in such a way that we could at least establish some what seem to be reasonable guidelines for granting such an exemption. I think that would have utility. It's not to say that the result of one specific can automatically be extended to many others, but at least it would provide some framework for consideration of others, and some feedback to the user community as to what might be reasonable in terms of seeking an exemption.

CHAIRMAN MALMUD: Thank you for that suggestion, Dr. Zelac. I hope that if the AAPM is preparing a test case that they prepare a test case which will be persuasive and select the test case very carefully. We'll move on to the next item on the agenda, which was to have been what - the break?

We have a choice - we can take a break, take a five-minute just stand up and walk around, or just continue on? I've minutes. The suggestions were made for five minutes, and that's five.

(Whereupon, the proceedings went off the

record at 4:23 p.m. and went back on the record at 4:37 p.m.)

CHAIRMAN MALMUD: We'll begin the afternoon session and first there are some issues that Mr. Essig wants to bring forth. Tom?

MR. ESSIG: Yes, just to point out that if you look at the agenda, we have Items 12 -- 11, 12, and 13 on the agenda and it's now 4:35 and those were to have started at 3:00 o'clock. So what we're proposing doing is the last presentation of the day which was going to be a working session with Mr. Lieto to help prepare his slides and all, we will do that tomorrow morning and so that we would have sessions 11 and 12 yet this afternoon, plus the five-minute session, Dr. Malmud, that you mentioned by the other presenter.

And then tomorrow morning Session 14 will go on as currently scheduled. Session 15 will be done in summary fashion, that is the status of medical events. That will take 15 minutes, thereby freeing up 30 minutes. And the other 30 minutes that we would free up would come from the closing session or administrative closing action item review which has budgeted 45. We'll cut that to 15, freeing up another 30 minutes, giving us a total of 60 minutes freed up.

We'll take the 60 minutes, put it in the time slot right after presentation 15, so from 9:00 until 10:00 will be the work session with Mr. Lieto and then the break will be from 10:00 to 10:15 and then 10:15 to 11:15 will be Session 16 or, I'm sorry, 10:15 to 11;45 will be Session 16. And then Session 17 will be 11:45 till noon.

I can reiterate that tomorrow morning, but I just wanted to put people who are maybe concerned about this afternoon's session and how late we were going to finish. So, we can proceed.

CHAIRMAN MALMUD: Will Mohammed give us a new printout for tomorrow of the new agenda?

MALE PARTICIPANT: Yes.

CHAIRMAN MALMUD: Thank you. All right, if I may, we have a member of the public, Dr. Salem who is here from Chicago and to whom we had promised five minutes on the agenda a little bit earlier today and I'll ask him to give his presentation. You can come up to the front if you wish, Dr. Salem. Yes. And Dr. Salem is an interventional radiologist at Northwestern University and has about five minutes of comments to share with us. Dr. Salem.

DR. SALEM: Thank you, Mr. Chairman, members of the panel. Thank you for the opportunity

to speak. I just have an approximately five-minute commentary to make. My name is Riad Salem. I'm an interventional radiologist at Northwestern University in Chicago, Robert H. Lurie Comprehensive Cancer Center. I'm Board certified in radiology by the American Board of Radiology and fellowship trained in interventional radiology. I'm an authorized user of Y90 microspheres. I'm accompanied by Dr. Robbie Murphy, interventional radiologist, M.D. Anderson Cancer Center and Vanessa Gates, certified medical nuclear physicists.

This statement is made on behalf of the Society of Interventional Radiology, SIR. The Society of Interventional Radiology is a non-profit, national scientific organization of more than 4,000 physicians and allied healthcare professionals committed to improving the health and quality of life through the practice of vascular and interventional radiology. Before I continue, I would like to disclose that I am a consultant for MDS Nordion, manufacturer of TheraSphere, and I have lectured for Sirtex Medical, manufacturer of SirSpheres. Dr. Murphy is a proctor for SirSpheres. I would like to speak about my experience with Y90 microspheres.

As of today, I have successfully performed

over 850 infusions of Y90 microsphere therapy as the authorized user. In this capacity as authorized user, I performed all aspects of clinical patient assessment, eligibility for treatment, dosimetry and long-term follow-up. We continue to have a busy clinical practice and we average 28 to 30 cases per month. We continue to publish the safety and efficacy of this data supporting the treating -- the usage of Y90 for the treatment of liver tumors.

The SIR is interested in collaborating with the NRC as well as the societies representing radiation oncology and nuclear medicine to recognize interventional radiologists as qualified authorized users for Y90 microspheres. The SIR is concerned with the public transcripts from the meeting held in October 2004 and April 2005 discussing the topic of Y90 microspheres. It is unclear why the significance of the interventional radiology role was downplayed. In fact, it does not appear that interventional radiology had any input in the decision making process for Y90 microsphere regulation given the pivotal role the play in the treatment process.

We would like to briefly discuss arguments supporting interventional radiologists as the authorized user for Y90 microsphere therapy. One,

interventional radiologists are certified by the American Board of Radiology which includes 960 hours of compulsory nuclear medicine training during residency. Furthermore, as part of their residency training, interventional radiologists must complete mandatory didactic physics training, including radiation biology, radiation physics and radiation safety.

Two, Y90 microsphere therapy has been available commercially in the US for six years. IR's have been at the forefront of Y90 research. Of the last 50 peer reviewed publications and book chapters, more than 55 percent were generated by the interventional radiology community. In fact, current clinical research endeavors are underway to study the effects of radioactive microspheres for the treatment of liver tumors. These physician led efforts as principal investigators and as investigational device exemptions are being held by interventional radiologists.

Three, one of the arguments for radiation oncologists as the authorized user stems from the fact that Y90 microsphere are classified as ACL source or radiation delivery device by the FDA. However, we believe this classification alone should not

determined who should be an authorized user for Y90 microsphere therapy, since it ignores the unique delivery methodology for this device. Y90 microsphere treatment is a process unlike other brachytherapy modalities in that it is not performed through a needle placed into position like prostate seeds injected into a closed cavity like leucite or after loaded into the lumen of a stationary catheter by an automated system, example, coronary brachytherapy.

Trans-arterial microsphere delivery depends on the knowledge of vascular anatomy. Central factors in insuring target delivery of Y90 microspheres are intro-procedural precession of the anatomy, dynamic changes in the capacitiness of the hepatic vascular bed, catheter infusion pressure and angiographic end points to avoid significant adverse events such as stasis. These scales are intrinsic to the practice of interventional radiology.

Four, restricting authorized user status to a radiation oncologist has resulted in limiting access of this therapy to patients. To my knowledge, there have been several hospitals unable to offer this treatment option given the difficulties and the simultaneous availability of IR's and non-IR AU's in the procedure suite at the time of dose delivery. And

finally, I would like to discuss possibly one of the most compelling arguments for interventional radiologists as AU's. As part of their regulatory approval, both manufacturers of Y90 microspheres, Nordion and Sirtex require users to undergo training for usage of Y90 that encompasses dosimetry, patient selection, infusion techniques and clinical follow-up. As of today, April 25th, the training of authorized users is being performed exclusively by interventional radiologists with the exception of one radiation oncologist.

As previously stated by members of this committee, the role of this committee is not to dictate the medical use and practice of Y90 microspheres but to regulate the handling of the radioactive material in a medical setting. We agree with this statement. However, given the reasons above, the infusion of Y90 microspheres share significant features of pharmaceutical delivery. We would like to emphasize, therefore, that interventional radiology offers the expertise for Y90 microsphere use and that this specialty should not be excluded. In conclusion, the committee clearly recognizes the requirement for collaborative efforts between multiple modalities for successful use of Y90

microsphere therapy. This is evident given its continued classification as 35.1000.

Hence, we believe the training and experience required for this emerging technology should also reflect its hybrid status. We would like to advocate that one, the training requirements for this modality not be limited to 35.490 which essentially mandates three years of radiation oncology residency and two, interventional radiologists, by virtue of their training and experience, be authorized users for Y90 microspheres, a recognition that is commensurate with prevailing clinical practice and ultimately supported by the fact that as of today, radiation oncologists and nuclear medicines are being trained by interventional radiologists.

In closing, I thank the panel for the opportunity to provide comments and I'm pleased to be open for questions that it may have. Thank you.

CHAIRMAN MALMUD: Thank you, Dr. Salem. Are there questions for Dr. Salem? Dr. Eggli and then Dr. Diamond.

MEMBER EGGLI: Actually, David has his hand up first.

MEMBER DIAMOND: I'm just going to ask a brief question because I think in Doug's presentation,

mine and perhaps Subir's we're going to address a lot of these issues but my one question to Dr. Salem is, are there instances right now where board certified interventional radiologists, who obviously, are authorized users for 35.390 uses are not being granted a use status? Is that what you're telling me?

DR. SALEM: Yes, that is correct.

MEMBER DIAMOND: Where did that happen?

DR. SALEM: Where did that happen or when did that happen?

MEMBER DIAMOND: Can you give us some details?

DR. SALEM: At hospitals, most hospitals that I'm aware of are not recognizing interventional radiologists as authorized users. They are mandating that it be a radiation oncologist and in some places, nuclear medicine physicians.

MEMBER DIAMOND: Okay, but this is a very important distinction. It is not a hospital's determination as to who is an authorized user or not. That's the Nuclear Regulatory Commission's statutory authority. I think what you're referring to is hospital, credentialing hospital privileges. Is that more specific?

DR. SALEM: Yes, sir, if you're asking

about 35.399, I do not know --

MEMBER DIAMOND: Yes, that's a very different issue that we'll talk about.

DR. SALEM: Okay, I do not know the answer.

CHAIRMAN MALMUD: Dr. Eggli?

MEMBER EGGLI: I think that we don't have any trouble and I think both David and I will support the concept, we are not looking at titles of individuals. We are looking at authorization status and I think we will argue that any user who is authorized for Part 300 or Part 400 uses has demonstrated that they have adequate qualifications and there's no reason why an interventional radiologist can't be an authorized user for Part 300 uses.

Many of them are trained for that. Many of them actually leave their radiology residencies with preceptor statements that qualify them as Part 300, the general Part 300, not 392 or 394, but Part 300 uses.

CHAIRMAN MALMUD: Dr. Eggli, are you saying that from your understanding that they can be authorized users if they experience that training during their residency?

MEMBER EGGLI: I think what we're going to be talking about is recommendations that we are making to the ACMUI generally and hopefully ACMUI to NRC as to what are reasonable training requirements for uses of therapeutic microspheres. That's the issue that we're going to address.

MEMBER NAG: Dr. Malmud?

CHAIRMAN MALMUD: Yes, Dr. Nag.

MEMBER NAG: Yeah, since there are going to be three more presentations on the same issue and all of them are going to basically talk about the same thing, shouldn't we have the discussion after the three presentations?

CHAIRMAN MALMUD: You mean, should this speaker have come after the others?

MEMBER NAG: Yes.

CHAIRMAN MALMUD: Yes, but this speaker has to catch a flight back to Chicago and we didn't expect that we would be this late. Other comments? Mr. Lieto? Where is the speaker?

MEMBER LIETO: Actually, it was a converse of Dr. Diamond's question; are you aware of any interventional radiologists that have been approved as authorized users?

DR. SALEM: Yes.

MEMBER LIETO: And were these only under broad scope licenses?

DR. SALEM: Yes, to my knowledge, yes.

MEMBER LIETO: Okay, thank you.

CHAIRMAN MALMUD: Any other questions or comments for Dr. Salem? If not, thank you, Dr. Salem. We have heard your position and it will be considered as the discussion goes on into the afternoon. You're more than welcome to remain if you can catch an alternate flight.

Dr. Diamond.

MEMBER DIAMOND: Thank you. I was asked by the Chairman as Dr. Eggli, to have a few comments regarding training and experience issues in the use of hepatic arterial microspheres and to present a personal perspective. I'd like to preface my remarks by saying that this does not have the imprimatur of the entire radiation oncology organized community but it is my perspective, although I think that many of the community do, in fact, share it. At the conclusion of these presentations, I believe Dr. Nag is going to update us on a recent meeting that he hosted at Ohio State University from the so-called REBOC, the Radio-Embolization Brachytherapy Oncology Consortium. Is that correct?

Okay, and the REBOC Consortium's recommendations were not available by the time I needed to submit these slides but I think we will have some consensus. How do I -- I think Polonius said brevity is the soul of wit, so let's try and move it along.

Very good. So as we've discussed our charge is simply to provide advice to the Commissioners and staff on medical and technical issues that arise in the regulated use of byproduct material. Our concern is public safety. Was we've talked about for many years, our interest is -- we have no interest in the so-called practice of medicine which is the purview of the medical community, per se. So microsphere therapy is a medical device. Well, as we've discussed many times here, the manufacturer specifically opted to go through the FDA device, not the drug pathway for approval and it was this fact and not any radiation safety considerations that was the premise for FDA regulation as a medical device.

Is it a brachytherapy modality, yes, of course. Physically, these are encapsulated sealed sources but as we've discussed many times here from a regulatory viewpoint, it is problematic to place these under the manual brachytherapy meaning the 35.490

rubric for many examples. Number one, one cannot count the number of individual sources and we know that each Sir-Sphere vial for example, contains 40 to 80 million spheres. And further, this is also problematic because Technetium 99 microspheres have been used for some time in nuclear medicine and have never been regulated in this particular manner.

The current guidance that we've heard in the past from Donna Beth and her colleagues has been that these -- that this particular modality is now fallen under the emerging technology section, 35.1000 and current NRC guidance specifically recognizes 35.490, manual brachytherapy AU's with specific vendor training as authorized for this purpose and the question, therefore, was should the guidance be modified specifically to allow nuclear medicine authorized users and for that matter specific -- and for that matter, 35.390 users of any particular title to use the modality.

I believe back in 2003 there was an initial joint letter between the Society of Nuclear Medicine, the American College of Radiology, ASTRO and the AAPM in which this draft recommended that both physicians certified in nuclear medicine who have met 35.390 training and those certified in radiation

oncology who have met 35.490 uses be authorized for this particular use.

My personal recommendation is that I concur that both nuclear medicine 35.390 AU's and radiation oncology 35.490 AU's have the technical training and experience to safely handle and administer hepatic microspheres, and I would also submit that titles aside, diagnostic radiologists with 35.390 authorized user status also have the technical training and the technical experience to safely handle and administer these microspheres.

In summary, though outside the purview of the Nuclear Regulatory Commission, I strongly support efforts by which the professional societies develop guidelines which promote optimal patient care through a defined multi-specialty team approach analogous to what we've done in the past with vascular brachytherapy when it first came through. We have a lot of experience in approaching these new modalities. I will point out that patient screening and treatment planning are complex and most of these patients have been heavily pre-treated with chemotherapy and externally with radiotherapy. And as such, it is in the medical community's best interest to develop working documents that talk about the roles of

radiation oncologists, interventional radiologists and nuclear medicine physicians. With respect to our previous speaker, I think he had a little bit of a misunderstanding. Any authorized user with 35.390 background by this approach, should be authorized to actually deliver this modality. The question is, whether it be an interventional radiologists, whether it be a nuclear medicine physician, whether it be a radiation oncologist, I think the individual question is, should that person, in fact, do it and I hold the same position I've held in many other modalities in the past, which is it's a particular individual's interest and expertise which is the main determinant in the community level who should be doing this because I think we all agree that 35.390 users, 35.490 users all have the technical experience and background to do it.

And again, that really is outside the purview of the NRC and that's what I -- and that's why I'm pleased to see organizations such as the REBOC consortium discussing these issues, and I think this is an example where I and Doug are in marked agreement. So thank you very much. And this actually will be the last presentation I make to this August body and I thank all of you for all of these -- over

the past eight years the outstanding public service that you all have afforded to us. Appreciate it.

CHAIRMAN MALMUD: Thank you, Dr. Diamond.

(Applause)

CHAIRMAN MALMUD: The next item on the agenda is the presentation -- I turned it off, didn't I? The next item on the agenda is the presentation by Dr. Eggli.

MEMBER DIAMOND: Mr. Chairman, I just want to let you know that I may have to leave before the entirety of this particular topic is completed, so my apologies if I have to leave while Subir or the discussion are still going on.

CHAIRMAN MALMUD: Well, if you have to leave before Doug finishes his presentation, I'll take the opportunity to once again thank you for eight years of service to the NRC and to the public and for all of your contributions to the constructive activity of this committee. Thank you again.

MEMBER EGGLI: My conclusion is going to be exactly the same as David's. I'm going to raise a couple of different questions, which I think need to be discussed but it doesn't change ultimately the conclusions. I don't know that I need to spend a lot of time belaboring this but basically there

therapeutic microspheres have features that are similar to brachytherapy devices. They have features that are similar to unsealed sources and they are regulated right now in the Part 1000 New Technologies. Basically the similarity is to typical radiation -- brachytherapy sources. They're registered as brachytherapy sources. They're either sealed in glass beads or in resins. The differences is the sources don't have serial numbers and they are too numerous to count.

The sources behave like large particles which have been used in nuclear medicine for years. Spills are handled like unsealed sources. The patient distribution and dosimetry studies use nuclear medicine techniques and the administration is similar to the intra-arterial administration of MAA which has been used for evaluating chemotherapy to the liver and hepatic carcinomas and metasticies for long, long time.

Again, there are differences. They are technically brachytherapy sources and they are sealed. The bottom line in training issues is that any experienced therapeutic physician trained for either 300 or Part 400 uses can be safely trained to handle therapeutic microspheres. The nuclear medicine

physicians can learn the appropriate dosimetry techniques. The radiation oncologists, many now, are trained in Part 300 uses as part of their residencies, but those who weren't initially can be trained to manage unsealed sources.

The question that I raised are three cases enough to be considered adequately trained? I don't know the answer to that. I would think that as risk increased, it's reasonable to increase the experience required for independent use. And again, that can, I think, be a discussion point. It's kind of like prunes; are three enough or six too many. But the question is, what is the right amount of training. And I don't think that that amount of training varies for some class of users. Part 300 users, Part 400 users have the same kinds of training and experience requirement. I think that training programs should be designed conjointly, I've said by oncologists and nuclear medicine physicians, but maybe what I should say are Part 300 and Part 400 users, to determine what are the appropriate training requirements. The 300 people can sort of contribute the concept of what's an appropriate training requirement for those characteristics of microspheres that are related to 300 uses. The 400, the people trained and experienced

in Part 400 uses can contribute what they feel are appropriate training and experience requirements that suit the 400 requirements.

I've listed some possibilities. Basically, everybody that's a 300 or 400 user is well trained in the basic knowledge of biology, the basic physics, the basic mathematics and radioactivity. Everybody needs to develop experience with the administration devices. The practical experience in radiation safety as applied to unsealed sources is something that can be learned without a whole lot of difficulty. The use of dose calibrator surveying packages for contamination, detection of contamination, cleanup of radioactive spills are all basic techniques that easy cross-training can be provided for.

Nuclear medicine physicians may need some experience in dosimetry theory, techniques and calculations, those who don't do dosimetries currently and they, again, need experience with administration devices. So my recommendation, again, a personal recommendation but again, I think follows along with everything I've seen so far is that with appropriate training, authorized users for both Subpart 300 and Subpart 400 uses should be able to obtain authorized

user status for therapeutic microspheres. Appropriate training requirements need to be defined for these users and appropriate experience levels need to be determined.

CHAIRMAN MALMUD: Thank you, Dr. Eggli. It sounds as if you and Dr. Diamond are in complete agreement.

MEMBER EGGLI: I think so. The only difference is I've raised questions about what the requirements should be but otherwise philosophically, I think we're in complete agreement.

CHAIRMAN MALMUD: Thank you.

MEMBER DIAMOND: Mr. Chair, I think the important issue is, Doug and I are in complete agreement that 300 and 400 users both have the technical experience to safely handle and administer this. I think we also both agree that who is actually doing this is a question of medical practice which is outside the NRC purview and I think we thirdly agree that these type of discussions that Subir are going to bring to our attention is really the best for optimal patient care. This is a complex treatment technically. These are very, very sick patients. There are a lot of issues regarding how these patients are being followed and we -- and I'm sure we're all in

agreement that's it really how these patients are optimally cared for which is the real issue that needs to be tackled.

MEMBER EGGLI: And again, I am in full agreement with everything that Dr. Diamond has just said.

CHAIRMAN MALMUD: We will now hear from Dr. Nag. Dr. Nag.

MEMBER NAG: Thank you very much. I will presenting it more from the viewpoint of the REBOC committee and as a user of yttrium-90 microspheres. Basically, about a year ago there was an yttrium-90 meeting and during the meeting we came up with the idea that there should be a consensus panel because the indication, techniques and so on for yttrium-90 microsphere was so varied and there was no standardization.

So we formed the Radioembolization Brachyherapy Oncology Consortium or REBOC which is an independent group and it has expertise from the field of medical oncology, surgical oncology, radiation oncology, nuclear medicine and interventional radiology. Well, we decided to meet in Columbus, were I am, and I was the host, in April, just a couple of weeks ago and we identified the various controversial

areas and we made them clinical guidelines.

The members of the REBOC panel, there was 12 of us, represented the various specialties and also there were official representation from various societies like MES, the Brachytherapy Society, Society of Nuclear Medicine and so on. We made a number of recommendations. I don't have time to go through all the recommendations; however, I have sent a summary of the recommendations to the ACMUI panel members by e-mail. We have now finalized the whole report. We have sent out the report to various external viewers for their comments before we send it out for publication.

Some of the summary there is sufficient evidence to support the safety and efficacy of Y-90 and that the patient should be rendered it by a multi-disciplinary team and not by single individuals. And the candidates should be patients with unreceptable primary or metastatic disease who have predominantly a liver disease with a life expectancy of greater than three months and absolute are those whose pre-treatment MAA scan showed potential of more than 30 gray shunt to the lung and those that show lower GI tract that cannot be corrected by catheter embolization techniques. Relative (indiscernible) are

those with poor liver function and even worse of all elevated bilirubin level. We do need angiographic techniques and therefore, it would be very important and we have to embolize the hepatic threshold or the hepatic artery that (indiscernible).

If you have bilobar disease, you can either do a single whole liver infusion or sequential unilobar treatment and those with unilobar disease received therapy only to the hepatic lobe. The dose estimation using the surface area method the method of choice rather than other alternate methods and glass microsphere the calculations is supplied by the manufacturer recommended. And we felt that by virtue of the rating, certification and involvement, and contribution of Y-90 microsphere, the following disciplines are qualified to use Y-90 microsphere; radiation oncologists, nuclear medicine physicians, and interventional radiology and in terms of the licensing the 35.390 and the 35.490. And I think that's a very brief, the summary from the REBOC group.

CHAIRMAN MALMUD: Thank you, Dr. Nag. It sounds as if you are in agreement also. Dr. Diamond.

MEMBER DIAMOND: Yes, I'd just like to congratulate Dr. Nag for putting that meeting together. I think it's very helpful and very

important. One comment I would like to make is that now that we are in agreement on so many topics, one concern I do have, and again, this is not really the purview of the advisory committee but it's something I want to put out to the consortium, to the REBOC panel, what I do not want to see happening is I do not want to see for example, interventional radiologists in community hospitals performing this type of procedure on an infrequent basis without a very, very thorough pre-procedure evaluation of the patient or without a commitment to long-term followup.

In other words, I have no concerns that an interventional radiologist who is a 390 authorized user is safely trained to handle this particular modality. And at some of these large centers I'm impressed by the numbers of patients that are being treated, but my concern is the potential that at community centers, these patients could not -- my concern is that there could be a potential that they are not being adequately evaluated beforehand and that they are not being adequately followed in longitudinal fashion. Again, this is not the purview of this committee, but I'm just putting this out as my little input for your REBOC panel.

They need intensive follow-up. They need

intensive pre-treatment evaluation for optimal patient care.

MEMBER NAG: That is where the multi-disciplinary approach takes place. In many places it is done by either surgical oncologists or the medical oncologists, so it is a multi-disciplinary between nuclear medicine. In many places, nuclear medicine may give the dose, but the follow-up is done by medical oncologists and so on.

CHAIRMAN MALMUD: Thank you. Dr. Williamson.

MEMBER WILLIAMSON: I would like to congratulate all three speakers on I guess speaking with one voice on this matter. I would like to take one issue with one minor comment Dr. Diamond mentioned and that is that clinical competence has no role in the determination of training and experience. And I'll go back. I've been on the committee a long time since the early 1990s when we first began the discussion of how to revise Part 35. And it was at 35.300 where the break point fell.

35.200 and 100 was fell to patients and public safety had very minor dependence, if any, on clinical competence but that as we moved up from 300, 400 and 600, the issues of the ability to properly

select patients itself began to assume greater and greater public health significance.

CHAIRMAN MALMUD: Thank you. Other comments? Dr. Eggli?

MEMBER EGGLI: Again, I would like to congratulate Dr. Nag and the REBOC committee for a well-measured and well-thought out recommendation. I think that their emphasis on a multi-disciplinary approach is very important. I think this is becoming widely accepted in large medical centers but may not have drifted out, way out into the community and as we look at this, to re-emphasize Dr. Diamond's point that people with interest and ability will do a good job, but people who are under pressure in a small community setting might be pressured to do this in the absence of a multi-disciplinary team. And again, I think patient care, although again, our primary issue isn't patient care, but patient care is best facilitated by these multi-disciplinary teams.

And I would again, congratulate Dr. Nag and his committee for their acknowledgment of this reality.

CHAIRMAN MALMUD: Thank you. I believe that our member of the public has another comment. Dr. Salem?

MEMBER NAG: By the way, if any of you want to be an official viewer of the document, I'll be glad to send it to you and you can be a viewer. If any of you have any interest, put up your hand I can send it to you.

CHAIRMAN MALMUD: Thank you. Dr. Salem.

DR. SALEM: Yeah, I just wanted to echo the comments made by the panel. Indeed in the training process when physicians want to learn how to use this type of therapy, it is almost exactly what Dr. Diamond was saying, that we emphasize the clinical follow-up, the assessment, the multi-disciplinary approach because this is a significant advancement in the liver and the treatment of liver cancers and that is the only model that we push or we advocate and we recommend for the use of Y-90 microspheres.

CHAIRMAN MALMUD: Thank you. Dr. Salem, in your institution, with whom do you collaborate in the performance of these studies; radiation oncologists, medical oncologists or nuclear physician or none of them?

DR. SALEM: We work very closely with medical nuclear physics, so nuclear medicine is really the team that we work with and we collaborate with nuclear medicine, not radiation oncology in our

institution.

CHAIRMAN MALMUD: So the dosimetry is done by the medical physicists.

DR. SALEM: Myself and the medical physicist, that's correct, confirmed by the medical physicist.

CHAIRMAN MALMUD: And the medical physicist is associated with the section of nuclear medicine?

DR. SALEM: That is correct.

CHAIRMAN MALMUD: Thank you. Other comments from the public or from members of the committee? Now, having heard what we've heard, what are we expected to do as a result of being so well-informed with such a consensus of opinions? Was there action that was desired?

MEMBER NAG: I think --

CHAIRMAN MALMUD: Dr. Nag?

MEMBER NAG: Yeah, I think right now the way the wording of the NRC rule is, that it only 490 physicians are allowed to be authorized users other than the broad scope licensee. Am I not right? So I mean, I think the panel or the ACMUI members are telling otherwise.

CHAIRMAN MALMUD: Thank you. May we move

onto the next item on the agenda? Mr. Lieto?

MEMBER LIETO: I think we need to make some formal recommendations to change the guidance document that's out on the website. And I guess I'll get the ball rolling here, hopefully, I'll get it right. But I think the first thing would be a motion to amend the guidance for the Y-90 microspheres to include physicians approved under Part 390 as authorized users for the Y-90 microspheres.

MALE PARTICIPANT: (Inaudible)

MEMBER LIETO: I think those are already listed, so this would be in addition to the --

CHAIRMAN MALMUD: The motion that Mr. Lieto is making would increase the authorization from 490 users to 390 users and is there a second to that motion?

MEMBER WILLIAMSON: Second.

MEMBER NAG: Before that --

CHAIRMAN MALMUD: Dr. Williamson seconded it. Now, there's discussion. Dr. Eggli --

MEMBER EGGLI: No, I was just going to second it as well.

CHAIRMAN MALMUD: Okay, now I believe that Dr. Howe had a comment that she wished to make.

DR. HOWE: Yeah, I'm hoping during part of

your discussion you'll talk about what you think the adequate training and experience will be and also discuss whether you think there's a role for the medical physicist in here, not necessarily the HDR gamma knife medical physicist but as our colleague there said, he has a medical physicist that assists him in calculating dosimetry. So is there a role for a physicist in this one, too?

CHAIRMAN MALMUD: Having heard Dr. Howe's first question, what do we think requirements should be and number two, what's the role of the physicist. Dr. Eggli?

MEMBER EGGLI: I think the multi-disciplinary team needs to contain someone who is comfortable with the appropriate dosimetry. I'm not sure it necessarily has to be an authorized medical physicist but clearly someone with both experience and comfort at the dosimetry technique needs to be a member of the multi-disciplinary team. In my own case, I would welcome the medical physicist but I'm not sure that that should be an absolute requirement. There should be a requirement for that experience to be in the team.

DR. HOWE: Could you expand on what you would consider that experience to be?

MEMBER EGGLI: I think that again, the experiences with dosimetry that's related to the administration of microspheres.

DR. HOWE: Would a dosimetrist, as more of a technician, would that be acceptable or do you want a higher level of --

MEMBER EGGLI: I'm not sure that -- being from the nuclear medicine world rather than the radiation oncology world, I don't understand either the skill set or the distinction between someone who is simply -- who is a dosimetrist for external beam sources and a medical physicist. I would suspect that a dosimetrist doesn't have the necessary experience with small particles and that a medical physicist probably would be a more appropriate person but I would ask Subir to speak to that.

CHAIRMAN MALMUD: Dr. Nag?

MEMBER NAG: Yeah. Actually, I think for the yttrium-90, first of all, the physical presence of a physicist is not required unlike the -- you know, unlike gamma knife and HDRs. I don't think it would require the physical presence. I think you need physics input as part of the multi-disciplined team just like a medical oncologist and a radiation oncology and a surgical oncologist are part of the

team. The calculation for the yttrium-90 is reasonably easy, you know, you could just leave it as medical input rather than having, you know, AMP meaning --

CHAIRMAN MALMUD: Dr. Nag, would that mean that an interventional radiologist and a physics technician would be adequate to provide this service?

MEMBER NAG: Many places it's dosimetrist and whether the nuclear medicine type of dosimetrist or the radiation oncologist kind of dosimetrist fills the role.

MEMBER NAG: I'm sorry, I didn't understand.

MEMBER NAG: Dosimetrist.

CHAIRMAN MALMUD: A technician dosimetrist or a physicist dosimetrist?

MEMBER NAG: All dosimetry I think comes from the physics side.

CHAIRMAN MALMUD: All right, so it would be a physicist and an interventional radiologist, that would be a sufficient team?

MEMBER NAG: That's part of the team, because then from the medical input, either a medical oncologist or a surgical oncologist, plays into the team.

CHAIRMAN MALMUD: Okay, thank you. Dr. Williamson, you had a comment?

MEMBER WILLIAMSON: Yeah, I don't think -- if you're going to put in the guidance that input of a physicist or somebody who's an expert at unsealed dose calculations is needed, a dosimetrist is the wrong person. A dosimetrist may be trained by a physicist to carry out the procedures but is not in a position, it's not in their training to be able to devise such procedures.

CHAIRMAN MALMUD: Dr. Suleiman?

MEMBER SULEIMAN: What you need is somebody who understands the formal kinetic properties of the drug and if it's all going to go to the liver, you're fine but if it doesn't, so you need somebody who understands imaging sufficiently to identify the bio-distribution, clearance and uptake of the administered drug and from that, you're traditional nuclear medicine type calculations, but these are therapeutic doses, so as somebody once said, you can be off by two or three with a diagnostic, but here I think it's much more critical. The person you need, whether they're a physicist or dosimetrist is somebody very knowledgeable, is going to be somebody that if there's a problem that pops up, where did it go and

how much of the yttrium landed there, and how much dose is the individual getting. So I don't think you should take this cavalierly and I think that's why I think they're using the MAA to sort of get an idea pre-yttrium-90 what the distribution is, similar, I think to the Bexar and Zeblen drugs where you're trying to predict what the distribution is before you administer the therapy. So I don't think people should take this lightly. I don't know what the individual is, but I think this inter-disciplinary team approach is clearly important. Some of our pharmacologists understand this much better than sometimes the physicists.

I'm concerned that you have the appropriate technical expertise and I'm not so sure you can label any profession as being sufficiently knowledgeable to deliver that. So I don't think this is a trivial issue.

CHAIRMAN MALMUD: If I may, the credentialing process of the institution that provides the service would be one which would require the skill sets that you are discussing, but I don't think that addresses Dr. Howe's question which is what training do we believe is necessary for any of the individuals or an individual in this team to provide the service.

Was that your question, Dr. Howe?

DR. HOWE: Yes, it was. I think we recognize that when we have it over in 490 we generally have a physicist available there also. When we move into 390, we may or may not have a physicist. Is that person really necessary? Who is it that gives that extra support?

CHAIRMAN MALMUD: Mr. Lieto?

MEMBER LIETO: There's really three issues, I think before us. The first is, I think we need to vote on the motion. The second one, I think, would be to address do we want to include in the guidance a multi-disciplinary team of interventional radiologists, radiation oncologists, nuclear medicine and then I think the third thing would be to address the specific training components maybe, I think that Dr. Eggli addressed; how many cases should this involve in terms of the training and maybe some of the specific aspects of dosimetry and so forth.

So if I could, I'd like to maybe vote on the motion that's before us and then we could maybe move on to the other two points. Does that sound reasonable?

CHAIRMAN MALMUD: The motion before us is?

MEMBER LIETO: The motion before us is to

amend the regulatory guidance on the NRC website for Y-90 microspheres to add Part 390 authorized users.

CHAIRMAN MALMUD: And that motion was seconded by Dr. Williamson, as I recall. Any further discussion of that motion? All in favor? Any opposed? Any abstentions? It's unanimous. Congratulations. The next part of your statement related to --

MEMBER LIETO: The --

CHAIRMAN MALMUD: T&E?

MEMBER LIETO: The team -- should a team components be specified on the regulatory guidance.

CHAIRMAN MALMUD: All right, Dr. Vetter.

MEMBER VETTER: I'm not personally in favor of becoming that specific. I think each hospital has to decide who makes up the best team and their case. In one case it might be interventional radiologists and nuclear medicine. In another case, it might be radiation oncology. So I'm not convinced that we should be that specific.

CHAIRMAN MALMUD: Thank you, Dr. Vetter. I have a question. Is there ever a situation in which this procedure would be performed without the participation of an interventional radiologist? No, so could we define the team, therefore, as an

interventional radiologist, plus someone who has expertise in the handling of radio-pharmaceuticals and/or particles? Dr. Eggli?

MEMBER EGGLI: Yeah, you sort of stole my thunder there with my hand up in the air. I think what we should be defining are the required skill sets and not the required individuals and I think you've in a generic fashion, touched on those skill sets necessary. You need someone skilled at placing a catheter. You need someone who has experience with particle therapies and you need someone who has experience with the dosimetry calculations associated with the delivery of particle therapies. And that individual has training credentials for either Part 300 or Part 400 uses.

CHAIRMAN MALMUD: So that you are recommending that the team consist of an individual who is skilled at placing the catheter.

MEMBER EGGLI: Yes.

CHAIRMAN MALMUD: An individual who is skilled in understanding the radiation dosimetry.

MEMBER EGGLI: Yes.

CHAIRMAN MALMUD: An individual who's skilled in understanding the pharmacologic implications of the administration of these particles.

MEMBER EGGLI: Yes, and part of the dosimetry part includes the ability to use the nuclear medicine computers to do the dosimetry calculations as well.

CHAIRMAN MALMUD: That's getting kind of specific. You want to talk about the dosimetry.

MEMBER EGGLI: Yeah, that's skill in the dosimetry.

CHAIRMAN MALMUD: So the skills are the placement of the catheter, the calculation of the radiation burden and the understanding of the pharm --

MEMBER EGGLI: Well, the experience with unsealed source therapy.

CHAIRMAN MALMUD: The oncologist and techni --

MEMBER NAG: Yeah, one more. And someone with expertise in the knowledge of pharmacologic knowledge of liver cancer or how liver cancer behave, so you do need some oncology input, whether it be a medical oncologist, a radiation oncologist or a surgical oncologist to be part of the team.

CHAIRMAN MALMUD: That would be therapy, generically and oncologist, it could be radiation, medical or surgical. So it's oncology, placement of the catheter and the radiation dosimetry, those three

elements?

MEMBER EGGLI: Safe handling of unsealed sources.

CHAIRMAN MALMUD: All right.

MEMBER EGGLI: Because you can be -- you can be expert in calculating the dosimetry and not have experience in handling unsealed sources.

CHAIRMAN MALMUD: Right. So those are the four elements. Now, we get back to Dr. Howe's question which is still on the table. Dr. Howe?

DR. HOWE: Well, I was just going to ask a question and that is, I'm not sure I understand why pharmacology is important here because in this case, you have a sealed source that will get embedded in a capillary bed and you do not have -- you do not have a molecule that goes and interacts with any system. You have just a radiation emitter.

That's why we put it in manual brachytherapy is because it is radiation.

MEMBER EGGLI: I disagree. The resin leaks so you do have to consider physiology. If you only use the glass beads, I believe you're correct, but the resin leaks. You'll find the stuff in the urine after a resin treatment. So the resin leaks. So you have to understand the physiology of where else

you're going to get radiation exposure in the body if you're going to use the resin microspheres.

CHAIRMAN MALMUD: Does that answer your question, Dr. Howe?

DR. HOWE: That does at insight to my question, yes.

CHAIRMAN MALMUD: Thank you. Dr. Suleiman.

MEMBER SULEIMAN: Regarding the pharmacokinetics or to be more simple the bio-distribution, the ability to determine the bio-distribution from available images, I mean, it's very easy to misinterpret and if there are complications, again, in the REBOC think that I picked up on, they actually are using MAA to sort of predict if that patient, how it's going to distribute. So you just can't look up the dose distribution from some text book. I mean, it's going to be different. These are patients that are pathologically serious compromised.

DR. HOWE: I think we recognize that when you're doing this procedure, there is a diagnostic nuclear medicine aspect to it, which would be done by a 35.200 physician and that is the initial monitoring to see what kind of shunting that you might have, but we're separating that, because that is a traditional

nuclear medicine procedure done by traditional nuclear medicine from the actual administration of the yttrium microspheres and so we're just looking at the yttrium microsphere administration assuming that the licensee knows they have to use a 200 physician for the other part.

CHAIRMAN MALMUD: Dr. Eggli?

MEMBER EGGLI: I don't think that can be a 200 user because that's where the dosimetry calculation is coming from is the micro -- is the MAA distribution study. So I think that distribution study needs to be supervised by a 300 rather than a 200 user.

DR. HOWE: And that may be true but the administration doesn't have to be by a 300 user. But certainly that's part of the dosimetry.

MEMBER EGGLI: Well, but in reality, you wouldn't separate the person who's going to administer the MAA from the person who's going to use that information to calculate the dosimetry. Those are -- that's going to use proprietary nuclear medicine equipment, proprietary nuclear medicine software to come up with some of those numbers. So I would be reluctant to say this is a 200 -- a Part 200 user activity. I think it is part of the dosimetry of the

administration of microspheres and that should be -- in this case should be a 300 rather than a 200 user.

DR. HOWE: Okay.

CHAIRMAN MALMUD: We have a member of the public who's been very patiently waiting to make some comments. Would you please introduce yourself?

MS. WARBICK: Thank you. My name is Ann Warbick. I work in regulatory affairs at MDS Nordion. We're the manufacturer of the yttrium-90 glass microspheres and I wanted to point out to you just to give you a little bit of background that very early on, we realized that training and education of the new users was extremely important as you've already eluded to this. So what we did was we established a Center of Excellence in the United States and our Center of Excellence, you may not be surprised, is managed by Dr. Riad Salem. He has a wealth of information and knowledge that he's gleaned from using these microspheres and treating patients.

Whenever a new physician is interested in using our microspheres, we send them to Dr. Salem's site where they receive a full orientation. They receive lectures on mechanisms of actions, radiation dosimetry, all the basic background that will -- that they'll need in order to do that job. We already know

that they have a good medical background to start off with, so we've given them a little bit more.

And as well, Dr. Salem does treatments, does several treatments the day that they're visiting his site. After the treatments are completed, three different visits are made to the physician's site. We have proctors at our company that travel from Canada to different sites in the United States to proctor the different hospital sites and provide them with assistance. And if they need additional assistance, well, we're there for them.

Now, as the hospitals set up their first patients, I wanted you to also know that Dr. Salem works with them. He helps them to understand any issues that they have, screening the patients, you know, anything that might be an issue for them, dosimetry, that sort of thing. So he will work with them to help them do those first three patients. And if they need additional help we're there for them as well. I think Vanessa Gates wanted to make a few comments. She's the physicist that works on the team and it is definitely a team approach and I think that's what Dr. Salem's team does stress when visitors come to his site, that it must be a team approach, as you've already eluded to this. Thank you.

CHAIRMAN MALMUD: Thank you. Now I have a question. Does this mean that in practical terms, that this therapy could be administered by an interventional radiologist and a radiation oncologist absent input from nuclear medicine or by an interventional radiologist plus a nuclear physician absent radiation oncology? Is that an acceptable pairing? Whose arm is that? Dr. Eggli?

MEMBER EGGLI: Again, I think we need to go back to the skill set. I don't think you say it has to be an interventional radiologist and a nuclear medicine doc or an interventional radiologist and a radiation oncologist. I think you just need to make sure that the defined skill sets are available. I would not want to put a sub-specialty label on those skill sets.

CHAIRMAN MALMUD: All right, I believe Dr. Salem had a comment. Dr. Salem?

DR. SALEM: Yes. I completely agree. I'm not sure that we would want to label all the specific skill sets but at minimum, I think you pointed out that every patient that is evaluated for this, needs to have nuclear medicine input by virtue of the diagnostic and the dosimetry portion. So nuclear medicine plays an integral role in this based on the

MAA scanning for gastrointestinal shunting or lung shunting.

CHAIRMAN MALMUD: May I ask another question? That is, who manages these very sick patients when the come in with all of the sequelae of their disease?

MEMBER NAG: Again, may I answer that?

CHAIRMAN MALMUD: Yes, I was hoping you would.

MEMBER NAG: Okay, it depends, again, on the various hospital. From a practical standpoint, in our center, if they need to be admitted, post-therapy for any complication they're usually admitted by the medical oncologist or the surgical oncologist. In some places, the radiation oncologist would admit in places where radiation oncologists have admitting privileges. Now, it depends and the immediate post-op period they're looked after usually by the interventional radiologist within the first two to three hours.

CHAIRMAN MALMUD: Thank you.

DR. SALEM: If I could add a comment, Mr. Chairman, I think the cornerstone of the management of, for example, the hepatocellular carcinoma patient is the medical oncologist and the hepatologist with

our without the transplant team. So those two form the basis. From there, I think what happens is they are out-sourced for various therapies for certain periods of time, so the patients that get sent to say surgery or radiation oncology or interventional radiology, get sent there for therapy, whatever that therapy is for a period of months.

So for example, our hepatoma patients we follow for six to nine months at which time they are returned to the medical oncologist or the hepatologist for chronic long-term care, given as you point out, they have significant core morbidities.

CHAIRMAN MALMUD: Thank you. May I ask Dr. Howe, are you satisfied with an understanding of what the skill sets are that are required and with respect to the Nuclear Regulatory Commission's concerns?

DR. HOWE: I think so and I think part of it is that you've defined skill sets not individuals and so it could be one person or two people that contain all of these skill sets. One of the thoughts that I had was that perhaps one of our best ways to define adequate training would be a preceptor attestation which is the same mechanism that we use for all other authorized users and would put the focus

on the person that's providing the preceptor training to sign off on the individual as being competent to function.

CHAIRMAN MALMUD: The current regs require three cases for I-131 therapy. Is there a number that's recommended to achieve a degree of competence in this therapy?

MEMBER NAG: Yes.

DR. HOWE: From what I'm hearing it's sounds as if the training that's provided by the manufacturer at say the Center of Excellence is a number of cases and then there's also a follow-up at the individual hospital because you have unique situations with different team members.

CHAIRMAN MALMUD: I was wondering if there was a specific number. Dr. Nag.

MEMBER NAG: Yeah, I believe again, that number 3 that we have in the regs but there are many factors. One is the MDS Nordion and the other is Sirtex and both of them have preceptor training. Both of them will not allow you to do any yttrium-90 therapy until you have been precepted on at least three cases, I believe.

CHAIRMAN MALMUD: So three is a consistent number. It satisfies the standards that were

established for I-131 therapy. It satisfies that which the manufacturer of the product is using currently and is that the number that visitors to your program, Dr. Salem, at Northwestern, generally receive before you're willing to certify them?

DR. SALEM: Yes, sir, Mr. Chairman. What happens is they usually see two to three cases, but once they leave our institution, the manufacturer physically sends proctors for the actual administration portion the physics portion, added support for nuclear medicine and they do an extra three cases, so it is quite comprehensive.

CHAIRMAN MALMUD: Thank you. Dr. Suleiman, you have a pained expression on your face. Would you like to say something?

MEMBER SULEIMAN: I wasn't planning on it, but I'm not going to pass up the opportunity. I think the iodine therapy is much simpler relative to this and I think just philosophically, I think three sounds to me is too few.

CHAIRMAN MALMUD: We appreciate your opinion. Dr. Eggli?

MEMBER EGGLI: That was the concern that I'd actually raised in my presentation, you know, are three really enough. It sounds like what they're

doing is their training three and preceptoring three for a total of six. I'm personally much more comfortable with that kind of level of involvement. It's sort of the old see one, do one and then maybe teach one at some point, but I think that you're under close supervision participating in three. And then under still fairly close supervision, you are being mentored on three more the way the vendor currently has it set up.

I think I'm personally comfortable with that and I would agree with Orhan's statement that this is more complex that some of the radio-iodine therapies which speaks to why this would go into 390 rather than 392 or 394, because the bar is higher for a physician practicing for -- training requirement for 390 than it is for 392 or 394, so I think that's appropriate in raising the bar a little on the training and experience requirement, I think, is commensurate with that, with that increased risk level associated with that training. I think I would be -- I am comfortable with the approach that the vendor is suggesting which is three and three.

CHAIRMAN MALMUD: So you're more comfortable with six, three plus three, and Dr. Suleiman looks less pained with three plus three. And

Dr. Salem, is that a practical number, three plus three?

DR. SALEM: The three of six, I don't know if that concerns me more than the fact of putting a strict guidance and regulation on -- I don't know what the first three means. I mean, we have a Center of Excellence and we provide training. I don't know what other vendors or manufacturers are performing. I don't know what that means for other patients.

CHAIRMAN MALMUD: At your Center of Excellence, how many cases does an individual see who's visiting your Center of Excellence with that intention --

DR. SALEM: It will range between two and five.

CHAIRMAN MALMUD: Two and five.

DR. SALEM: There is no strict number that we follow. The strict number that I believe the manufacturers both follow and I fully support is three of the proctored at their own site, at their own institution, ironing out all of the technical nuances that are required for this therapy at their own site. The three for the manufacturer at the site, I believe is solid and compulsory. The other ones, I think, are a benefit. I don't know how easy or difficult it is

to mandate people actually see infusions before actually starting them.

CHAIRMAN MALMUD: The reason that I'm pursuing this is, if there are going to be guidelines, the guidelines have to have firm numbers and it seems to me that we have this active discussion ongoing now. This is a time to make a recommendation.

DR. SALEM: I believe if I could make a recommendation that three on site proctored infusions is reasonable.

MEMBER NAG: Dr. Malmud?

CHAIRMAN MALMUD: Dr. Nag?

MEMBER NAG: I mean, having done these procedures, I feel the -- I agree with Dr. Salem. The practical experience of having proctored in your own institution under your own environment is much more important than visiting someplace and seeing what others are doing. And you know, I believe that three proctored cases in your own institution is what I would go by.

CHAIRMAN MALMUD: Well, I'm sorry, I'm puzzled. How can one have three proctored cases in one's own institution when one hasn't done them before?

MEMBER NAG: Because what happens is that

the -- let's say I would go over to a place where they are going to do a new case. I would be there from the beginning. I would coach them or Dr. Salem would go and Dr. Salem would coach them from the beginning. They're there from the beginning of the day to the end of the day and they do that for at least three cases and therefore, all the practical problems that come up are solved right there.

CHAIRMAN MALMUD: Dr. Howe.

DR. HOWE: I think possibly one solution to this is to think about it in terms of training and work experience. And we could put cases in the training aspect which would be the vendor training, so people have a chance to see the experienced person using and then put three cases in the supervised work experience. So that we could meet both things at the same time, because I would hate to see this be a lecture part of training devoid of patient care on the first part.

CHAIRMAN MALMUD: So from the Nuclear Regulatory Commission perspective, it would be three supervised cases plus -- three proctored cases, is that the term, plus additional experience with regard to the radiation issues. We're not discussing credentialing here. That's a hospital issue, but from

the radiation perspective a minimum of three cases.

DR. HOWE: I'm looking more at possibly six cases, three being in the training aspect of it and then three being in the supervised work experience under the supervision of an authorized user that can do this procedure.

CHAIRMAN MALMUD: Thank you, I would -- Dr. Vetter?

MEMBER VETTER: Well, why are we -- it sounds like we're increasing the requirements and the question I would have is why are we increasing the requirements? Currently, it's three proctored cases.

DR. HOWE: I think part of the reason is that this is a complicated procedure that has many places where things can go wrong, just mechanically and with the material itself. So it's not your typical therapy administration.

MEMBER VETTER: But what is causing us to want to increase the required number of cases?

CHAIRMAN MALMUD: In other words, have there been any problems which would cause the minimum number to increase from the three that you have been using, Dr. Salem? Have you had any unusual circumstances that you --

DR. SALEM: No, I don't think so. I think

the ability of a site to see another hospital, see how they do this, is extremely helpful for hospitals. But I don't want to forget -- we don't want to forget the fact that we don't want to take that aspect for granted. It is not easy to find centers where you can find this type of training and this type of experience. And so the most -- the common denominator is at the own institution with a trained authorized user or therapist that uses this therapy that can literally navigate that site and hospital through their own process from A to Z.

You can theoretically train a site if you had an onsite authorized user in three day's time, having three or four or five patients to treat where all of these things are done. I think I am concerned about imposing this other training elsewhere because of the logistics and the ability to perform that.

CHAIRMAN MALMUD: When someone leaves your program, do you feel satisfied that he or she has had adequate experience in seeing three cases?

DR. SALEM: Absolutely. When they leave my program, I'm comfortable that they are ready to start.

CHAIRMAN MALMUD: With three cases.

DR. SALEM: They are ready to start their

own program, but they nevertheless need significant hand-holding and support by the manufacturers.

CHAIRMAN MALMUD: Yes. Dr. Schwarz, I think was next.

MEMBER SCHWARZ: I just have a question similar. Are there documented misadministrations, have there been problems with this particular modality that you're thinking that we need more cases?

DR. HOWE: Yes, we have had a number of misadministrations and we've had a number of problems in the delivery of the microspheres into the patient and we've had all aspects of it, but with SirSphere and with TheraSphere. So it does have a track record as being a kind of a unique procedure that needs special care and there are differences between the two devices that people need to be aware of when they are administering the different kinds of spheres.

MEMBER SCHWARZ: So you are thinking that additional training -- I mean -- would be a good thing. That three hands-on cases plus possibly three observed cases.

CHAIRMAN MALMUD: I think Dr. Vetter's question still remains unanswered. Would you care to say something, Dr. Vetter?

MEMBER VETTER: Yeah, just briefly. Once

again, I recognize it's a complicated procedure. I know there have been problems, especially early on, but what is the current root cause of the problems and can it be tied to a lack of training? I'm not arguing it ought to be three or six. What I'm arguing is, we ought to have a good reason for increasing the number of cases if we're going to increase the number of cases. So if there's a root cause tied to the lack of training, that's a reason to increase the number of cases.

CHAIRMAN MALMUD: Dr. Williamson was next.

MEMBER WILLIAMSON: I just have a simple question of fact. In the current vendor supplied training protocols for both agents, is the proctor necessarily an authorized user or is it just a technical representative from the company?

MEMBER NAG: No, it's an authorized user, someone who is doing it every day.

MEMBER LIETO: My interpretation is that what's occurring is that, say in Dr. Salem's case is that these individuals come. They observe the performance of three procedures going through all the motions, if you will, of what needs to be done and how it's done and so forth. Then they go to their institution and perform the procedures proctored by

the manufacturer's representative. Okay, and so I think what Donna Beth is recommending is just simply, I don't want to say codifying it but putting it into the guidance document is that there would be these three cases under an authorized user in which they go through training and experience -- through training. They then go to their institution and actually experience performing these procedures proctored by -- another three procedures proctored by -- very closely by the manufacturer vendor rep. That's my understanding of what they've been saying, which would be, I think the six cases we're talking about but really isn't any different than what's been done.

MEMBER NAG: I don't think that's so. The proctors are authorized users. They're either radiation oncologists or interventional radiologists who have done a large number of this procedure. They are not just technical representatives. So they are proctoring who have done a lot of cases themselves, they're authorized users.

MEMBER LIETO: But the authorizes user of the licensee that's performing the procedure okay, that's the three cases done on their own -- at the licensee's site, not the three cases -- they're not doing procedures at Dr. Salem's site. He's doing them

and they're basically monitoring sort of like, if you will, shadowing his staff and so forth. So I think the actual hands-on doing it, okay, is the three proctored cases at the licensee's site.

MEMBER NAG: Right.

MEMBER LIETO: So that's where the experience come is, not -- and the training is occurring in the first three cases. So I think what we're talking about are three training cases, three experience cases.

MEMBER NAG: But I think there are two different manufacturers and they do not necessarily do it the same way. And --

MEMBER LIETO: That's understood. What I'm saying is, the recommendation, I think, should be that we have the same thing regardless of the manufacturer of the microspheres so that the NRC can put this into their guidance.

MEMBER NAG: Right, but I think the important -- from a practical standpoint, and I have seen and I have done it and have be proctor also. The important component is the proctoring at your own site because that's where you learn all the practical problems that can go wrong. The other thing, you know, we had the yttrium-90 symposium series that goes

on for two days. Many of those things are the theoretical part, but the practical part is they proctored things that you have in your own institution.

CHAIRMAN MALMUD: Dr. Nag, are you recommending that three cases be seen at the original site and that two be proctored at the home institution?

MEMBER NAG: No, three be proctored at the home institution.

CHAIRMAN MALMUD: Three plus three is your recommendation.

MEMBER NAG: No, the other three is really not the important component. The three that is in your own institution is the important component.

CHAIRMAN MALMUD: So you are recommending three at one's own institution.

MEMBER NAG: Yes.

CHAIRMAN MALMUD: And who would be the proctor, the manufacturer's representative?

MEMBER NAG: No, the proctors are authorized users that the manufacturers send. I mean, they're sent by the manufacturers but they are not technicians. They are authorized users from other sites.

CHAIRMAN MALMUD: Is that a practical solution in terms of the willingness of the manufacturer to do this and the expense associated with the physician coming to the site? I'm just asking a question. We have a member of the public.

DR. MURPHY: Mr. Chairman, thank you very much. My name is Dr. Rodney Murphy from MD Anderson. I'm an interventional radiologist and I'm a proctor for Sirtex Medical. Dr. Salem is a proctor for Therasphere Medical or MDS Nordion, manufacturer of Therasphere. Sirtex Medical is a different approach. They do not have a Center of Excellence and proctors go out the individual sites. I am not an authorized user. I am a proctor for Sirtex Medical and the majority of proctors are not authorized users. And they're there in a shadowing capacity. So we're there to assist and answer questions till we feel that they are comfortable where they can actually the procedure on their own. I just want to add a little perspective on what's actually happening, the reality. So there is no Center of Excellence for the other manufacturer. So it's three cases, proctored at their home institution.

CHAIRMAN MALMUD: Thank you. That's three cases proctored at their own institution but not by an

authorized user.

DR. MURPHY: That is correct.

CHAIRMAN MALMUD: Thank you.

DR. MURPHY: And I do not necessarily follow up on the issue of whether or not these three cases have been proctored. In other words, the manufacturer follows up on the number of proctorings at that unusual site. When I go out to proctor a case there may be only one case on that particular day and on subsequent days another proctor may come out to necessarily proctor additional cases in order to achieve a minimal threshold number of three.

CHAIRMAN MALMUD: Then if I understand you, it's three cases proctored by the manufacturer with the manufacturer keeping the record of the three cases having been proctored.

DR. MURPHY: Correct.

CHAIRMAN MALMUD: And these are not by authorized users, necessarily.

DR. MURPHY: Correct.

CHAIRMAN MALMUD: They can be but they're not necessarily.

DR. MURPHY: Yes, that is correct.

CHAIRMAN MALMUD: And Dr. Salem is nodding his head in agreement, I see.

DR. SALEM: Yes, if I can just add, the reason for the authorized user distinction is because I'm fortunate to be authorized user in my state. Dr. Murphy is equally qualified as I am to be an authorized user and it varies from state to state. So he could be an authorized user.

CHAIRMAN MALMUD: So if one were to continue the practices that the two of you have introduced with respect to the two companies that you work with, it would be three cases proctored at the institution that wishes to do the procedure with the proctor not necessarily being but an authorized user.

DR. SALEM: But a representative of the company, yes, sir.

CHAIRMAN MALMUD: Thank you. That should answer the question as to what's been happening thus far which would help NRC establish policy for what will happen in the future. Did anyone else wish to make a comment about this issue. Time, yes. Oh, Dr. Williamson.

MEMBER WILLIAMSON: Well, I'm wondering what the qualifications of the proctor should be, just experienced physicians?

CHAIRMAN MALMUD: If I may, it would seem to me that the qualifications of the proctor should be

someone who has the experience of greater than three cases.

MEMBER WILLIAMSON: And not an authorized user, because that won't be practical it sounds like.

CHAIRMAN MALMUD: It sounds like it has not been an authorized user at least on one instance and it may not be practical for the individual to be the authorized user if these are relatively young physicians and who have not necessarily wish to be authorized users themselves being at large teaching institutions.

MEMBER NAG: The reason because they're not authorized user is as of now the NRC rule is that only 490 are authorized user for Y-90. Once the new rule comes in, both nuclear medicine physicians and interventional radiologists, who will have experience in 390 would also be authorized user. These are all physicians who are doing it every -- you know, who are doing it routinely but they are not necessarily authorized user because of the NRC rule.

CHAIRMAN MALMUD: I believe Dr. Vetter wishes to make a comment.

MEMBER VETTER: Just a quick one. Just remember that you can't do this without an interventional radiologist and that might give you a

clue as to why so many of them are the proctors.

CHAIRMAN MALMUD: You are, of course, correct. The other thing we should recognize is that while our goal is to achieve radiation safety practices which are in the best interest of the patients, we don't want to create hurdles which will prevent this procedure from being used broadly to the betterment of patient care. We are running far behind. If I may, I'll take the Chairmans' prerogative and close discussion on this issue right now.

Thank you, we'll move on. I wish to thank the members of the public who participated in this discussion. Your input was very valuable, thank you. If we may, we'll move on now to Item Number 12, which is Proposed Breast Brachytherapy Using I-125 Seeds, and the presenter will be Michael Cutrer. Did I pronounce it correctly?

DR. CUTRER: Yes, you did.

CHAIRMAN MALMUD: Thank you. With North American Scientific and he will present to the ACMUI the proposed breast brachytherapy using I-125 and the associated shielding issues. Mr. Cutrer.

DR. CUTRER: Thank you, Mr. Chairman and members of the committee. I appreciate the

opportunity here today to introduce to you a -- what we feel is an exciting new option in the treatment of accelerated partial breast eradiation using brachytherapy. I think everyone here will agree that the best part of my presentation today is that it's the last one, if I understand the schedule correctly.

I apologize that some of this presentation was done for individuals that were significantly less technical than the committee, so I can bypass a lot of this in the interest of time, but there is definitely a need for the accelerated partial breast radiation and a need for new options. The primary driver for that is that whole breast eradiation is taking six to eight weeks. The accelerated partial breast eradiation options that are currently out there provide a number of important options, primarily one being that patients are able to initiate their chemotherapy earlier as opposed to waiting the six to eight weeks for the treatment time.

With accelerated partial breast we've seen a number of Phase 2 studies that are supporting its use. We're seeing that the majority of the recurrences in these patients that are undergoing lumpectomies are in or near the tumor bed, which was the driver for accelerated partial breast in the first

place. The two current methods that are out there, one is using multiple catheters, 15 or 20 catheters placed in the breast, high dose rate treatment being used to treat these patients, coming in twice a day for five days for their treatment.

The challenges there obviously are that it's invasive. It's not easy to learn. It is high dose rate only at the present time. There has been low dose rate treatments having been done historically but the treatment time was 96 hours and so it was certainly not logistically possible for widespread adoption. Skin dose was also an issue with low dose rate because the breast would shift over that course of time.

The other challenges, that it does require the capital investment of the high dose rate system. There is also a balloon catheter out there, I'm sure many of you are familiar with the mammosite (phonetic) device. It certainly is more elegant from the standpoint that it is a single incision and placement. It forces the resection cavity to conform to the balloon as opposed to conforming to the resection cavity. Some of the concerns there are that it does put compression in areas of the breast and the tumor bed and restricts blood flow to those areas.

So the challenges there are that it's non-conformal. The inflation can cause areas of hypoxia. The seroma or air in the device itself can lead to areas of less superior deployment. There have been balloon ruptures. There's only a signal luman in which to place the high dose rate source. So it does restrict the conformality that a physicist or radiation oncologist could provide if there were greater catheters for them to use for the high dose rate treatment.

What we wanted to do was to blend what is good about the two existing systems; the first one being that it's a single site placement and that there's a single incision. There's not multiple incisions being made. There are multiple channels that allow for maximum dose conformity, whether it is high dose rate or low dose rate. What I approached our state health department with and then ultimately was directed to the NRC to get additional guidance was from the low dose rate perspective, what are some of the challenges or recommendations or concerns that the group might have.

So we also wanted to avoid any possibility of rupture. We wanted it to be conformal to the resection cavity, not forced conformality around the

device and not compress tissue. Essentially, what we have is a device that when it arrives at the site is compressed. It has eight to 12 catheters that are compressed there. And you'll see on the back end here, those little sliders, if you will, allow for you to do a secondary deployment. So this would be the initial deployment in the resection cavity and then the device, this little hand-held plier would be removed. Each of these sliders can be adjusted so that the device not conforms to the tumor bed as opposed to forcing conformality around the device itself.

So you would have multiple channels. High dose rate or low dose rate or a combination of either of those. In the scenarios where the resection cavity is very near the chest wall, you might opt for low dose rate there and high dose rate further out. Similarly, if it's very near the skin surface, you might be able to utilize a combination therapy as well. However, having multiple channels will allow for greater flexibility.

The device in the case of low dose rate, the patient would simply go home with this device capped. There are no catheters that would be outside the breast. In the case of high dose rate, we

envision an adaptor that would go on so similarly patients would go home with just the cap, not a number of catheters or even a single catheter hanging out of the breast. The low dose rate application, the drivers for low dose rate are the continuous dosing and improved biological effectiveness. The reduced dose to healthy tissue. There is no shielded facility required specifically for using Iodine 125. The convenience, we are looking at a number of areas that are of importance.

Identification on the patient in the event this patient were in an accident, they need to -- you know, people need to know that they need to have this device removed in a specific time frame. So there needs to be identification. This is also shielding for these patients in some cases. The data that we -- the preliminary data that we have seen, as you can imagine with Iodine 125 is very specific to the depth that it is in the tissue.

Patient education prior to release is certainly going to be critical. There are a number of existing surgical garments that are out there and a number of shielding materials that can be used. Demron, lead, bismouth, all of these can be incorporated into devices. The one here on this far

side here is a device that has been -- we have a manufacturer that can make these devices using demron or the bismouth device so that there is complete shielding if it's necessary. It's lightweight. There's no need, necessarily, for patients to be wearing anything that's excessive or bulky. And again, we think it's important that patient education and physician training be part of this introduction.

So again, some very preliminary measurements; we are estimating that we could be using as much as 300 millicuries of iodine, so certainly if there was absolutely no shielding on a patient where it is very near the surface, five millimeter depth, the dose is high. With bismouth or demron, we can reduce that significantly. At a meter those dose rates, as you would expect, would drop off significantly and can be shielded effectively to zero.

So what we're looking to do again, is to bring what is good about the two existing methods into one device. We actually just received FDA approval today on the low dose rate applicator and we're looking to roll this out later this year in the November time frame.

Obviously, there are a number of important drivers here but the primary one being accelerated

partial breast eradiation is something that is coming into the mainstream for a variety of reasons. There are two Phase 3 trials that are currently ongoing. Reimbursement is in place and I also believe that there is a significant opportunity outside of the US as well. That's it, as quickly as I could do it.

CHAIRMAN MALMUD: Thank you. Dr. Williamson.

MEMBER WILLIAMSON: So the sole regulatory issues before us is, this is a modality that would require a temporary implant patient to be released from the hospital and come back at some point in 96 hours to have the sources removed. Other than that, it would be handled completely under 35?

DR. MURPHY: Correct, and the high dose rate application, obviously, the patient is in the hospital or in the free-standing center. In the low dose rate application, much like with the ocular myeloma patients, where they're treated with the Iodine 125, placed in the eye and then they are released for some time period.

CHAIRMAN MALMUD: Dr. Howe.

DR. HOWE: I think the issue here is that the low dose rate patient, can they be released under 35.75 without additional shielding required and then

how do we insure that the patient complies with any additional shielding requirements, because the sources are left in place and the question is, 35.75. And it appears as if you need additional shielding in order to release anybody under 35.75. So that is the real issue here.

DR. MURPHY: We think that that is the case probably in the majority of cases. Where the resection cavity is near the chest wall, large breasts small resection, it is possible that that patient is not going to need additional shielding, but by far the majority of them will to some degree.

CHAIRMAN MALMUD: Malmud. The guidelines that we give to patients who receive I-131 therapy and who go home on an outpatient basis are existent. Wouldn't similar guidelines be applicable but even less so because of the range of the I-125?

DR. HOWE: The issue is with the 131 patients that you're releasing, you don't require additional shielding and so in this case, you're only -- they may only be able to allow them to be released if the shielding is in place and remains in place.

CHAIRMAN MALMUD: Dr. Nag?

MEMBER NAG: Yeah, I think the issue here is exactly similar to the OI myeloma patient treated

with I-125 where we have I-125 placed on the eye. Many places do them in the hospital for two or three or four days. Some send them home as an outpatient. And what we do is we measure and see if the exposure rate is more than 0.2 or something, we put a shielding in place and we send them home with instructions to keep the shielding on their eye. So I think similar instructions can be done with these patients.

DR. CUTRER: Right. In this case, what we felt was important was that as the manufacturer, we also offer options for the shielding as opposed to leaving it just strictly up to the physician in that any of the surgical garments that I showed or we can incorporate the bismouth material or the demron which is very flexible and can actually be cut and put into the surgical garments very easily.

CHAIRMAN MALMUD: Dr. Williamson.

MEMBER WILLIAMSON: Well, I think the conditions for release of 35.75 are clear. It doesn't specify that it needs to be a permanent implant or unsealed radioactive source. It just says that the dose equivalent has to be less than 500 millirentgen, period. And it would seem the only issue might be, I suppose, that the ancillary requirements for documentation and patient instruction don't cover the

shielding, if that's necessary, so that would be the only like one little paragraph added to 35-1000 would do it.

CHAIRMAN MALMUD: Mr. Lieto?

MEMBER LIETO: Could you go back to the slide that shows the shielding and the dose rates that -- it was a table, yeah, right there. How long are these sources left in?

DR. CUTRER: The typical treatment for accelerated partial breast today using the mammosite device in high dose rate is five days. So what we would envision here is that this is a dose that is going to be delivered continuously over a five-day period.

MEMBER LIETO: So they would come back and then it would be removed.

DR. CUTRER: Right, and while the -- you know, one scenario would be the patient comes in on Monday morning and they come back Friday afternoon and it's removed but the reality is from initial conversations with physicians is that certainly initially they're going to want to see that patient more frequently.

MEMBER LIETO: You know, looking at some of these numbers, I would say that, you know, with

even the thinnest shielding involved, you know, releasing these patients with, as Jeff pointed out, you know, precautions and guidance to be followed over a five-day period probably is not unreasonable and I would say that they could -- you know, I don't see the problem with releasing these under 35.75.

CHAIRMAN MALMUD: Dr. Nag.

MEMBER NAG: Although for high dose rate given over five days, because it's high dose rate, you can only give it two times a day. For LDR, very easily three to four days, so for LDR I think that could me more like four days in most places. In the eye patch it's as many as seven day, most of our eye plant is done in three to four days.

DR. CUTRER: Right, and we can certainly adjust that with activity levels that are in the same activity range as the eye plant patients.

CHAIRMAN MALMUD: Dr. Vetter?

MEMBER VETTER: Does the NRC have any experience relative to the compliance with wearing the shield for eye plant patients? To the best of my knowledge, patient compliance is excellent, so there would be no reason to believe patient compliance wouldn't be excellent here as well.

CHAIRMAN MALMUD: Any other comments?

Thank you very much.

DR. CUTRER: Thank you.

CHAIRMAN MALMUD: Is there any action that needs to be taken? Mr. Lieto?

MEMBER LIETO: I think NRC was looking for some recommendation from us on this and I would say that -- I would say that these patients being released with these shields in place and following the written instruction and requirements of Part 35.75 there would be no problem in releasing them with the activities -- up to the activities that were mentioned.

CHAIRMAN MALMUD: So you recommend that this go forward. Is there a second to the motion?

MEMBER WILLIAMSON: Second.

CHAIRMAN MALMUD: Second by Dr. Williamson. All in favor?

(Aye)

CHAIRMAN MALMUD: Any opposed? Any abstentions? It carries unanimously. Thank you very much. May I make a motion for adjournment for the day? We will recover and meet tomorrow at 8:00 a.m.

MR. ESSIG: Yes, we will, but it's in a different room remember, Room E1 and E2.

(Whereupon, at 6:18 p.m. the above-entitled matter concluded.)