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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES

(ACMUI)

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THURSDAY, NOVEMBER 13, 2003

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ROCKVILLE, MARYLAND

The ACMUI met at the Nuclear Regulatory Commission, Two White Flint North, Room T2B3, 11545 Rockville Pike, at 8:00 a.m., Manuel Cerqueira, M.D., Chairman, presiding.

COMMITTEE MEMBERS:

MANUEL CERQUEIRA, M.D., Chairman

DAVID A. DIAMOND, M.D., Member

NEKITA HOBSON, Member

RALPH P. LIETO, Member

LEON S. MALMUD, M.D., Member

RUTH McBURNEY, Member

SUBIR NAG, M.D., Member

SALLY WAGNER SCHWARTZ, Member

ORHAN H. SULEIMAN, Ph.D., FDA Representative

RICHARD J. VETTER, Ph.D., Member

JEFFREY F. WILLIAMSON, Ph.D., Member

ACMUI STAFF PRESENT:

ANGELA WILLIAMSON

THOMAS H. ESSIG, Designated Federal Official

LINDA M. GERSEY

PATRICIA K. HOLAHAN

ROBERTO J. TORRES

ALSO PRESENT:

John Szabo	NRC/OGC
Charles Miller	NRC/NMSS
Michael Layton	NRC/NSIR
Lynne Fairobent	ACR
Nancy R. Daly	
Angela Lee	
Bill Uffelman, Esq.	SNM General Counsel
Gerald A. White	AAPM
Andrew Kang	
Donna-Beth Howe	NRC/NMSS
Ronald Zelac	NRC/NMSS
Sami Sherbini	NRC/NMSS
Raymond Horn	
Kristin Swenson	
Roshunda Drummond	
Michele Burgess	

I-N-D-E-X

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

8:05 a.m.

CHAIRMAN CERQUEIRA: Just a few little administrative things up-front. I have sort of this last minute schedule changes at Georgetown, and since I'm local it's hard for me to miss it. So this afternoon I'm not going to be here, but I spoke to Dr. Malmud yesterday and he will sort of take over as Chair for the afternoon session.

Also, the session this afternoon at 2:15, dose reconstruction and unexplained exposure/extremity monitoring at materials facilities, due to some scheduling conflicts by Dr. Sherbini, that will be given this morning at 10:15, and the update on emerging technologies will be shifted to the afternoon.

We also had a little bit of discussion this morning, Angela had sent out the notices about the Commission briefing, and March 2 seems to be the date that everybody had agreed would work. And to avoid unnecessary travel what I'd like to do is if we could arrange the regular ACMUI meeting on the 1st, which would be a Monday, and then we could meet all day Monday, half a day Tuesday and then meet with the commissioners. That would sort of consolidate the

travel. Is everybody in agreement with that? Okay. So, Angela --

DR. WILLIAMSON: What are the dates for this?

CHAIRMAN CERQUEIRA: We would meet -- the full Committee would meet on March 1, which is a Monday, and then on March 2, which is a Tuesday, we would have the -- depending on the agenda, either have a half day meeting in the morning and then meet with the commissioners or depending on their time schedule the other way around. Basically, we would consolidate everything into March 1 and 2. Dick?

DR. VETTER: Would it be possible to get that nailed down prior to when we try to make airline reservations, because it's very difficult to make airline reservations and then try to adjust things afterwards.

CHAIRMAN CERQUEIRA: Yes, especially from Rochester, Minnesota, it's -- yes.

MS. SCHWARZ: I do agree with that. Maybe Angela could look into this room availability before we leave, because --

CHAIRMAN CERQUEIRA: Right.

MS. SCHWARZ: -- that was the problem --

CHAIRMAN CERQUEIRA: Last time, right.

MS. SCHWARZ: -- last --

CHAIRMAN CERQUEIRA: Now, Angela, is she here?

MR. ESSIG: She is here today.

CHAIRMAN CERQUEIRA: I did see her this morning, but she's not --

MR. ESSIG: She's here. We'll make sure that she does that.

CHAIRMAN CERQUEIRA: Okay. Because that would be important. That way we would lock the date in now with enough time, and I think we'd consolidate the meeting.

DR. NAG: That would help with hotels, because hotels are hard to get.

CHAIRMAN CERQUEIRA: Yes.

DR. MILLER: What day of the week are those days? Anybody have a calendar?

CHAIRMAN CERQUEIRA: Monday and Tuesday.

DR. MILLER: That might work okay. I mean the one -- that was a good suggestion because I know the ACRS meets, I think, with full Committee the first week of the month, if I remember right. Sometimes they'll attach a subcommittee meeting before the full Committee meeting, and the room may or may not be available.

MS. McBURNEY: So that's a Monday, Tuesday, and so we'd travel on Sunday.

DR. NAG: The meeting with the commissioners will be on the second afternoon or on the third?

CHAIRMAN CERQUEIRA: Again, it depends on their availability, but I think we could, depending on the agenda items that we have, we could sort of work around the Commission meeting.

DR. NAG: But I mean on the 2nd or 3rd?

CHAIRMAN CERQUEIRA: On the 2nd.

DR. NAG: On the 2nd.

CHAIRMAN CERQUEIRA: Yes.

DR. NAG: The other possibility you have it on the 3rd.

CHAIRMAN CERQUEIRA: That would be the other possibility, although sometimes it's ideal to try to --

MS. McBURNEY: To meet before.

CHAIRMAN CERQUEIRA: -- to meet before we actually have the meeting with the commissioners. But I would be in favor or -- if that's the only way we can do it, to do it on the 2nd and 3rd, do it that way rather than do what we did last time which was to have separate meetings.

DR. NAG: The actual meeting, radiation oncologists meeting, is the 26th, 27th, 28th, 29th.

CHAIRMAN CERQUEIRA: Is that March or April.

DR. DIAMOND: February.

CHAIRMAN CERQUEIRA: February.

DR. NAG: I guess the day before --

CHAIRMAN CERQUEIRA: And see the week after is the cardiology meetings, so I think the other option is the 9th. All right. So maybe if Angela could look into the possibilities of either the 1st or the 3rd for the regular meeting and to finish the business on the 2nd and to meet with the commissioners.

The other thing is John Szabo had come up with some -- we had questions yesterday about the subcommittee meetings, and he has come up with some other information that at 10:15 he's going to come down and just take about five minutes to go over those. And then the last item is that Dr. Miller mentioned the fact that the presentation made yesterday on safeguards, training and update, some of that information may have been covered under the Safeguards Act, and we may have to give up our notes and everything. So, Charlie, do you want to --

DR. MILLER: Yes. We got a call from Mike Layton saying some of the information that he presented yesterday may have wandered into safeguards territory. So I think the best thing to do to be safe is they will review the transcripts from the closed meeting, but in the interim if any of you took personal notes on that session, could we just put your name on them and borrow the back -- let us borrow them back and give them to Angela, and then we'll let the Safeguards people look at it. And then if they need to be redacted because of that, they will be, and anything that's not safeguards we'll make sure we get back to you.

CHAIRMAN CERQUEIRA: Okay. Good. All right. So we then move on to our regular agenda item, and the first one is SeedSelectron and 35.1000, and Dr. Howe will be --

DR. HOWE: Okay. What we're going to talk about this morning is essentially a new device that -- well, it's produced by Nucletron, called the SeedSelectron, and, actually, the SeedSelectron can be marketed in a number of different formats. The Nucletron SeedSelectron system itself I'll show you a picture of, and it is a seed delivery system, it is computer driven, and it has cartridges that include

the seeds, which are the isotron brachytherapy sources. And the package can also be expanded to include additional software that puts three-dimensional ultrasound images, real-time into the treatment planning part of the SeedSelectron so that you can do this procedure in the OR at the time of evaluating a patient. And you go directly from the ultrasound through the treatment planning system to the delivery of the seeds, making up the seed matrix and delivering the seeds all at one time.

Okay. Well, let's see what the SeedSelectron is. First of all, it's a computer-driven seed assembly and seed delivery system. It has cartridges that are located here that include either the isotron seeds or the spacers. The SeedSelectron drive cable is connected in here to the needles that go into the -- this is used for prostate treatment, and this is a view of the cassettes. One is the seed itself, and the other is the spacer system.

And this is a low dose remote-afterloader. It is computer driven, you use the computer to assemble the seeds in the configuration that you want, and you use the computer to deliver the seeds into the patient. You do manually move each time you want to delivery a new seed train, you'll connect it to a

different needle that's already implanted into the patient. So you'll manually reconnect the SeedSelectron to the needle that you're using for delivery. And you can use auxiliary treatment planning systems to do your treatment planning, and then you can manually put the information into the SeedSelectron. Or if you get the complete package of the FIRST system, you will get additional software.

Now, this is the same unit that you would see with the SeedSelectron, but there's additional software in here that will connect to the ultrasound probe is right in here so that you have a spiraling, three-dimensional. You get an image of the prostate, you do your mapping and your planning off of the three-dimensional image of the prostate here, and then you use the SeedSelectron software to map out where you want to put the seeds and the spacers, and then you use the SeedSelectron software to deliver the seeds to the prostate. Yes?

DR. WILLIAMSON: In the -- so the device actually without -- deposits the seed under motor control.

DR. HOWE: Yes.

DR. WILLIAMSON: Once the operator connects the meter to the device, there doesn't have

to be a manual intervention to get it to deposit seeds.

DR. HOWE: It will assemble the seeds, and it will also deliver the seeds by backing back out of the needles that are already placed in. Dr. Nag?

DR. NAG: Yes. I think we have to associate some of the marketing hype from the reality. First of all, isotron does not mean a new seed. Isotron just means I-125c --

DR. HOWE: But what it means is this is a specific model of a seed and put into a cassette so that this particular seed is not used independently for brachytherapy. It is put into this cassette and used with the seeds.

DR. NAG: But what I'm saying is the same as a regular iodine seed.

DR. HOWE: Absolutely.

DR. NAG: So there is no stain in the seed. Manually we can always put a seed baser on our own, so although the company hypes it as something new, it's not really something new in terms of radiation safety. That's what I'm trying to point out.

DR. HOWE: Well, the device is new then.

DR. NAG: Right, the device is new. I

mean you could manually put the needle in and pull it out yourself. And here the motor is doing that for you, so that's -- it's been hyped up, but we have to differentiate the hype from the reality. Otherwise, the way they say it it's like a brand new thing. The online software, I mean for years we have been taking a computer up to the OR, doing the treatment planning in real time. So, again, that is not new.

DR. HOWE: It's a package --

DR. NAG: Yes.

DR. HOWE: -- that comes from one company.

DR. NAG: Right.

DR. HOWE: And the other point I wanted to make is that this is a remote-afterloader, but it's a low dose remote-afterloader. And most low dose remote-afterloaders have a certain activity source that goes into a dwell time and then comes back out. This is different because it is permanent implant. So if you were to look at the regulations for the remote-afterloader, even the low dose after-loader, you'll find that there are many parts of the regulations in 600 that don't apply to this particular device.

So then you look at its unique characteristics, and you say, well, the actual delivery of the seeds into the prostate, the permanent

implant aspects are very similar to, as Dr. Nag said, as the manual brachytherapy. But there are the remote-afterloading aspects of the device that don't fit into the manual brachytherapy. So what we've done is we've said, okay. our basic guidelines are if you can fit a device or a drug exactly into a portion of the regulation, that's the portion it goes into. This particular device does not fit exactly into 600 and it does not fit exactly into 400. And if it doesn't fit exactly into one of those categories, it goes into 1000.

So the next thing you do is you try to figure out what are its unique characteristics and what are its characteristics that are similar to the rest of the regulations? Part 35 has just been revised. It tries to be performance based, risk informed, and so we don't want to reinvent any wheels. So what we do is we sit down with this device and we say, okay, which attributes does it have that can fit under 400, which attributes does it have that will fit under 600? And you start at the beginning of the regulation and you go through and you identify those elements that fit it well and you keep those elements. And then you identify those elements that don't fit it well and you develop guidance for those particular

parts. And we do have a Section 3512.

And my next question before I get to you, Dr. Nag, is how many people brought their regulations with them? Okay. If you don't have your regulations, I made copies so that we can follow along. Okay.

CHAIRMAN CERQUEIRA: Dr. Vetter and Dr. Williamson got extra credit for bringing the --

(Laughter.)

MS. McBURNEY: That's right.

CHAIRMAN CERQUEIRA: I have them, I just don't know which version to use.

DR. HOWE: Well, hopefully, I've given you the most current version. Dr. Nag?

DR. NAG: Yes. Actually, almost everything is the same as any permanent implant. The only difference being that the -- you have everything the same as a permanent implant. Only that last part where instead of manually pushing the needle in, it's a mechanical thing that is pushing the needle in. So all the regulations and all the steps are the same as a permanent implant.

DR. HOWE: But there are additional requirements for the 600 that address the device and the functioning of the device and its use that are applicable to this unit too. So what you're saying

about -- is true, but there are also some other aspects on the device that come into play with 600. And one of the first things you do is we use 3512 to provide this information -- to submit an application to use this device. And in 3512, you have to submit a 313, which includes a 313(a), and you have to identify facilities, individuals responsible for the radiation safety program and the radiation safety program.

And so the first thing we're going to look at is who can be an authorized user for this? Well, it's both manual brachytherapy and remote-afterloading. So, clearly, the remote-afterloading people understand the computer-driven aspects of it, the manual brachytherapy people understand the permanent implant seed part. So there is no reason to exclude either one of these types of authorized users from using this device, provided that they have -- that we ensure they have the training and the other aspect that is not covered under 600 or under 400.

DR. NAG: Again, I think I went even further, because all the training you need is the same as the manual brachytherapy because online treatment planning is done in manual systems. The computers are planning where the seeds are going. That is also in

the manual system. Again, I want to point out the only difference is instead of you manually pushing the seeds in, it's the machine pushing the seeds in. So everything is the same as the manual permanent brachytherapy system.

DR. HOWE: And I think you're right. It's just that in 35.490 and 35.940 there wasn't a distinction to pull out the interfacing that comes into the 690. So I think what I've essentially said here is that if you're an authorized user with 490 or 940, with work experience in remote-afterloading brachytherapy, and in that I just went to the key points of the remote-afterloading work experience criteria that talked about more of the interfacing.

DR. WILLIAMSON: What is 960 just for our reference?

DR. HOWE: Nine-forty. This is 490, 940. This is the manual brachytherapy.

DR. WILLIAMSON: Okay. All right. I see.

DR. HOWE: Okay. I may misspeak some digits here.

DR. WILLIAMSON: Yes. So you mean for an authorized user either under 400 applications or 600 applications would be acceptable is what you mean to say.

DR. HOWE: And what I'm saying is that in this particular case, because I'm -- you use 490, 940, but you want those interfacing experiences, which you may already have because that's how you do manual brachytherapy. But in our regulations it's not in there, okay? So I don't think this is a huge hurdle or a hurdle. I think it just has to be explained. And then the HDR people you meet the criteria of 690, 960 with work experience in manual brachytherapy. Now, I think probably if you come through your residency programs, you probably have manual brachytherapy in addition to HDR and --

DR. WILLIAMSON: It's a required component of the ACGME approved residency.

DR. HOWE: Right. And what our -- I have more detailed guidance that just pulls out -- if you look at 490 and 690, you'll see that there's some elements in the experience part that are just slightly different, because one is more instrument oriented, and the other is more purely treatment oriented.

DR. NAG: I agree with Number 2 because even if you have remote-afterloading experience for permanent brachytherapy, you do need the manual brachytherapy. But I don't agree with your Number 1 because basically someone who can do a permanent seed

implant can basically do -- you know, use this without knowing what an HDR afterloading is.

DR. HOWE: Well, this was not supposed to be HDR experience, it's supposed to be --

DR. NAG: Yes, remote-afterloading.

DR. WILLIAMSON: She's basically saying it can be either one, Subir, so I don't see why there's a problem.

MS. McBURNEY: Yes. And I think that you do need some experience or the training from the manufacturer, even if --

DR. NAG: Yes, always.

MS. McBURNEY: -- all you've been doing is manual, because the nuances of that device.

DR. WILLIAMSON: Or even if you have been doing HDR, you still need --

MS. McBURNEY: Sure.

DR. WILLIAMSON: -- training on the specific device. So I think the inclusiveness of the order seems quite appropriate.

MS. McBURNEY: Right. That seems reasonable.

DR. HOWE: And if you look at the elements for the 490 that I would look for that are not addressed in 490, they will be preparing treatment

plans, calculating doses, using survey meters, selecting the proper dose and how its administered using remote-afterloaders. That's not a high barrier. I think those things are already being done, it's just that they're not in 490 right now. They're over in 690. So those are the tasks that you would indicate you have work experience in.

DR. NAG: Okay. Now, again, I don't want to belabor the point, but the way you have it someone who has excellent knowledge of permanent brachytherapy, has never done a remote-afterloading brachytherapy will not be able to use this system, and that's what I object to.

DR. HOWE: Okay.

DR. WILLIAMSON: Well, is that true?

DR. NAG: Yes. The way you have it written here it is. The way I read it, that if I came to a permanent implant and I have done that for 20 years and I have never done a HDR, I wouldn't be able to use the system, which is wrong.

DR. WILLIAMSON: So do you consider acceptable experience to supplement 490 qualifications?

DR. NAG: Yes.

CHAIRMAN CERQUEIRA: Ralph?

MR. LIETO: I guess kind of if we can -- I'm trying to understand, and maybe you can refresh my memory, is why does this fit into the 600 also, just simply because it's remote?

DR. HOWE: It is a remote-afterloader, so it would go into 600 automatically. But if you try to fit it in 600, you can't fit it into 600 because it is really a cross between the two. It is more like a permanent implant in certain aspects. It is a device with the characteristics of remote-afterloading in another.

MR. LIETO: I ask Jeff a question. Remote-afterloaders I always thought you couldn't be in the room --

DR. NAG: No, no. That's high-dose rate remote-afterloader.

MR. LIETO: Is that just --

DR. DIAMOND: The reason this is a hybrid is except for this one device, which is new and I have not used, the purpose of having remote-afterloader is so that you can deliver a high dose rate source remote from the patient and the source protection. In this particular case, the reason they're using a remote-afterloader system is because there's a sense or a claim at least on the basis from the manufacturer that

by having the seeds delivered mechanically as opposed to under manual dexterity, you'll have a more uniform spacing of the seeds and therefore a more perfect implant.

So, really, although it is a remote-afterloader, the entire basis, the entire logic of it being a low dose rate system really pushes it much more towards the 400 series with the exception that it's a device delivering it.

MS. McBURNEY: But it's a device.

DR. WILLIAMSON: It's an automated seed positioning device, I would say, rather than --

DR. HOWE: Well, it's also a seed assembly and positioning.

DR. WILLIAMSON: But there are other such systems besides this that assemble seeds.

DR. NAG: Yes. Manually you can do that.

DR. HOWE: Manually, yes.

CHAIRMAN CERQUEIRA: Dick, you've been waiting patiently.

DR. VETTER: Well, if a person has -- if an authorized user has experience with manual afterloading and receives training from the manufacturer on this device, wouldn't that satisfy the requirements?

DR. HOWE: Well, I think what I'm hearing you say is that I could probably keep most of my elements except for the one with using remote-afterloaders and make that more -- that can be met by the user training and experience under the vendor.

DR. NAG: Yes.

DR. HOWE: Not user training but the vendor training.

DR. WILLIAMSON: It is really an incremental advance upon an already established clinical art.

DR. HOWE: Yes.

DR. WILLIAMSON: I agree. If you were going to require some additional kind of remote-afterloading experience beyond normal training and familiarization with this device, I think that would be a mistake.

DR. HOWE: Okay. And then when you go to 600, you look at the things that are not in 600 because of the type of devices you have, and you end up with tasks like ordering, receiving, unpacking radioactive materials safely, performing the related radiation safety surveys, preparing, implanting and removing brachytherapy sources and maintaining running inventories. Because an HDR person doesn't have to do

any of those things. So those are not high barriers to the 690 person either, but those are important elements that they may not do every day.

Now, we have not put -- I have not put any hours on this because it's performance based, okay? Different people are at different levels. You may be through a residency program that you've handled manual and remote-afterloading, so you come already prepared, okay? Now, the next one is --

CHAIRMAN CERQUEIRA: I guess sort of as somebody who isn't involved in this area for the radiation oncologists in the room, I mean what you're basically doing is you're basically using the ultrasound to define where to put the seeds, and then the computer algorithm will locate the coordinates and do the implants. But how well validated is the algorithm? How consistently does it --

DR. NAG: This has been done for many years by --

CHAIRMAN CERQUEIRA: Manually, right.

DR. NAG: You know, the computer has been through the treatment planning for many, many years, but what we used to do is after the computer gave the coordinates, we were manually pushing and you can assemble the seed and spacer outside manually too.

And then were pushing the needle in and putting the seed in manually. The only difference here -- the computer part is not new, the computer treatment planning is not new, seed and spacer assembly is not new. The only new thing is instead of manually pushing that seed train in, a robotic system is basically pushing it in.

CHAIRMAN CERQUEIRA: But I guess the question is how -- I mean with computer algorithms, if you're off by 90 degrees or something, you could basically --

DR. NAG: Yes. That has been well regulated with implants for the last ten, 15 years.

DR. WILLIAMSON: That's also covered in the provision which replaced the QMP, which outlines a minimal protocol for commissioning radiotherapy planning systems in general.

CHAIRMAN CERQUEIRA: Okay.

DR. WILLIAMSON: So that would be covered, at least from a regulatory point of view.

CHAIRMAN CERQUEIRA: Yes. Dick?

DR. VETTER: When placing the seeds manually, the radiation oncologist or urologist is very careful that the seeds don't follow the needle when you withdraw it. What prevents that from

occurring in this case with the remote-afterloader? What prevents the seeds from being drawn out with the needle?

DR. NAG: I think the manufacturer can probably tell a little better about mechanism, but I know basically the needle sort of -- you join it and the needle gets pulled out with the seeds remaining there. But if one of the manufacturers wants to tell a little more detail, they can.

DR. HOWE: I think the needle stops --

DR. WILLIAMSON: If the manufacturer would like to come to the microphone, we'd welcome your input.

DR. VETTER: The needle has to be withdrawn, and the seeds will follow that needle --

DR. NAG: No, if you have a stylet.

DR. VETTER: Oh, the machine has a stylet?

MR. HORN: Good morning. My name is Raymond Horn. I'm with Nucletron Corporation, and I have the business responsibility for this product. The SeedSelectron uses a push wire, and that push wire remains in place while the needle is pulled back for the length of the seed spacers. And then the push wire is retracted so the claim of the manufacturer is that this is done in a repeatable way as opposed to a

manual method, which is completely based on the dexterity of the clinician.

DR. HOWE: Okay. So the next area is in remote-afterloading you have an authorized medical physicist. And in looking at this the authorized medical physicists, the only ones we list on our license are those that are actively dealing with HDR units, teletherapy units and gamma knife units. Now, if we required an authorized medical physicist, we would be eliminating those medical physicists that are dealing on a daily basis with manual brachytherapy, and so I believe that we want to have a physicist that does not have to meet all the requirements of the authorized medical physicists. So I've given them a name, permanent implant low dose rate remote-afterloader medical physicist.

(Laughter.)

DR. HOWE: Just to clarify that this is what they're capable of. And who would I put in this category? Clearly, I would put an AMP with work experience in manual brachytherapy. I don't think there's any question about that. The next one is how do I characterize those people that are not qualified to be AMPs because they're not -- and the other thing is this device will go into facilities that don't have

HDRs and teletherapy units and gamma knives, and so there won't be any authorized medical physicists listed on the license. So I can't use an authorized medical physicist listed on the license.

DR. WILLIAMSON: Unless they do strontium 90 therapy.

DR. HOWE: But they won't always be in Puerto Rico and Hawaii.

(Laughter.)

So this device will go other places. So I said, okay, let's use what we currently have: Board certified with work experience in manual brachytherapy and full calibration measurements and period spot checks for low dose remote-afterloaders. What I did was I picked those elements that I thought were probably more under --

DR. WILLIAMSON: Okay. So some questions: Board certified by whom? What would be the criterion?

DR. HOWE: The same boards that you see in the --

DR. WILLIAMSON: Subpart J?

DR. HOWE: In Subpart J.

DR. WILLIAMSON: And when Subpart J disappears, then what?

DR. HOWE: Then it will be the boards that

are recognized for the 600 authorized medical physicists.

DR. WILLIAMSON: Are these seeds when they are supplied by the vendor, do they come in cassettes or does the operator manually load them into cassettes?

DR. HOWE: The do come into -- they come in cassettes. You're not supposed to take them out until you get ready to ship them back, but you can also ship them back in the cassettes.

DR. WILLIAMSON: And what calibrate -- where's the vendor person? What provision is there for the user to calibrate or to verify the calibration for the seeds?

MR. HORN: Sure. The seeds arrive pre-sterile and pre-shielded, and I'd point out that we claim higher level of red radiation safety and ease of use with this product than even the manual method. They come with a certificate of calibration. Then the user would excise one of the seeds into -- or multiple seeds into a well chamber. We make an insert that fits PTW or standard imaging chambers that connects directly, so there's no manual handling of the seed, and then the insert is placed in the well chamber and the standard measurements are made the way they are

now. The activity level is entered into the planning system exactly as you would now with the manual system. Does that answer your question, Jeff?

DR. HOWE: The part that hasn't been addressed yet is that in Part 35, both for manual brachytherapy and HDR, seeds have to be calibrated in accordance with nationally recognized standards and using instrumentation that meets the qualifications in 630. And so if the manufacturer can provide evidence that that's how the seeds are calibrated, then the licensee can use the certifications coming in from the manufacturer that these are the seeds in a certain activity and then do a check. Does that help answer your --

DR. WILLIAMSON: I guess. One follow-up question for Mr. --

DR. HOWE: Horn.

DR. NAG: Horn.

DR. WILLIAMSON: -- Horn, Mr. Horn. The APM protocol for doing this is currently specified by Task Group 56, which suggests you should ask, say, ten percent of the seeds. Is there a provision for when you calibrate these seeds not violating their sterility in being able to get them back into the cassette?

MR. HORN: No. You consume the seed when you use it for an external calibration. And I'll point out that the system will also provide 100 percent relative check on each seed, and you can generate a report that provides the variance.

DR. WILLIAMSON: Is there some sort of detector --

MR. HORN: Yes.

DR. WILLIAMSON: -- inside the machine?

MR. HORN: So there's a detector.

DR. WILLIAMSON: What kind?

MR. HORN: I don't know the exact diode makeup.

DR. HOWE: And so by -- as you'll see later, by using some of the criteria in 35.400, the user and the facility can use the manufactured in place of having to measure each seed individually but then can use the machine to kind of verify a relative precision, not accuracy.

DR. WILLIAMSON: One additional question about this. At least some systems that have been proposed and some that have been put together or assembled by individual institutions on an investigational basis actually have feedback between the two parts of the system so that there would be

some mechanism for determining where the seeds were positioned, feeding this information back to treatment planning, and then the computer would churn away and develop a modified treatment plan that would take into account positioning errors. Is there any such feedback loop with this system that you know of? Is there, for example, a seed position detection capability beyond simply positioning the needle in the stylet at a given coordinate?

MR. HORN: So the system here that we call the -- has the trade name of SeedSelectron is specifically the automatic delivery mechanism, and that's, I believe, what's at question for licensure. We make treatment planning systems that can be used with this that allow for not an automatic but a manual identification of seed juxtaposition or needle positioning. But that's all composed in the treatment planning system and it's not part of the seed delivery system itself.

DR. HOWE: Actually, what --

DR. WILLIAMSON: I'll repeat my question because it didn't get answered. So, a --

DR. HOWE: But let me just clarify one point first. What I'm providing guidance for is not just the SeedSelectron but also the SeedSelectron and

the FIRST. And it depends on whether they buy the SeedSelectron independently or they get the whole package on the FIRST, because the FIRST does bring in a criteria for 600 on computer program verification. And so if you're getting the FIRST, you've got to go over there and make sure you meet that criteria. If you're just getting the SeedSelectron, then you have to verify your computer treatment planning programs under 400. So this guidance will cover both packages, the SeedSelectron by itself and also the FIRST, which will be your treatment planning program with it.

DR. WILLIAMSON: Does the SeedSelectron claim to have the capability either through analysis of the ultrasound images or by fusion of radiographic projections with the ultrasound images, of being able to independently confirm the location of the seeds and the capability of feeding that information back to the treatment planning system?

DR. HOWE: I don't know whether the FIRST --

MR. HORN: The answer to that is no.

DR. WILLIAMSON: Okay. Thank you.

DR. HOWE: I thought the FIRST --

DR. NAG: There is no system that can identify the seed reliably on ultrasound after the

position. I mean the closest you can do is say this is where it will drop and therefore assume it's there or you can manually locate within one or two millimeters of where you dropped it and say, "I think this spec is the seed."

DR. WILLIAMSON: Well, there's actually one commercial product that claims the capability of doing that, so that's not completely true.

DR. HOWE: So my question to the manufacturer is what about the FIRST system? Does the FIRST system say it can identify that the seeds are placed?

MR. HORN: It does not automatically identify them without manual intervention of the user.

DR. HOWE: Okay.

MR. HORN: It is possible to identify them in the plan manually.

DR. HOWE: So then I have -- getting back to my medical physicist, I have an alternative pathway and that is that you meet -- you have training and experience in the elements that are in manual brachytherapy and those things for low dose remote-afterloaders, so that you can come through by either being an authorized medical physicist, being board certified but having your experience in manual

brachytherapy or being a medical physicist that's not board certified but meets the training and experience criteria that would have made you eligible to be an authorized medical physicist if you had HDRs, teletherapies and other things.

CHAIRMAN CERQUEIRA: Dick?

DR. VETTER: How many low dose remote-afterloaders are there in the country?

DR. NAG: Handful.

DR. VETTER: Yes. I just don't think there are many physicists that would fit category 2 or 3.

DR. HOWE: Okay. Then what I can also do here is I can address the elements I'm looking for and put the low dose remote-afterloading experience into the vendor training part.

MS. McBURNEY: Yes. That would work.

DR. WILLIAMSON: That would work better, yes.

CHAIRMAN CERQUEIRA: Ralph and then Dr. Nag.

MR. LIETO: I really think we're making a mountain out of a molehill here, because if a physicist is qualified to do manual iodine seed brachytherapy, they should be qualified in the

radiation safety aspects in terms of control, accountability and treatment planning. I think we really -- this new definition is really unwarranted, because if you're going to do this for this type of device, then my feeling from a radiation safety standpoint would be, well, why don't you do it for anybody that does iodine seed implants, even if it's manual? Why shouldn't they have those qualifications? And right now you don't.

CHAIRMAN CERQUEIRA: Dr. Nag?

DR. NAG: Yes. Actually, that was part of my point that, a, are you going to -- because of the remote-afterloader, are you going to have the witnesses that are required to be on-site at all time, because that's not needed. I mean in the same kind of implant where we are using a computer online, you don't have witnesses standing by you at all times; you don't need to. And are you going to be asking witnesses to be on-site. Basically, all you need is same as the authorized user, someone with training and experience in manual brachytherapy with vendor training in the remote-afterloading portion of it. That's all you need.

DR. HOWE: The criteria I was going to use for who had to be physically present was going to be

this particular medical physicist --

DR. NAG: Why?

DR. HOWE: -- or an authorized user.

DR. NAG: Okay. Well, authorized user to be there. He's the one pushing it in.

DR. HOWE: And then if you had the medical physicist there, you could also have somebody under the supervision of the authorized user.

DR. WILLIAMSON: Like a resident, I guess, but that would -- I'm wondering if this couldn't be simplified to put in something that's equivalent to the old alternative, the Subpart J alternative pathway or board certification and the equivalent of vendor supply training in this specific system. I mean I think that would cover it.

DR. HOWE: Well, essentially what I have is I have board certification here.

DR. WILLIAMSON: Yes.

DR. HOWE: And then I have the alternative pathway. And the reason I'm not identifying these as authorized medical physicists is because they may not be at a facility where you would have an authorized medical physicist. So I did not want to exclude --

DR. WILLIAMSON: No, I appreciate that. It's just the additional conditions that have been

pointed out that LDR remote-afterloading experience is rather rare.

DR. HOWE: Right.

DR. WILLIAMSON: Secondly, those remote-afterloading devices are not this device. And, really, what is needed is specific training and practice with this system.

DR. HOWE: Okay.

DR. WILLIAMSON: I mean that's what we would say. So I would say there's -- it's certainly useful experience to have had either high dose rate or conventional low dose remote-afterloading experience, but it isn't -- it's neither necessary nor sufficient to guarantee somebody can use this device. So I'd say the minimum we want is --

DR. HOWE: So essentially take this part out and put it into the vendor training.

DR. WILLIAMSON: -- sort of a common core requirements for the alternative pathway or board certification and an appropriate orientation with this specific system.

DR. HOWE: Okay. And move the experience part into the vendor training.

DR. WILLIAMSON: I'd say that would be reasonable, like you have -- has been proposed --

CHAIRMAN CERQUEIRA: So, Ralph, are you happy with that or do you have --

MR. LIETO: No, because -- well, let me ask, do you have requirements for manual brachytherapy for physicist requirements in the regulations?

DR. HOWE: For strontium 90.

MR. LIETO: For any of the other -- for iodine seeds or anything like that?

DR. HOWE: We had one that you had to -- the authorized medical physicist had to sign off on something and the rule was changed so that it's now the person that's doing it has to identify, but they don't have to be an authorized medical physicist.

MR. LIETO: So, again, I think we're making more regulations, and it's not going to improve anything regarding radiation safety on how things are done in the clinical environment, okay? There's not been anything that's demonstrated a problem with the manual iodine seed brachytherapy, so why are we making it that they have to be an AMP, okay? I mean there are situations where you may not have an AMP there or a board certified physicist.

DR. HOWE: That's why I'm saying --

DR. WILLIAMSON: Well, I think that's maybe the question.

DR. HOWE: That's what I'm saying is you don't have to be an AMP.

MR. LIETO: Then let's not put it in the regulations is my point. Why does it have to go under regulatory space?

MS. McBURNEY: It's not a regulation, is it?

MR. LIETO: Well, it's going to be a license condition. So in a sense what you're doing is making a regulation.

DR. WILLIAMSON: Ralph, are you arguing that NRC should not require as a condition of licensure of this device that any physicist be involved? Maybe that's what you're saying because right now manual brachytherapy doesn't require a physicist to be involved.

MR. LIETO: Right. I mean I guess pretty much that's what I'm saying. In the real sense, in the real world, pretty much there's always a physicist there, pretty much, okay? But I just --

DR. WILLIAMSON: I would be uncomfortable.

DR. NAG: No. If --

DR. HOWE: I know, but even with our worst manual brachytherapy misadministrations, there always seems to be a medical physicist that was present.

CHAIRMAN CERQUEIRA: So it sounds like we're in favor of keeping that in. And, Dr. Howe, I'm looking at the time and the number of slides that you have left. Are we going to be able to cover everything?

DR. HOWE: Well, I can do -- the next thing you have to do is you have to do the radiation safety program. In the radiation safety program, I'm saying you use -- you go to the regulations and what the regulations -- the regulations that pertain for permanent implant brachytherapy in Parts A through C, then you follow those. And those parts of the regulation that pertain to low dose remote-afterloaders in A through C you follow those. So you've captured everything and then there are a few things that may not be captured quite right. And this one you may or may not like. We're having problems defining what completion of the procedure means. So I wanted the licensee to define for this particular procedure what do you mean by completion of the procedure in the written directive so that we have a -- everybody has a fair understanding of how you determine that you delivered what you expected to deliver?

DR. NAG: But that's the same problem with

any permanent implant, even the manual permanent.

DR. HOWE: Absolutely.

DR. NAG: I think what I'm trying to say that you are making it unnecessarily complicated. Only thing you need to do with the whole system is make it the same as a permanent implant, requirement for authorized use, requirement for witnesses, requirement for everything else, plus training from the vendor on the use of the equipment. That's the only sentence you need to add. Everything else will follow automatically.

DR. WILLIAMSON: Well, in manual brachytherapy there is no requirement for a physicist.

DR. NAG: Right. So why do you need it here?

DR. WILLIAMSON: Well, I think you do.

DR. NAG: Why? I mean then you will need for it a manual one.

DR. WILLIAMSON: But I certainly would be very uncomfortable going on record supporting that we don't need a physicist involved.

DR. NAG: But then we are seeing a permanent implant in the OR, using computer, using treatment planning, again without any witnesses. What difference is this? There's no difference at all.

The only difference is instead of us putting the seeds in manually we are connecting it and letting the machine push it in.

DR. WILLIAMSON: Well, the only difference between remote-afterloading is that a machine is putting the source in place and then automatically retracting it.

DR. NAG: Right.

DR. WILLIAMSON: And we've come to the conclusion that that device requires some supervision or review, an assessment, commissioning and so on by an authorized medical physicist.

DR. NAG: The commissioning of the machine, not placing of the seed.

DR. WILLIAMSON: Even something as simple as the Novoste remote-afterloading device also requires an element of physics attention in regulatory space. So why would you think that this element does not?

CHAIRMAN CERQUEIRA: So we're getting -- Ralph and Dr. Nag feel that you don't need a physicist. Now, Dick, you felt that it was very important to have one.

DR. VETTER: Well, I'd be -- since this is a new device, I have no experience with it, perhaps

that's why I'm a little -- I'd be a little uncomfortable without having a physicist involved relative to confirming the treatment, not the actual implant procedure but confirming the treatment plan, making sure things are working out okay, and then if there are problems that develop, having a physicist involved in investigating those.

DR. NAG: Right. I mean I'm not against having the physicist as part of the whole plan, on the team, but I don't think you need a physicist to be physically present there for each application.

DR. WILLIAMSON: This isn't even being argued. This is not being argued.

MS. McBURNEY: No, that's not being argued.

DR. WILLIAMSON: We're talking about quality assurance -- and spot checks and basically having a physicist involved in the assessment and implementation of this device. Donna-Beth has not mentioned physical presence. I would agree with you that we don't need to require physics presence at every single treatment. I think the physicist maybe can substitute for authorized user under some circumstances that's been decided previously, but we haven't discussed that yet.

CHAIRMAN CERQUEIRA: But, Donna-Beth, how do we then make sure that there's a physicist involved at some point during this procedure but make it clear that during the actual procedure itself the physicist doesn't have to physically be there?

DR. HOWE: Well, I think you really do that through physical presence, but because you indicate that you have to have one of these physicists or the authorized user physically present, that doesn't mean the physicist has to be physically present every time, but that tells you that there is an authorized medical -- there is a physicist that's involved in this procedure, that's going to be listed on the license, and he's going to do what he's supposed to be doing. And then the licensee has the option of having either the physicist or the authorized user or someone under the supervision of the authorized user present during treatment. But you get at it, I think, through physical presence, because that's where you say I need a medical physicist associated with this device.

DR. WILLIAMSON: The implementation of a system in clinical practice through the full and spot check calibrations. Really, that's all that's being discussed here.

DR. VETTER: I think I like that, because then it allows the licensee to have the urologist actually present rather than the authorized user, but the physicist would have to be there. So one or other. The authorized user, the physicist, urologist can work on a team and decide which of the two, the authorized user or the physicist, would be present during the actual procedure. I like that. That gives some flexibility.

MS. McBURNEY: I do too.

CHAIRMAN CERQUEIRA: Ralph, do you want to make a comment?

MR. LIETO: This is where we're getting -- like here, they're talking about the physical presence.

DR. NAG: Yes.

MR. LIETO: And 615 requires --

DR. HOWE: And this is a conforming change. In other words, 615 doesn't fit exactly. So there's a conforming change for physical presence, and that would be either/or.

DR. WILLIAMSON: It's either/or.

DR. HOWE: Not both; either/or. But that does say that there's a physicist with the right level of training and experience associated with this device

somewhere in the process, and securing the room. This is a conforming change to 610. Six-ten says you've got to have the room locked whenever the device is there. This thing has cartridges. When you finish a procedure the cartridges are taken out and the device has no radioactive material. So they're conforming changes. You only have to have it secured when the sources are there. So there are conforming changes to address this device and the fact it does not need all of the bells and whistles that you see in the regular part of the regulations.

CHAIRMAN CERQUEIRA: So it seems like we have agreement on what we want to do, and I guess I would ask the people the way it's written would it basically assure that a physicist is involved at some point, yet allow the flexibility at the time of the actual implantation you're not going to put undue burden on the team?

DR. WILLIAMSON: I think it hangs on how exactly we define the minimum requirements for full calibration measurements.

DR. HOWE: In the full calibration measurements, what I did was I looked and I said, well, most of these things really don't pertain to this device.

MS. McBURNEY: Right.

DR. HOWE: So I went through and I said do you have to calibrate it every time you change the source? No, because this gets new sources every time it's used. So, first use, annually you need to check the device to make sure it's working, and I went through and just fit it for this device. And I think you'll see I have extra slides that -- well, I guess they don't go into too much detail, but --

DR. WILLIAMSON: I'm curious to know what you came up with as the sort of required elements.

DR. HOWE: Okay. So for radiation safety --

DR. WILLIAMSON: You could make it either very reasonable --

CHAIRMAN CERQUEIRA: Let's just try to keep one conversation going here. Go ahead.

DR. HOWE: And so this is just kind of a quick outline. The next slides go into more detail. I think these are in A, and we can skip through a lot of these. So these are the parts of manual brachytherapy that I think pertain to this device. Four-ten is except a(1), and a(1) I've modified to address -- where is 410? No, not 410. Sorry, that was 610. These are the manual brachytherapy things

that address permanent implant. These are the low dose remote-afterloader elements that I think fit. And 610 is except a(1), because a(1) says you've got to lock the room for the device and the sources aren't there most of the time, so I'm saying, hey, you may want to lock it to keep the device from walking away, but it's not a radiation safety problem, so you only have to keep the device secure when the sources are there.

CHAIRMAN CERQUEIRA: Ralph?

MR. LIETO: This isn't an operating room. Most of these are done in an operating theater, okay? You can't just -- I mean securing the room isn't going to happen. You're going to have people coming in and out.

DR. HOWE: And that's what I said. The only time you have to have it under surveillance is a conforming change to 610, and that's only when the sources are there, and then the people are there.

MR. LIETO: But this is always done when you have the seeds in the room. It's not anything different than what's always done when you seed implants in this type of situation. Why are we making it --

DR. WILLIAMSON: I don't know that we are,

but, Donna-Beth, may I make a suggestion?

DR. HOWE: Yes.

DR. WILLIAMSON: I think by putting up the numbers here and not telling us the substance in words of what you're recommending is leading to a lot of --

DR. HOWE: Confusion.

DR. WILLIAMSON: -- hypothesizing and misunderstanding on the part of the Committee members. So could you like make a brief verbal description of each one of the requirements and explain in a positive way what your bottom line is for --

DR. HOWE: Now, I think I'll probably run out of time here.

CHAIRMAN CERQUEIRA: Yes.

DR. HOLAHAN: I think your later slides do that. I was going to suggest that when we get an application in --

DR. HOWE: We have an application.

DR. HOLAHAN: We have an application in. We'll send you out the draft conditions that we're putting on the license to review. Would that work?

CHAIRMAN CERQUEIRA: It would be ideal to standardize it so you wouldn't have to review each application individually.

DR. HOLAHAN: Yes. Well, that's what I

was saying, that we could do a sample of what we're planning on putting in the license and send it over to the ACMUI for review.

DR. HOWE: But I've got it now in concurrence. I can make modifications based on what I'm hearing, and depending on how quickly the ACMUI can get back to me, the licensee is not going to want to wait another six months. So we may go ahead with licensing guidance that will get modified based on your comments later, and you will see that I -- I might talk this afternoon about emerging technologies. I've got a provision that we're putting up on the web site that allows people to change their program to match whatever is current in the web site without having to come in for an amendment. So it will give the licensees the flexibility to revise their program.

And the assumption is that when we revise the web site as we gain more experience, we're going to be reducing some of these things that we've put on them earlier. So that would kind of meet our criteria to get our licensee up and running and allow them the flexibility. As you come out with maybe a release of an easier system and we change that on the web site, the licensees can take advantage of that. So I think that's probably our compromise.

CHAIRMAN CERQUEIRA: That would be a preferable system, but, Patricia?

DR. HOLAHAN: Well, I was going to suggest if the ACMUI could look at it quickly, we could do it before -- we could do the first license.

DR. WILLIAMSON: How quickly is quickly?

DR. NAG: One week?

DR. HOLAHAN: One week.

DR. WILLIAMSON: One week? Two weeks?

CHAIRMAN CERQUEIRA: How many of these are we anticipating?

DR. HOLAHAN: Well, we'd like to standardize it.

DR. NAG: The first one.

DR. HOLAHAN: The first one, and then we could send --

DR. MILLER: I'd like to keep ACMUI out of the licensing business.

MS. McBURNEY: Right.

DR. MILLER: Because John Szabo told me that if you get into that, that puts different ethics restrictions on you than you currently have as a committee. But if you were to look at a sample of standards that we could use, and we get buy-in on that, well, then I think that gives us a path forward

that we're all comfortable with.

MS. McBURNEY: Would you want our individual comments or have the Emerging Technology Subcommittee send in that way.

MR. LIETO: Probably quicker individually.

DR. NAG: Individually.

CHAIRMAN CERQUEIRA: I think so too because some of us won't have any real expertise in these areas and be able to give you much insight. I think just going to the Committee members where they have the expertise in that area would be the appropriate way of doing it.

DR. MILLER: I'm comfortable with that if the Committee's comfortable with if those members that are expert in this area make the comments that the Committee -- they're speaking for the Committee.

DR. WILLIAMSON: I will be happy to volunteer. I think it would be good for my esteemed physics colleague, Ralph, to also participate.

(Laughter.)

DR. HOWE: Well, how timely that you volunteered him.

DR. WILLIAMSON: Well, I think the two us will look carefully and see. I think that the way we're conducting this, because we're not really

understanding what Donna-Beth is exactly requiring, it's difficult to give you the feedback.

DR. MILLER: You're struggling with it, and you need a way to get past that.

CHAIRMAN CERQUEIRA: But I guess we have to make it clear that even though the initial recommendations that go on the web site are published and available, that they will be modified depending on the initial application and the recommendations of this Committee. I think most people feel that once it's on the web site and it's -- you know, it may not be regulation but it's guidance and it's difficult to change.

DR. HOWE: Well, one of the reasons our 35.1000 guidance is on the web site is that it is much easier to change it and bring it up to date as we gain additional experience. And I'll be talking to you this afternoon about just one such case and what we've done, and I think we've done it in a global manner to make it more flexible for everybody.

DR. NAG: Basically, Donna-Beth, what I'd like to say is that whenever you're making any regulation on this, instead of trying to -- just because the word, "remote," is there in all the 600, basically this is nothing but a 400. All the

regulation of 400 has to be in there rather than the 600.

DR. HOWE: Subir, if you look at the parts of the regulation that I've referenced, you'll see that if I had an option between a 400 and a 600 and the 400 addressed everything I needed, I left the 600 out. I only brought the 600 in when it addressed instrument calibration, instrument QA and the types of things you want to do to make sure the system is doing what it's supposed to do. So I've done that balance. And that's one reason that even though I'm saying this is a remote-afterloader, you're seeing an awful lot of references to 400, because this is also a permanent implant which is much more closely covered on the actual implantation part by the 400 system.

DR. WILLIAMSON: May I make a suggestion to our Chairman? I think since there is the possibility that there could be some disagreement between the three of us individuals who seem to be really interested and with some experience in related applications, maybe the three of us should be delegated as like a --

DR. NAG: Subcommittee.

DR. WILLIAMSON: -- little subcommittee, working group of the Emerging Technology Subcommittee

to get together and try to achieve consensus so that we don't present the staff with a divergent body of opinion.

MS. McBURNEY: That was what I was trying to get at.

DR. WILLIAMSON: So we have a conference call if this is allowed to sort of go over it and iron out differences if we have differences in our individual views.

DR. HOWE: I think I'd also like to see at least one conference call where you could include me and Ruth, because --

DR. WILLIAMSON: Sure.

DR. HOWE: -- that way you get the regulator viewpoint also.

DR. NAG: And I think we should combine that with the first application. Send the first application in --

DR. HOWE: No.

DR. WILLIAMSON: No.

DR. NAG: -- we will look in, and then --

DR. WILLIAMSON: We shouldn't look at the application.

DR. HOWE: No, no.

DR. WILLIAMSON: We should just look at

the criteria.

DR. HOLAHAN: The criteria. Right.

CHAIRMAN CERQUEIRA: That's the only thing that we should review.

DR. WILLIAMSON: Yes. Let's just look at the licensing guidance.

CHAIRMAN CERQUEIRA: Charlie?

DR. MILLER: I don't want to get ahead of ourselves today. I think we need to listen to what John Szabo's going to tell you a little bit later with regard to some FACA changes. I think the idea of having a small subcommittee look at this is a great idea, but John's going to give you some information concerning when it has to be public, when it doesn't and what the responsibilities of the subcommittee are in reporting out to the full Committee in a public forum. So I think that will help better frame how we proceed on this if we could just --

DR. HOWE: Okay.

CHAIRMAN CERQUEIRA: Now, who were the three that -- Williamson and Subir, okay. Right. I think -- okay, that's fine. And then we'll talk to John.

MS. McBURNEY: And Ruth.

CHAIRMAN CERQUEIRA: And Ruth is --

MS. McBURNEY: Or was.

CHAIRMAN CERQUEIRA: Is Emerging Technology.

DR. HOWE: Ruth, is this pretty much your whole subcommittee?

MS. McBURNEY: Yes.

DR. HOWE: Who else is on the Subcommittee?

MS. McBURNEY: Who was on that Subcommittee?

DR. HOWE: Jeff, you had a question about what was going to be the full calibration and the spot checking. And if you look into your slides in the eight series, you'll see that I did bring forth what I thought was going to be part of the full calibration. First one says when it has to be calibrated before first medical use, and then following reinstallation of the unit in a new location or facility, repair of the unit that includes repair components associated with source exposure assemblies. So I deleted a lot of the things that were in the 600 series because it just doesn't pertain to this. And I thought B was in intervals not to exceed a year.

DR. WILLIAMSON: Well, some of this we'll have to look at, because I'm not sure whether --

DR. HOWE: That's where it is.

DR. WILLIAMSON: -- guide tubes and so on is relevant to the accuracy.

CHAIRMAN CERQUEIRA: Charlie?

DR. MILLER: I think it's critical that Ruth be involved in this effort from the perspective of the states.

DR. HOWE: I do too.

DR. MILLER: Since we have agreement states that you're licensing and getting the states' participation.

MS. McBURNEY: And several of those states are going to be among the first to get applications for this type of application.

CHAIRMAN CERQUEIRA: Yes. No, you clearly should be in it. So you've got four members that -- okay.

DR. HOWE: So if you look at those slides, you'll see what I've put in and I deleted a lot of stuff under 600 because I just didn't think it pertained. And as a group, you can discuss that more.

MR. LIETO: So, Donna-Beth, in your slide these are your recommendations of what should be the spot check content and what should be the full calibration content.

DR. HOWE: Yes. And you'll see some of these things like when you do source calibration you go further down, maybe not in this one but you go further down and you'll see that there is an option for using the manufacturer's calibration. So that deletes some of the things up above it. And that's the way 610 is written also, once the manufacturer confirms that they're meeting our requirements and their initial source calibration.

DR. WILLIAMSON: And there is no reason we couldn't -- if we had wanted some detailed information about the system operation, we couldn't have a vendor contact and ask them some questions.

DR. HOWE: I don't think so.

DR. WILLIAMSON: Okay.

MR. HORN: Thank you. I'd be delighted to also provide you with --

CHAIRMAN CERQUEIRA: If you could use the mic just for the record, please.

MR. HORN: I'm sorry. Thank you. I would also be delighted to provide you with one or two medical physicists that are using the system at academic institutions that -- I think they're people you know.

DR. WILLIAMSON: That would even be

better.

CHAIRMAN CERQUEIRA: Could you please identify yourself for the record.

MR. HORN: I'm sorry. I'm Raymond Horn. I'm Nucletron Corporation. And there are -- for the record, there are several systems in operation already in North America. So it's not a question of the first one to go into operation. It is the question of approval or guidance for additional systems that are not in broad scope license locations.

DR. NAG: How are these, the ones that you have, how are they being licensed? Are any of them in a non-broad scope area?

MR. HORN: No.

DR. HOWE: And that's what we're dealing with now is the first application for the non-broad scope and developing the guidance for the limited specific, because we in our regulations require the broad scope licensee to do a safety evaluation before first use and have the Radiation Safety Committee review and approve that safety evaluation. So we're comfortable with the broad scopes and figuring out what they need.

MS. McBURNEY: Where is your company located, and where will the device evaluation be done

or has --

DR. HOWE: It's been done in Maryland.

MR. HORN: Nucletron Corporation is based in Columbia, Maryland, so we're local. The company is a Dutch-based firm.

MS. McBURNEY: So Maryland has done the --

DR. HOWE: Maryland has done the sealed source and device registration already, so that's part of it is done.

Now, this may be controversial. This is part of procedures for administrations requiring a written directive. So I'm expecting that you guys will have a lot of comments about this. We're finding most of our -- this is computer driven. If you get the FIRST system, then you're really tied into the treatment planning and the three-dimensional ultrasound. It's all tied together. And we're having a lot of misadministrations with prostate brachytherapy, and most of the root causes are ultrasound imaging related, not being able to identify where the prostate is, getting the wrong identification, putting the seeds in the wrong place.

So I'm proposing that within your program to assure that you're delivering what you have written in the written directive, that you include procedures

that assure the specifications for your ultrasound unit are compatible with the SeedSelectron so that you really can see them if you're supposed to be seeing them and that the probe is properly positioned and assure that the image system is properly functioning. Now, those would be part of what in the old days was a QM program. Those are noticed by licensing conditions, those are internal procedures that are not required on the license. So we're just suggesting that you consider addressing these issues to try to assure that you're delivering what you're expecting to deliver.

DR. NAG: Again, I'm sorry. How can the manufacturer confirm -- this is something an operator who's putting the system in has to look and see where the prostate is. I mean you cannot have --

DR. HOWE: This is the licensee's program. This would be how the licensee ensures that what they're using is fully functional and is compatible and can see what it's supposed to be seeing.

DR. NAG: Again, to assure the ultrasound will be properly positioned. Now --

DR. HOWE: That's the position, the physicist, whatever the licensee is.

DR. DIAMOND: Donna-Beth?

DR. NAG: And how is that different from a permanent --

DR. DIAMOND: This is ridiculous. I mean I don't mean to be too difficult here but just when I read a sentence like that or a phrase like that, it's ridiculous. I mean you're doing a prostate implant. Who the heck is going to do a prostate implant if they can't reasonably visualize the prostate gland? That's like telling me that I should go and make sure the patient's alive before I treat the patient with radiotherapy, I mean it's just ridiculous.

DR. NAG: Except that I know that there have been cases where the person who's doing an implant for the first time is putting seeds in the bladder. But you cannot -- I mean in a permanent implant the same things happens.

DR. HOWE: Within the last year we've had prostate implants where they haven't gone in the prostate; they've gone into a different area that's centimeters away. We've had -- a little bit further back, we've had users that used an ultrasound unit because they believed ultrasound was ultrasound that couldn't even image the prostate. Now, what they saw we have no idea, but we do get those dramatic events.

DR. WILLIAMSON: Remember the tale of the

distribution of practitioners that these regulations are targeting. I mean there are some people who are so many standard deviations out of what you'd consider acceptable practice. What this is trying -- this is what this is targeted to, not --

DR. DIAMOND: I'm not going to be reading this, I assure you.

CHAIRMAN CERQUEIRA: The problem we're having here it sort of goes into this -- I mean these are issues that the local Privileging Committee at the hospital needs to address in terms of who should be qualified to do that. This really goes beyond the issue of radiation safety.

DR. NAG: Question.

DR. DIAMOND: This goes far beyond radiation -- the purview of this Committee. This is practice of medicine, and we've had this discussion whether we are talking about this in many different context before, but this is really why any time a physician, for example, applies to perform a given privilege, let's say an individual wanted to electrophysiology or an individual wanted to do interventional cardiology, that's why the Credential Committees exist. They wanted to know about your training, the number of cases you've done. This is

what they do.

CHAIRMAN CERQUEIRA: There are mechanisms in place for doing these things, and there is QA that goes on with this, and if people have problems such as this, it is reviewed by the hospitals. I understand what you're getting at here, it's obviously very important, but I'm not sure that it's the role of the NRC to set regulations or guidance that would deal with this.

DR. HOWE: The other thing you need to understand is that this won't be used exclusively in hospitals, so you're not going to have that safety net for all of our users. And this is more QA than getting into --

DR. NAG: But this is exactly the same as the permanent manual implant. I mean if you were are going to have this requirement for the SeedSelectron, I mean you have to have it for the permanent implant. I mean if the person is going to make a mistake putting the probe in the wrong place here, that person is going to make the same mistake pushing the wrong probe and manually putting the seed in. There is absolutely no difference. That's all I'm trying to tell you.

DR. HOWE: I think in some respects when

you get these computer interfaces where you're not doing those manual moving data from one point to the other, it does become a bigger part of the problem of ensuring the whole package.

DR. NAG: You still have to know where the prostate is.

DR. WILLIAMSON: Yes. I think Subir's point is right on. The misadministrations have been reported, not for the SeedSelectron but for manual brachytherapy with prostate implants. This is a really important point I think you bring up. I would like to say in response to David mainly I think that NRC has no choice but to get involved in this in some respect, because misadministrations are being reported. They have to do something if only as information notices and guidance where they can. I think the legal problem is is there is a basis for requiring something additional beyond 35.400 as a 1000 device because this device, this Nucletron system has some additional novelty and engineering involved in it. I don't know that you -- other than putting the same thing in an information notice saying, "We advise you do this," you can require people to do this as a license condition. It doesn't seem that 400 gives you that authority the way it's written.

CHAIRMAN CERQUEIRA: Will these systems be used in office settings independent of hospitals.

DR. HOWE: Yes.

DR. NAG: Yes.

DR. WILLIAMSON: Yes.

MS. McBURNEY: Yes, absolutely.

MR. LIETO: I think we're getting ahead of ourselves. I mean I don't know all the details of the incident regarding the ultrasound and the manual brachytherapy misadministrations, and maybe the issue is not the ultrasound but the training of the individual that's doing it. I think before -- and I think this gets back to maybe one of the things that the commissioners brought up at the meeting when we met with them in the spring was that maybe we need the details of these events, because I think maybe we're discussing and trying to come up with administrative procedures to address a problem that it's not really the ultrasound equipment but who's operating it, okay? And that's two different things. What you're addressing here is something entirely different than what I'm suggesting. And so I'm not really sure if this is a really an appropriate thing for that right now.

DR. WILLIAMSON: I think this is a good

point if you want some meaningful feedback on this from us. And, clearly, since the basis of this is some experiences you've had with manual brachytherapy, perhaps it would be very prudent for you to release the details of some of these events to us much as you did with the Novoste brachytherapy, and then we can give you much better advice, I think, with a full understanding of what's going on.

CHAIRMAN CERQUEIRA: Yes. This is getting into sort of a real complicated area. I mean I think that the views that David and I have expressed are still appropriate, and I'm not sure that it's the NRC role to regulate the practice of medicine. But yet at the same time there are mechanisms in hospitals, but once you get out of the hospital environment there is no oversight, and so I think we do have to worry about it, but I'm still not certain that it's the NRC that has that role. But trying to think who does regulate what happens in an office and you do have minimal regulation. So it gets to be a difficult situation, and I --

DR. HOWE: And the other thing you really need to keep in mind is that these programs under -- are totally the option of a licensee. It's what do you as a licensee think you need to assure you're

giving what you have in the written directive? And I caveated with consider and none of this is tied to your license. You won't be cited against this program. You will be recognized if you have medical events. And what I did was I used our experience with manual brachytherapy to say there is a root cause out there and it is normal.

CHAIRMAN CERQUEIRA: I think getting back to the point that's been made that if we knew the specifics, and, clearly, there are people who are probably not fully trained, and my question originally about how well this algorithm works sort of gets at this issue, that if you're doing it manually, at least you've got some idea. You can still make the same mistakes but it's not going to be systematic. But if somebody is doing this totally wrong, using the wrong ultrasound system or having the thing rotated to some extent, then you can make fairly major systematic errors. But I still -- again, I'm not sure that this is an area that the NRC wants to get into.

DR. WILLIAMSON: Well, I think you could argue that you're not going to have much choice. I mean welcome to the brave new world of image-guided therapy. This is refining and changing our definition of what the target site is. So I think that the

agency needs to confront the issue and at least decide at some point what their boundaries are, and I think it sounds like these cases in permanent brachytherapy and prostate therapy provide a really sort of good basis for defining a policy.

CHAIRMAN CERQUEIRA: It's a little bit more complicated than that, because it's a site of service issue, and there are safeguards within hospitals, and when you get out of the hospital environment, it doesn't exist there.

DR. WILLIAMSON: I'm not arguing you're wrong. I'm just saying --

CHAIRMAN CERQUEIRA: Yes. No, no. Right.

DR. WILLIAMSON: -- I think it needs to be considered and confronted as a problem and a change in technology that invalidates an older regulatory paradigm. And maybe the limits will be as you suggest, and maybe they won't. That's the issue, and we can probably offer a lot of advice if we're given more information.

CHAIRMAN CERQUEIRA: Right. Yes, please.

DR. SULEIMAN: My experience is that, as Dr. Williamson had mentioned, you've got a tail and writing regulations is an art. But you're not writing it for the people that are doing it right; you're

writing it for the people that are going to be on the fringes or that are maybe even doing it wrong without any concern. But I think with multiple imaging and ultrasound and MR, you have a whole multitude of imaging modalities out there. Sometimes you say, well, isn't that obvious, verification beforehand, but sometimes if you don't write the very obvious in a non-prescriptive manner, then say, well, why do you write it since it's not very detailed, but sometimes asking for the obvious it's not for you, it's for the fringe operator so that they may do something that they wouldn't have done otherwise.

CHAIRMAN CERQUEIRA: But we have to be careful that we don't penalize all the people that are doing it right. You know, maybe there's other mechanisms by which to eliminate the tail, the people that aren't -- don't even know where to start. Again, I'm looking at the time and we're about half an hour --

DR. HOWE: I think I'm done.

CHAIRMAN CERQUEIRA: What have we concluded, though?

DR. HOWE: I think we've concluded that the Emerging Technology Subcommittee will -- I'll give them my guidance that's more fleshed out into words

and sentences, but I'm going to take back what I've heard from the ACMUI and bring it into what I think I heard the ACMUI say before I pass it on to them, and I should be passing that on probably next week.

CHAIRMAN CERQUEIRA: Okay. Good. Okay.

DR. NAG: What about some timelines? When are you going to be sending it to the Subcommittee?

DR. HOWE: I'm going to try to send it to the Subcommittee next week. I'll be sending it -- emailing it to Rick.

DR. WILLIAMSON: What about the other proposal for reviewing these events you've made illusion to?

DR. HOWE: Let me get this done before I start going into NMED, and I'll try to get you those events.

DR. HOLAHAN: Tom will address that this afternoon.

DR. WILLIAMSON: Okay.

CHAIRMAN CERQUEIRA: Okay. Then we have you again for listing sources on -- yes, it does list you -- listing sources by model/serial number on licensees.

DR. HOWE: Okay. Fine.

CHAIRMAN CERQUEIRA: Can we do that in

half an hour? It seems like it's straightforward.

(Laughter.)

It never is.

DR. HOWE: Yes, right. Where's my computer help? How do I get back to the regular screen? It's probably not going to be that non-controversial.

CHAIRMAN CERQUEIRA: Of course.

DR. HOWE: But part of it I think will just be starting dialogue and will involve the ACMUI's work for a very long time.

CHAIRMAN CERQUEIRA: Job security.

DR. HOWE: Okay. I've termed this potential Part 35 rulemaking, because the first thing was the ACMUI feels very strongly that it is an undue burden to have to amend licenses to provide information for new manufacturers, new sources from the same manufacturers or certain device use, primarily the manual brachytherapy. And the requirements are in 10 CFR 30.32 and I've written the requirements here.

Now, the last time we met we had to bring you the sad news that you wanted an exemption for the medical use people from this requirement, and we brought you the sad news that NRC did not believe we

could give you an exemption because of what was going on and after 9-11 the importance of security, the importance of knowing where sources are and who has different kinds of sources. And what I'm bringing you today is that same message, we're not going to give you an exemption but we think we've come up with a way that will satisfy your major problem and also satisfy our major concern. And that is to go into Part 35 and recommend revising the requirements for a license amendment and the requirements for notification.

And by revising those two things, we could move -- we still want the information. We want to know when you use new sources and new devices, but if you're already authorized for, say, manual brachytherapy and a given manufacturer but not this source and we think we could write a new regulation in such a way that you could notify us that you're going to be using a new source, we would have the information, you would be able to use it without seeking an amendment, and we think this would be a good compromise.

And we would -- that would give you flexibility in obtaining sealed sources from new manufacturers or new models of sealed sources from manufacturers that you already have listed. We'd have

to write it tightly enough so that it fits your license and you're just adding something you're already authorized for globally, like you're already authorized for 400 or for 600 and there's a new device coming in.

So that's going to be our -- what we're bringing to you is not giving you an exemption but going an alternative pathway and that's the notification pathway. Any comments?

DR. VETTER: Question.

DR. HOWE: Questions, yes.

DR. VETTER: It's still acceptable for a licensee to ask for -- to submit a license application that says either/or; is that correct? So they could -- in their original application, they could say, "We want to use any one of the following sources, and you wouldn't know which one they are actually using but they would be allowed to use any one of the -- let's say they ask for three.

MS. McBURNEY: Several models.

DR. HOWE: Yes. Yes. That's acceptable.

DR. VETTER: And then if a fourth one became available on the market, they would simply have to inform you. That wouldn't show up on their license, but they would simply inform you that they

are going to be using this fourth --

DR. HOWE: I see it being similar in how it functions to authorized users, medical physicists and nuclear pharmacists. We would not amend your license at that point, but the next time we amend your license we'll put it on your license.

DR. VETTER: Okay.

DR. HOWE: It's in your folder that you have authorization for it, but the next time we amend the license we'll add it to the license. Now, we'll have to figure out exactly how to work this for ensuring that you can receive it from your suppliers, and that may be a little trickier, but I think we can work those things out.

DR. VETTER: I personally like that flexibility. I'm just a little concerned that, again, for the fringe they'll lose -- as long as you keep track, as long as the agency keeps track of what they're doing in terms of what they've submitted and updates the license periodically, that should help. I'm just worried about the fringe people losing track of what they're authorized to use and what they aren't.

One subsequent question is if they decide they want to order the fourth source and the vendor

says, "Show me a license that says you're authorized," how will that be handled?

DR. HOWE: Well, that was what I was just alluding to. We have to figure out how to have a document that allows them to get that fourth source because they've notified NRC that they have it.

DR. WILLIAMSON: So you'd write them a letter back and say they're allowed to have this source or what?

DR. HOWE: Normally what we do in notification we review the information that comes in and if it is acceptable for the notification, the licensee gets nothing back. If it's not acceptable, we send back a letter and say, "What you've submitted to us is not acceptable under the notification. You need to amend your license." So that's how we handle it now. We'll have to figure out something to keep you in conformance with your manufacturers.

CHAIRMAN CERQUEIRA: Subir?

DR. NAG: There are about 15 or 16 of these different kinds of iodine sources, essentially, very similar. Is it possible when we are making the initial license application we just list all the 16?

DR. HOWE: You can list all 16.

DR. NAG: I mean that would solve the

problem.

DR. HOWE: That will solve the problem for you today. You can list all 16. Tomorrow --

DR. NAG: Yes.

DR. HOWE: -- the 17th comes out and the 18th and the 19th. So this would give you the flexibility --

DR. WILLIAMSON: Sometimes they change the names and model numbers of these things too, so there are --

DR. HOWE: Do I hear that the ACMUI likes this proposal?

CHAIRMAN CERQUEIRA: Ralph?

MR. LIETO: Yes. I don't have an objection to the general process. I think it's that end piece of how does the licensee notify the vendor. Maybe a couple things to consider -- or is that coming up?

DR. HOWE: No. We haven't figured out -- I mean I'll be doing a --

MR. LIETO: I mean anybody that's done interactions with the --

DR. HOWE: -- what do you call it, a user need memo up to the RGB Group, so I haven't really outlined anything in detail how we would solve it.

MR. LIETO: I would suggest one of two things. Maybe simply an email from the reviewer who gets it and says everything's there, it's okay, or just some type of stamp, and Nicki suggested just a stamp on there and fax it back to the licensee.

DR. WILLIAMSON: Well, I think there may be even some easier way. I mean I think if the Part 35 is amended and they then send to the vendor their existing license plus evidence that they've sent this notification to NRC, that would be an obvious compliance with Part 35, and it's simply a matter of an information notice to inform the vendors that this is the new process. Because they're anxious to sell seeds. I'm sure they're not going to subvert it. As long as they know they're not going to get into trouble, that would be the solution.

MS. McBURNEY: That was going to be my comment, that if the procedure changes, that the licensee can do it by notification by sending a copy of that notification to the vendor that would indicate that they're meeting the regulation.

DR. HOWE: And then the implementation time is going to be dependent on whether we -- and I'll go through some other changes that we'd like to see -- whether we think we could go direct final rule

or we think we have to go just regular rulemaking. So that's still up in the air.

Okay. I have some other what I think are fairly insignificant but important changes to Part 35. In 35.49, it permits a licensee to use sealed sources that are non-commercially transferred from a Part 35 licensee. And the question isn't what's in here, the question is what's missing? And what's missing is that this did not permit an NRC licensee to receive sealed sources and devices non-commercially transferred from an agreement state medical state licensee, and so we're proposing that --

MS. McBURNEY: Especially a renegade one.

DR. HOWE: Yes, especially a renegade one.

DR. DIAMOND: In terms of the ACMUI --

DR. WILLIAMSON: Could you define non-commercially transferred and explain to us what the sort of typical clinical application would be so we understand better the --

DR. HOWE: Actually, you guys discussed this for a long period of time during the Part 35 development, and this was that instead of -- you've got a hospital or a clinic and they want to transfer their device to another facility, not a manufacturer but transfer the device over. Now the new facility

takes it. So in the past, the new facility could only get it from someone authorized under 3274. So this allows that transfer between --

DR. WILLIAMSON: So this would be for mobile remote-afterloading, it would be an application?

DR. HOWE: No, it's for any device.

DR. NAG: I have 100 iodine seeds left over and you need 100 iodine seeds. I give it to you.

DR. WILLIAMSON: All right.

DR. HOWE: He has an HDR. He wants a new HDR and maybe he wants to transfer it to someone else that for them that would be a great advantage. So this allows the non-commercial transfer, so he's not in the business of transferring his seeds. If he wants, he'd be under 3274. So I'm going to recommend that we add, "or equivalent agreement state medical use licensee."

DR. WILLIAMSON: Excellent.

DR. HOWE: Thirty-five.sixty-five(b), we've had a number of questions coming through for the implementation of the new Part 35, and this appears to be a little confusing, and we think there are at least two places that need to be fixed and possibly break this into simpler sentences might help. This permits

the redistribution of sealed sources that don't exceed 30 millicuries provided you -- the person you're getting it from is authorized to redistribute it and the sources were originally authorized for manufacturing distribution under 3274. And it's confusing when people read this to understand who needs to be authorized under 3274. Is it the sources or is it the person redistributing? It's both.

And the other thing that you'll see is also there's something missing here. This says that the sealed sources had to be manufactured and distributed by a person licensed under 3274. And what are you missing? "Or equivalent agreement state regulation." So we're proposing to revise it and add, "equivalent agreement state authorization," and also to revise it to make it clear that the person redistributing it needs 3274 authorization or equivalent agreement state and that the sources themselves needed to come through that route.

DR. WILLIAMSON: Notwithstanding that we may have extensively discussed it in the past, can you again explain a typical scenario where this might be used, what the intended application is?

DR. HOWE: All right. This one is to permit for the most part commercial nuclear pharmacies

to redistribute brachytherapy sources that are not their brachytherapy sources but were originally manufactured and distributed by a brachytherapy source manufactured under 3274. The commercial nuclear pharmacy comes under 3272, and they must have an authorization under 3274 in order to do this. So this is to clarify that they are not transferring under 3272; they're transferring under 3274. Okay? So that's the main thing. And then we want to the equivalent agreement state so that there is this additional flexibility.

And I think this is -- we had an inquiry. Thirty-five.six-fifty-five requires the licensee to have each teletherapy unit and gamma stereotactic radiosurgical unit fully inspected and serviced during source replacement or at intervals not to exceed five years, whichever comes first. That makes sense for a teletherapy unit, but what we found is that the fully inspected and serviced for a gamma stereotactic unit can only happen when we do source exchange, because there are parts of this device that you cannot get to when you have the sources in. And we have a licensee that will not exactly make the five-year period. The manufacturer can come in --

DR. NAG: Five and a half years.

DR. HOWE: Well, December is when their five years is up. The manufacturer can come in February. So we don't want to shut them down from December to February because they can't do it in five years, which is first, and there isn't anything that can be done until they replace the sources. So we're recommending that we decouple the five-year requirement from the gamma knife for inspection and servicing.

DR. NAG: One question. That this will be only to cobalt because if it's a gamma stereotactic and if it's a cobalt, yes, the five years applies, but if someone makes up a new one with a new material that has different half-life, then the five years is not applicable. So this has to be only referenced to a cobalt system.

DR. HOWE: Give me an example of a different source and what you think --

DR. NAG: No, but I'm asking.

DR. HOWE: -- and what you think that source exchange would be.

DR. NAG: I mean if it is a different radioactive material, then if it's a shorter half-life, five years is obviously far too long and if it's a longer half-life, then it could go on for more than

five years.

DR. HOWE: Okay.

DR. NAG: So if you want the flexibility of -- I mean right now I agree cobalt is the one that we use, but if we are using any other radioactive material --

DR. HOWE: What we're recommending is taking us five years out.

DR. DIAMOND: I don't think we need to spend too much time on this.

MS. McBURNEY: No. No, I don't think so.

DR. HOWE: Okay. What we're recommending is we're taking the five years out of the gamma stereotactic and whenever the sources are exchanged that's when you do the full inspection. So if for some reason you end up with an isotope with a short --

DR. DIAMOND: Subirium.

DR. WILLIAMSON: Subirium.

DR. HOWE: Subirium. It will be done whenever it's exchanged. If that's three years or if it's 20 years, it will be done in 20 years, okay?

DR. MILLER: I guess what I would propose is if that happens we visit it at the time.

MS. McBURNEY: That's right.

DR. HOWE: No. Actually, if we make the

change that we're expecting for this gamma knife, it will automatically be covered.

DR. NAG: Yes.

DR. MILLER: I don't think you're understanding what I'm saying.

(Laughter.)

DR. NAG: I withdraw my question.

DR. MILLER: All I'm saying is if we ever have Subirium, then we can visit what the servicing and inspection period should be.

MS. McBURNEY: Right.

DR. HOWE: Now, up to this point, I think the --

MR. LIETO: I had a quick question just on the gamma knife in general in terms of the servicing and source exchange. Is it normally a five-year period?

DR. DIAMOND: Yes. Most institutions five years. Sometimes we do it a little more frequently if we want to have quicker treatment times, obviously. So, for example, our center would usually do it at closer to four years than five years, but five years would be a standard.

MR. LIETO: Okay.

DR. HOWE: Right. And it's just the

question of --

MR. LIETO: Because I was just thinking this might be just sort of a one-time only thing and maybe it could just be handled as a one-time only exemption. But if it's something that is going to be coming up more often, then I guess probably it would be --

DR. HOWE: We routinely -- well, we don't get them as much now because we don't have as many, but there are -- routinely, there are scheduling difficulties even with the teletherapy units, and we've granted our regions the option of granting short-term exemptions for it. So I think this would come up more frequently than you think.

MR. LIETO: Should this then be for not just gamma knives but teletherapies also?

DR. HOWE: No. The teletherapy can have a full servicing with the source exchange, but the gamma knife cannot.

MR. LIETO: Okay.

DR. HOWE: Okay. Up to this point, I think most of the changes -- I think the wording for the notification process might be a little complicated. We have to figure all of that, but these other changes have been pretty minor and might

possibly subject -- maybe if we could go direct final rule would be a good candidate. So the ones I'm going to be talking about now may be more controversial and you may want to discuss them in more depth. So having said that, I will continue.

In 35.4(b)(6), and this is the issue that you guys have really wanted to get to all along, is manual brachytherapy, the written directive. Before implementation you have the treatment site, the radionuclide and the dose. After, you've got the -- after implantation but before completion of the procedure, you've got the radionuclide, the treatment site, the number of sources and the total source strength and exposure time. We have problems with what do you mean in a permanent implant as what is after implantation and before completion of the procedure? What is completion of the procedure?

DR. WILLIAMSON: Forever.

DR. HOWE: Yes. And so we'd like to decouple the permanent implant from this and have you help us develop what should really be in the written directive for the permanent implant and it also opens up the issue of -- and I have another one I think later on about what's a medical event for a permanent implant, and so I think this is a much longer term, a

lot more discussion. I don't think this is an easy fix, but we're seeing a number of cases that we believe are clear medical events. Most of them are in the prostate. Thirty seeds go to the bladder. OGC says it's not a medical event because the authorized user changed the written directive before completion to only require 40 out of the 80 seeds to go into the prostate. Now, that's an error. That's something that the whole misadministration medical event was designed to have reported so that we could go back with information notices or other things. It's not punitive to the licensee but those are the kinds of errors we want to hear about.

We had an agreement state licensee that was doing a prostate implant. They had two patients, one with I-125, one with palladium. They realized after they had given a few of the palladium seeds to the I-125 patient that they had given the wrong seeds. So they revised the written directive for the palladium. Now, should that have been reported as a medical event? It was a misadministration for them under the old rule but not for the new rule. So you'll see something else on that.

So what is this -- how much change can you get between prior to implantation and this second

part? Our understanding originally was that you, especially for the prostate, you don't know exactly what size it's going to be when you get ready to put the seeds in, so you need some flexibility to take it into effect that it's grown and modify your written directive at treatment time. But does that allow you to modify your written directive six months later? It doesn't quite seem like it should, especially if it was an error that you're modifying it to correct.

And this is 40(c). This is existing written directive can be made if the revision is dated and signed. And it also includes an extraction dose. Well, our -- this is also -- what do you do about a procedure that's supposed to be given in only one procedure, and the authorized user realizes they put 30 seeds in the bladder and they decide, "I'll switch it to fractionalization now."

DR. WILLIAMSON: What do you mean fractionalization?

DR. HOWE: The writing of the written directive for the second fraction.

DR. WILLIAMSON: You mean do two permanent seed implants?

DR. HOWE: Yes.

DR. WILLIAMSON: All right. That's what

I'm asking to clarify the sequence of events.

DR. HOWE: Yes. And this is not a procedure that you would normally have fractionalization. So in our mind, with the old misadministration rules and things, you would have identified this as a medical event and reportable because it should only be given once.

DR. SULEIMAN: So they calculate the dose from the first -- what does get to the prostate and then they recalculate what they need from the second?

DR. HOWE: That's what he was going to do, and then eventually he decided that he wasn't going to go back and treat at all.

DR. NAG: Yes. Just add 30 more seeds. I mean that's --

DR. HOWE: But he wasn't adding them in; he was going to have the patient come back at some later time.

DR. NAG: Right. Yes. Next week or whatever. I mean that's the reason why you do the dosimetry so that in case you are under dose you can reimplant. And I think that's been done -- this is not an exceptional case. That's been done routinely -- I mean not routinely, but that's been done quite often.

DR. HOWE: I think there's -- what you're doing in the normal practice in medicine when you're saying it's bigger, it's smaller, you have to go back and put more in, that's -- we don't -- but when you make a significant error, a human error, and it clearly is a mistake in what's administered, can you use these what we consider to kind of be loopholes? So this is going to be much more controversial --

DR. NAG: But that is what medicine is.

DR. HOWE: -- and you guys are going to want to discuss this forever.

DR. VETTER: Yes. We could discuss it forever, but just one point I'd like to make. The ultimate outcome is what's important.

DR. NAG: Yes.

DR. VETTER: Treatment could be interrupted for a variety of reasons, one of which could include a mental error on the part of the radiation oncologist. But he catches it, it's a close call, but he catches it and he corrects it, and the outcome is just fine. So those -- I know, where do you draw the line at? I think it's too difficult to draw that upstream anywhere. You really have to look at the ultimate outcome. What's the outcome?

DR. HOWE: And I think what you look at is

in our regulatory space we hope the physician makes the right medical decision and does what is right for the patient. And we don't get into that aspect. But we do have a requirement that what the physician directs is delivered, and that if there is a significant departure because there are some -- there is wobble room here in the difference between what they are projecting to give and what they give. But if there is a significant departure, then there is some kind of error in the administration, and those -- and they fit the criteria of the medical event, and we those medical events reported to the NRC. In many cases, we'll send out an information notice, we'll make other licensees aware of common factors. It's not a punitive type of thing. The Commission has a long history of wanting to be informed when there are significant errors to what was supposed to be given. We don't get into whether they asked for the right thing to start out with, we don't get into that. We don't get into whether it would have been acceptable over here and it wasn't acceptable. We just want to know if it wasn't administered. Trish, you look like you want to say something here.

CHAIRMAN CERQUEIRA: David?

DR. DIAMOND: Donna-Beth, just speaking to

this one particular point, this is probably the one point that you've made that I don't agree with in that I'll give you a real-life example that you could get into a little bit of trouble in a good medical center with good physicians. Let's assume that you have a patient with prostate cancer with a lot of disease at the base of the bladder -- at the base of the prostate, excuse me. The bladder is large in this particular case, there's a big bladder diverticulum. You go ahead and you do your prostate implant, and at the conclusion of it you find there's a couple seeds in the bladder, which is not to be unexpected because the urologist does cystoscopy, he removes the seeds -- he or she removes the seeds. There's no harm done to the patient.

Now, in the past we would always go and order extra seeds so that at the time of fluoroscopy at the conclusion of the implant you could go back and add a couple more seeds. But because of changes in reimbursement and costs, we don't do that anymore, because the hospital loses a lot of money if you order five or six extra iodine seeds. That would be a case where that patient may have to come back the next day or two days later when you've acquired some more seeds to go and have a few more seeds placed to go and

optimize room plant. And that would be an example, a real life example that you would have to go ahead and report that under your revision in which there has been no harm or no foul, to use the lingo. Do you understand what I'm saying?

DR. HOWE: I understand what you're saying, and I don't think we're going after --

DR. DIAMOND: Yes, but you just -- I understand what you're trying to do, but I'm just saying it's all in the wording. And this would be an example -- you know, you're spending a lot of time talking about this one horrendous anecdote and I appreciate that. I don't know how often this occurs, but I'm just a little concerned, as Subir was also mentioning in his examples of how we sometimes do repeat a procedure. I wouldn't use the term, "fractionation," really, but that we go back -- you know, if a woman has a very big cervix cancer and you have to a big sidewall implant, oftentimes you really don't know how many seeds to order up-front, and there are instances where you may have to go back a second time, and I wouldn't want those situations to somehow cause a problem.

DR. HOWE: We wouldn't want those either.

DR. WILLIAMSON: But then the law allows

you this wiggle room from time zero. At the moment when you insert the sources to the time you remove the sources, that's the allowed period where you can --

DR. NAG: Removal for implant doesn't create the problem.

DR. WILLIAMSON: That's sort of off the table. So the issue is that you don't have that kind of control over a permanent implant. You know, Dr. Diamond is absolutely right there. There are inherent limitations to the physician's control over these seeds, and even a well-experienced investigator due to some anatomical oddity or challenge that some particular patient may present, we'll find that maybe the D-90 falls short occasionally of the target dose. And one has to supplement with external bean or additional seeds, and somehow you don't want to capture those events.

It all goes back to the philosophy of what a medical event is, and you may remember when we were negotiating this some years ago, a group of us recommended that a medical event be identified as a wrongfully delivered dose due to a technically avoidable error on the part of the caregiver and then list the specific criteria. And that somehow you've got to sort of have that qualification in here, I

think, when you revise this to sort of exclude the many legitimate circumstances that may require a revision. And you probably want to avoid philosophical difficulties such as trying to define the end of treatment for a prostate for a permanent implant by probably completing rewriting in a separate written directive section what are the rules for writing a written directive for prostate implant that don't refer to that concept. That would solve it.

And if you think there needs to be some sort of a legitimate deadline for the physician being able to say what are the number of seeds he or she prescribed to the prostate 24 hours or something, you say that. And don't argue about is the treatment complete at time infinity or 30 days or 14 days, because that's very arbitrary and different practitioners will do the definitive imaging at different time intervals and you simply can't prescribe a standard. That is the practice of medicine.

DR. HOWE: Right. And I think if we could decouple the permanent implant and get the discussion as to what is it really that you guys do and how to characterize it.

DR. WILLIAMSON: Just a practical

suggestion. You're obviously being motivated in your thinking by a number of incidents that have been reported. And maybe, again, if you bring us up to speed on the database that conditioned your experience, maybe then we can be more helpful.

DR. HOWE: Okay, I can do that. And 35.3045, which is the number of reporting, it requires you to report a medical event for a dose that exceeds a certain level for the equivalent dose equivalent or to an organ tissue for the wrong radioactive drug containing byproduct material. Now, in the old misadministration rule, we also identified that you had to report if you used the wrong radioisotope in brachytherapy, and so we're recommending that you'd have to report if you used the wrong radioisotope for a brachytherapy procedure, and this goes back to your palladium/I-125 mixup.

DR. NAG: I mean palladium and iodine we use fairly interchangeably. If the -- not the number of --

DR. HOWE: You use them interchangeably but in this case you've got a -- you have two patients coming in. One is in I-125 treatment, the next one's a palladium. You start treating the I-125 patient. They don't put I-125 in; they put palladium in.

DR. NAG: Right. But if the equivalent number of molecular, not the exact number of millicurie, I think it's about a ratio of -- but the equivalent number of millicurie the same, the end result is going to be exactly the same, and therefore if -- let's say I wanted to have 30 millicurie of iodine, which would be equivalent to about 90 millicurie of palladium, if I put 90 millicurie of palladium instead of 30 millicurie of iodine, my dose distribution, et cetera, is going to be exactly the same. And not the second dose but the equivalent dose would be the same.

DR. HOWE: Ruth?

MS. McBURNEY: That may be true in iodine and palladium, but there may be cases where a really wrong isotope is used in brachytherapy, and that's not in the rule. So that probably needs to be addressed.

DR. WILLIAMSON: I think it's reasonable to address it. I think that while the medical event sort of is designed to capture events that are clinically significant in terms of hurting patients, that's not a necessary or even sufficient condition for something to be a medical event. It's kind of a surrogate for there's questions about the underlying quality of this technical program if they do this

thing. Even if it doesn't hurt a patient, the fact that the controls are so loose that one winds up putting palladium instead of iodine when that was the intent, I mean I think that in a performance-based system that's a reasonable endpoint to have as a regulatory endpoint, that you get the right radionuclide in the intended patient and to have a mechanism for capturing those events. Regardless of whether the operator compensated for it properly upon detecting the error, it's a useful bit of information that I don't see any problem collecting.

CHAIRMAN CERQUEIRA: Ralph?

MR. LIETO: I was going to say kind of actually -- I can't believe I'm going to say this -- but expand it and just to say wrong radioisotope for a therapy procedure, period. Whether it's a brachytherapy sealed source or a non-sealed source, I think that that based on even using just reasoning would be justified as being reportable.

CHAIRMAN CERQUEIRA: And usually if you know ahead of time that one is available and not the other, you can change the directive to reflect that. But if you unknowingly administer the wrong one even though the medical event is going to be -- the outcome will not be any different, I think it still needs to

be reported. So I think you have pretty good agreement on this.

DR. HOWE: And then I guess I should be -- you guys need to mentally back up to the written directive and the medical event part. And we have a case now with a licensee that has multiple brachytherapy medical events, and this particular -- and we've included some of the information that was submitted by the region in your packet, I don't have a slide for it, and it gets to the issue you guys have really wanted to talk about for a very long time, and that is how do we define a medical event for permanent implant brachytherapy? And the licensee wants to use -- I'm not sure I can get all the --

DR. NAG: D-100.

DR. HOWE: D-100 that's 80 percent -- and then there's the D-90 and then there's all kinds of permutations combinations in here. Generally, when we do wrong site, it's a real clear-cut case. Here's the prostate, here's where all the seeds went. We aren't quibbling.

DR. WILLIAMSON: So where were -- you know, I can't believe these were 12 percent of the D-90 and ten to D-90. So why was that, I might ask?

DR. HOWE: I don't have the root cause for

this particular case.

DR. HOLAHAN: The issue was it was a previous licensee there before and a current licensee -- well --

DR. HOWE: Previous group.

DR. HOLAHAN: -- a previous group was there before, and they used AP films to localize the prostate. And then the current group has come in and done MRIs on all the prostates that have been -- MRIs or CTs?

DR. HOWE: CTs.

DR. HOLAHAN: CTs. CTs on all the previously treated prostates and they found this out recently, but they were treated in 2000 and --

DR. HOWE: I think they also had films that were never read, and they went back and started reading the films and realized that most of the seeds did not get into the prostate.

DR. NAG: One thing, you gave us the numerator. What was the denominator during that period of time? I think you had about, what, 16 or so --

DR. HOWE: I think there are 21 of them.

DR. NAG: Yes, 21, but how many implants was that? One thousand, 20, 21 or -- that is an

important factor.

DR. HOWE: I don't know that right now, but there were a number of problems with this particular licensee. They were taking the films after the fact but they weren't reading them. They were not checking to see where the seeds were going. They were just putting the implants in and then they got a new contractor. The new contractor came in and started reviewing and -- well, the reason the new contractor started reviewing was they had a patient that came back after brachytherapy treatment that had --

DR. NAG: A recurrence.

DR. HOWE: -- recurrent cancer, and they looked at the images and they found out that -- I may have the numbers wrong -- maybe only 30 percent of the seeds went into the prostate. And so they said, well, okay, is this generic to the practice that was here before or is this an isolated case? And they went back and found 21 cases.

CHAIRMAN CERQUEIRA: Now, is this health care -- is this a hospital base or is this an out-patient facility?

DR. HOWE: It's a hospital.

DR. DIAMOND: Where is it?

DR. HOWE: It's in Pennsylvania.

DR. NAG: Pennsylvania.

CHAIRMAN CERQUEIRA: But, again, there should be mechanisms in place. I mean, clearly, if people aren't reading x-rays and are going back, I mean that's a standard of care that's certainly not up to standard, and so the hospital needs to take some action on this. But, again, from our perspective, it's clearly --

DR. HOWE: But from our perspective, it is you have always had the issue, how do I define a medical event for the prostate which is hard to image? I don't think these are -- most of these are borderline. I think they're way off for the prostate, but the issue is here, you guys get a chance to address it.

DR. MILLER: There were two aspects to this that we looked at -- are looking at through our regional office, and that is the former group who was performing this is no longer at the hospital, so the hospital did take some action. Our concern is also what happened to that former group? Are they all --

(Laughter.)

DR. DIAMOND: That's the main concern, because if they're still doing this with these protocols, that cannot be allowed to continue.

CHAIRMAN CERQUEIRA: But it's beyond the NRC's purview --

DR. DIAMOND: Correct.

CHAIRMAN CERQUEIRA: -- to control that. But, obviously, notification of some sort for these events needs to be made.

MR. LIETO: Mr. Chair, I would disagree. I mean if they know that these guys are out there and may be potentially providing medical events for other individuals or patients, I think there is a patient or member of the public concerning it.

DR. WILLIAMSON: And there is a mechanism for saying these individuals have to be barred from handling licensee --

MS. McBURNEY: From being an AU.

DR. WILLIAMSON: -- licensed byproduct material for --

CHAIRMAN CERQUEIRA: Concerning for the licensee, yes. We agree this needs to be done. Both from radiation safety but then also from the practice of medicine, this is clearly not appropriate.

DR. NAG: Yes. I think we have to recognize that historically before the day of the CP people were implanting and we were all implanting seed into the prostate and taking AP and lateral films

only. So you would get the dosimetry in relation, in this case, you know, your dosimetry would be quite good. It was only after the days of CP-based planning and CP-based dosimetry that we found out that even though you may have a very good dose distribution in your relation to the seed, the dose distribution may not be that good in relation to the prostate. So these physicians may have been doing it the old way rather than the new way.

DR. WILLIAMSON: But there was a difference, though. In the pre-CT era, they were doing open surgical procedures, and they were using the traditional surgical palpation and visualization technique. Now this is done in a more indirect way with ultrasound guidance. So you can argue that the ancillary 3-D imaging procedure is more essential in some ways for perineal trans-rectal ultrasound-guided implants maybe than it was in the old surgical open procedure.

CHAIRMAN CERQUEIRA: Leon?

DR. MALMUD: Dr. Miller took the words right out of my mouth, and I fully agree with Dr. Miller and of course with Dr. Howe's concern. A practical question of interest: Does the hospital administration know that there were these, for lack of

a better term, misadministrations, and is there any way that the hospital or organization to which this group went knowing of their past experience currently?

DR. MILLER: Our region was trying to investigate that, and I don't know if we got the results of that or not. The last that I checked with them they had not located this new medical -- this former medical group and if they were still a group if they had split up and gone their various ways. And we got into a debate with regard to where does our jurisdiction end and what should be done, but I'd have to -- I think we need to follow up on that to get --

CHAIRMAN CERQUEIRA: But your license must have individual names, so you should be able to track down the physicians.

DR. MILLER: Right. There ought to be some way to track that, yes.

DR. MALMUD: But, again, is the -- you said those occurred at a hospital.

DR. HOLAHAN: Yes.

DR. MALMUD: Is the hospital aware of what had happened?

DR. HOLAHAN: They are now.

DR. MILLER: They obviously are because they reported it.

DR. MALMUD: The hospital reported it to you. So the hospital is aware of it.

DR. MILLER: Yes. So as the licensee they reported it to the NRC that this had happened, yes.

DR. MALMUD: Okay. Fine.

DR. HOLAHAN: And the offered to go out and do 100 percent review of patients that have been treated by the former group during those two years.

DR. MALMUD: That hospital has a significant risk management issue.

(Laughter.)

PARTICIPANT: They should move to Philly.

DR. MALMUD: I hope it's not one with which I'm familiar. My concern is our role on this Committee and our not allowing something to slip through the cracks simply because we believe it is not our responsibility and it has not been our responsibility because this is an issue of significant clinical concern that this could have happened and may still be happening elsewhere and may happen again if this particular group fractionates and then practices that way in two different places. Then we have a metastasis of this kind of practice.

So I think this is an issue where if there is ambiguity in this instance, that we take the

aggressive position and try to pursue it until someone assumes responsibility for this. If it is not going to be this Committee then some other body but not allow the public to be subjected to this from this moment forward. This is a very serious issue for patients who have presumed that he was treated adequately, and for some body of knowledgeable individuals to know that that patient was not treated adequately is a significant issue, we would all agree.

DR. DIAMOND: Do we know if these patients are aware, the individual patients are aware of this?

DR. NAG: They have to be.

DR. MILLER: What the NRC elected to do, what the regional office elected to do is the hospital itself was performing an investigation, and what we will do with any licensee sometimes is to allow them to perform their investigation and then we evaluate the investigation that they've done. And then if it's insufficient, then we would step in and take further action. So that was an ongoing process I underwent weeks ago.

DR. DIAMOND: I understand.

DR. HOLAHAN: But the patients were all called back and to have CTs done.

DR. DIAMOND: They were.

DR. HOLAHAN: So I don't know if they know specifically what was going on.

DR. DIAMOND: And they were told the results of the dosimetric analysis?

DR. HOLAHAN: I don't know that.

DR. HOWE: Now, clearly, if they're identified as medical events --

DR. NAG: They have to be.

DR. HOWE: -- they have to be notified. But part of what we have to do is whether we agree with how the licensee identified their medical events or not. That's part of what we're asking.

DR. DIAMOND: I understand -- I mean we all understand that, and the point is well taken. If we cannot agree a unified or a meaningful definition of the event, then how do we go in pursuit from here? What is our jurisdiction? What's our purview? And we have a legal question and an ethical question.

DR. MILLER: What I'd like to propose to do is let us follow up with the region to see what the status of the investigation is. I will pass on to our regional staff that there's a lot of concern on the part of this Committee and the staff with regard to this, and we'd like to get some follow-up activities and we'll get back to you.

CHAIRMAN CERQUEIRA: And the concerns are for specifically what happened but also the fact that these individuals, especially since this was probably an institutional license, their names should have been on it, but we're concerned that this group in whatever form, or these individuals, are now allowed to continue to practice. And so if they're going to practice, they could go to an agreement state in which case it would not come to you, but some effort should be made to try to track them down and identify which ones are responsible to make certain that they aren't allowed to be on a license again to do this without further investigation. Is that the sense of the Committee?

DR. WILLIAMSON: Yes. I mean I think this motivates --

CHAIRMAN CERQUEIRA: Ruth has been waiting patiently.

MS. McBURNEY: My point was that if you are able to find out or if the hospital is able to find out where these individuals have gone, I think it would behoove you to contact the regulatory jurisdiction in that area where they have moved. Because I know we can take compliance history into account when licensing folks or not.

CHAIRMAN CERQUEIRA: Subir and then Dr. Miller.

DR. NAG: Yes. A couple of things. Number one, obviously, this does represent a substantial deviation from normal practice, but I would still like to know the denominator of this, and I'm sure they are investigating how many.

DR. MILLER: I think that's what they're looking into.

DR. NAG: But that number I would like to have, the 21 out of how many. Secondly, the 80 percent of the D-100 that is a wrong criteria to use, but even if you use the other one, the ABS, the American Brachytherapy Society, and also AAPM, they prefer the D-90 dose, even if you use that, it's still a substantial deviation. But I would suggest using the D-90 rather than the V-100. Those are the two things.

CHAIRMAN CERQUEIRA: Leon and then Nicki.

DR. MALMUD: I would just like to reiterate that this is really an ethical concern, and if we are aware that, as you reported, there were unread films, meaning that the group never really intended to check on their work, that it would seem to me that it's the responsibility of the NRC, which is

aware of the issue, to site visit these individuals where they are practicing now, wherever they are practicing now, if they are in the United States, and just do routine checks on them, because we now know that they were guilty of not reading films that they should have read. And, therefore, we have an ethical concern, if not a legal concern, with regard to the way they're practicing radiotherapy currently. Is there anyone who disagrees with me?

CHAIRMAN CERQUEIRA: Wait. Nicki next and then -- if you want to go, go ahead.

MS. HOBSON: Well, I just wondered what happened to the patients and what would be a normal procedure if you find out that you didn't give the full dose or is the patient called in and given an option to go through the procedure again? Were these patients actually informed that, "Oh, you only got 11 percent or something."

DR. HOLAHAN: Well, that's what the investigation is doing and they've called in 100 percent of the patients that they think are involved, and I don't know --

MS. HOBSON: But I thought you said that you weren't really sure that if the patients understood why they were being called in.

DR. HOLAHAN: Yes. And we'll have to find out from the region.

DR. MALMUD: If I may, you are -- Dr. Holahan's correct, the hospital, knowing what happened at that institution, is responsible for the follow-through, and the hospital's own risk management department and lawyers will make certain that the hospital follows through with a high degree of certainty.

My concern is from this point forward the hospital at which these incidents occurred is aware of their problem. We are aware of the error of the way in which these patients were treated. We now have the ability to know where these physicians have moved. All we need to do is monitor them under the existing regs, not excuse them, just casually monitor them. Do we not do that? Does the NRC not do that, have that ability?

DR. HOLAHAN: Yes, but if, as Donna-Beth says, they didn't read some x-rays or things like that, would we know of another event?

DR. WILLIAMSON: I think that one --

CHAIRMAN CERQUEIRA: Let's -- Bill?

MR. UFFELMAN: I just wanted to comment, as former council to the Medical Malpractice Study

Commission, it strikes me that this is an event that is reportable to the Pennsylvania -- the Medical Board of Pennsylvania, this over and above NRC-related issues. I mean the fact that these gentlemen -- or these people have done films that they haven't read, that they haven't done these other things, I mean they, in my mind, it's a very clear allegation of malpractice that is now known to physicians who practice in Pennsylvania, and I believe you have an obligation once the folks are identified to in fact report them to the Pennsylvania Medical Board.

CHAIRMAN CERQUEIRA: Jeff and then Subir, and then we should end.

DR. WILLIAMSON: I think this -- I just want to point out that I think this does underscore that we really need to revisit the definition of medical event and written directive for prostate brachytherapy because in principle the way, as I understand the rule, there is a big loophole in it now, and these physicians, had they read their films, could have come back and revised the prescription to say 11 percent of the initial dose. And I think that is wrong for such a big loophole to be left that really gross mistakes can be concealed. And even though coming up with a clear criteria is going to be

a very difficult and probably not totally successful undertaking, it's something I think we definitely should work on.

CHAIRMAN CERQUEIRA: Subir?

DR. NAG: If the films were taken and if the films were billed for and the dosimetry was billed for and the dosimetry and the films were not read, that becomes a fraud and anyone who has found that -- who has discovered that fraud has to report it. Now, I don't think we have an option. We have to report it to Medicare or whatever organization.

CHAIRMAN CERQUEIRA: Well, it's fraud or malpractice. And I hate to -- we don't know all the facts. I mean --

DR. MILLER: Let us get that.

CHAIRMAN CERQUEIRA: Yes. But I think that if the concerns are if these facts as presented are indeed true, that films were not read and decisions were made and especially if they were billed for, then if that's true, then the NRC does have some obligation to --

DR. NAG: And we get ten percent.

(Laughter.)

CHAIRMAN CERQUEIRA: -- to report that.

DR. SULEIMAN: The entire issue of medical

error and reporting there's a whole initiative in Health and Human Services on that very issue. And I think the fact that the NRC even picked up on this obviously somebody came forward and reported it. So I would assume I think what you want is just validation that the appropriate authorities are taking action. Otherwise you're going to have everybody running around like a three-ring circus trying to get involved here. I think it's important to make sure the right groups are aware.

CHAIRMAN CERQUEIRA: Leon, one last comment and then we'll --

DR. MALMUD: My last comment will be my first comment. This is an ethical -- this is a basic ethical breach. We are aware of it. Being aware of it we have a responsibility to pursue it. To know about something like this, to have the thought that it could be happening to other, in this case it's men, male patients, while we are talking if this group has not changed its mode of practice becomes our responsibility as well by simply knowing about it. And, therefore, though it may not be a legal responsibility, it is, I believe, an ethical responsibility to make certain that those individual are located and that someone's monitoring their

practice so they don't continue to make the same errors that they made in the past.

CHAIRMAN CERQUEIRA: I think that really expresses the sentiment of the Committee. All right.

MR. LIETO: There was a question I think that Donna-Beth asked, and I don't know if we got to what was the criteria for classifying -- classifying may not be the right term -- but determining whether an individual falls into a medical event or not.

DR. HOWE: I think Subir said that he would go with the D-90.

MR. LIETO: I think that would be at least some justification is, is that is certainly a parameter that retrospective studies --

DR. NAG: Right.

MR. LIETO: -- have been shown to be correlated with --

DR. NAG: And also that it's advised by both AAPM and ABS.

DR. WILLIAMSON: So all 21 events fall into that.

CHAIRMAN CERQUEIRA: It looks it uses the D-90. All right. So why don't we take a ten-minute break.

MR. ESSIG: Mr. Chairman, John Szabo

showed up at 10:15, as he was --

CHAIRMAN CERQUEIRA: Okay.

MR. ESSIG: We did take our break between ten and 10:15; we didn't realize it.

(Laughter.)

PARTICIPANT: You just didn't notice it.

CHAIRMAN CERQUEIRA: Okay. All right.

MR. ESSIG: So if we could have John come on since he's been waiting for the last ten minutes or so.

MR. SZABO: You can't get rid of me. But I got a question regarding subcommittees this morning, and some of the things we also work on is the Federal Advisory Committee Act. And for those of you who aren't familiar, that's the law that back in 1971 that sort of tried to get some control over the kinds of advice that the government was receiving from outside the federal government. And it established a whole bunch of regulations. We have regulations for our advisory committees that are published in the Code of Federal Regulations, and Tom Essig is for the ACMUI what is known as the designated federal official, which is brought over here.

If you have -- basically, the law requires that when you get a group of people who are not

permanent federal employees together to provide some advice to the federal government, you have to follow some requirements, including the ACMUI and ACRS. There has to be a charter filed and every meeting has to be open and notice for it happens. Detailed minutes have to be kept, and there are procedures for closing parts of the meeting, very specific rules such as we had yesterday personnel issues, proprietary information, classified information, security information.

The Federal Advisory Committee Act was remanded a number of times and recently new regulations came out and then, in our regulations, updated ours. The most important one is mentioned about subcommittees. The old rule until actually earlier this year was that if you had a subcommittee of a FACA committee, you had to go through all the requirements of openness and notice and et cetera. Under our new regulations, you do not have to follow those rules. You can have a closed subcommittee meeting. The only requirement is that if the subcommittee makes a report or some recommendations, it must go to the parent committee, and the parent committee has to review those recommendations under the regulations.

A couple other things that we have that are different is that if there is a meeting between full-time employees with state and local government officials, those meetings are not subject to these requirements as well. Those are some --

DR. NAG: What does that mean, I'm sorry.

MR. SZABO: If you had a federal employees meeting with state employees or local employees or members of Indian tribes, for example, just those people, that's not a FACA committee. It wouldn't have to go through those requirements. They've made an exception for state, local and tribal governments with federal employees. So if that ever happened, you wouldn't have to go through those requirements.

There are some other things, but I don't think they're really too relevant to the ACMUI. But if there's anything else on FACA, you can always contact me about it.

DR. NAG: Ruth is a state employee.

MR. SZABO: Right. So if the meeting were between her and Tom, then -- or a group of other NRC employees, you wouldn't have to have the openness requirement for meetings or something like that.

DR. NAG: Now, the subcommittee -- I mean it would be between her and three or four of us.

MR. SZABO: That's right, but if it was strictly under those --

DR. DIAMOND: John, how large can it be? In other words, could it be eight members of this committee, ten members of this committee and still be defined as a subcommittee?

MR. SZABO: You could define a subcommittee any way you want to define it, but, again, if you had most of your committee members as a subcommittee, still whatever you did had to be --

MS. McBURNEY: Reported.

DR. DIAMOND: Back to the main committee.

MR. SZABO: -- reported to the full committee, and the full committee would have to review it, just like a FACA group.

CHAIRMAN CERQUEIRA: John, with regard to the full committee reviewing it, then their obligation would be to do that in a public forum.

MR. SZABO: Oh, yes. Oh, yes.

DR. HOLAHAN: They can't email it to the full committee and get reviewed and comments.

MR. SZABO: No. That action has to be kept in a public forum other than for those topics that --

DR. DIAMOND: But also the key is whether

it's three of us or six of us or eight of us working on a particular topic, we can go and schedule phone conferences without doing notice, without the Federal Register and get some business done.

MR. SZABO: Absolutely. There's no minimum number. You can define the subcommittee any way you want to.

MS. McBURNEY: So what we do as a subcommittee and feed that comment back to the NRC staff then as long as we report it out and have it reviewed by the full Advisory Committee at the next meeting --

MR. SZABO: That's correct.

MS. McBURNEY: -- the noticed meeting, that would meet the --

MR. SZABO: That would meet the requirements.

MS. McBURNEY: Okay.

CHAIRMAN CERQUEIRA: Does it have to be posted anywhere? Does their report have to be made available to the public or can it just be reviewed orally at the next committee meeting?

MR. SZABO: Well, if you have the meeting and you're reviewing the report, the report should be available just like any other document.

MS. McBURNEY: Right.

CHAIRMAN CERQUEIRA: So it should be part of the material.

MS. McBURNEY: The agenda packet.

CHAIRMAN CERQUEIRA: Right. Right.

DR. MILLER: Ruth has brought a key statement to make sure we get things in the right order. The full committee only meets twice a year. The subcommittees will meet as needed. If a subcommittee does some work for us in a closed forum, develops a report, the requirement is that they report that out to the full committee. But the NRC, if they're going to take an action based upon that report, would have to have the full committee's endorsement in a public forum before we take the action or we're violating FACA. So that's a key innuendo.

DR. WILLIAMSON: But couldn't the --

DR. HOWE: John, why can't we --

DR. NAG: Mic.

MS. McBURNEY: State your name for the record, please.

DR. HOWE: Donna-Beth Howe. Why can't we take information that we collect from the subcommittee and take some kind of action which is not a final

action? I'm thinking specifically of my emerging technology. I can put guidance up on the web site, I can revise the guidance at any point. Can I take information I get from them, put it up on my web site and then when the full committee meets and talks about their report and finalizes what they want to recommend, I can go back and modify the web site.

MR. SZABO: You can use individual comments, remarks, recommendations made by members, but if it's the subcommittee itself making a report, an agreement of some sort, recommendations, then it has to have the sanction of the full committee. Now, maybe you don't have to have a -- bring everybody here.

DR. WILLIAMSON: It could be done by a telephone call.

MR. SZABO: It could be done by chronicling, yes.

CHAIRMAN CERQUEIRA: Oh, okay.

MR. SZABO: But still there would have to be some openness to this.

CHAIRMAN CERQUEIRA: All right. So if it's sent out to the Committee members, do we need to take a vote on it? Can we just --

MS. McBURNEY: Just an open meeting.

DR. NAG: Has to be open.

DR. WILLIAMSON: Well, since you're planning to institutionalize the sort of mid-meeting phone conference, couldn't that be noticed in advance and then you could --

MR. SZABO: Yes, absolutely. Sure.

DR. HOWE: That could, but I don't think our licensing actions want to wait for you to have quarterly meetings.

DR. MILLER: I mean what it would require if we had a subcommittee, given what you all have said, is that the subcommittee would have to report out in some way to the full committee before the full committee to tell the NRC, "This is our recommendation for you to proceed."

DR. HOWE: But also it sounds like I could take information during the discussion and incorporate it.

MR. SZABO: Absolutely.

DR. HOWE: As long as I'm not depending on their recommendation.

MS. McBURNEY: Right.

MR. SZABO: That's right.

MS. McBURNEY: As long as we didn't make a formal recommendation that we involve the staff with

our discussions on the subcommittee and she could use that information --

MR. SZABO: That's right. If you made a -- and these are my views.

MS. McBURNEY: Right.

MR. SZABO: That can be used --

MS. McBURNEY: And these are Dr. Vetters' views, and these are Dr. Williamson --

MR. SZABO: Not the so-called subcommittee's views.

MS. McBURNEY: Right.

DR. HOWE: So I can use the information before they put it into a report.

MR. SZABO: Yes.

DR. HOWE: But once it's in a report, I have to wait for the full committee.

MR. SZABO: Yes. Before you can say this is the subcommittee's views.

DR. HOWE: Right. Okay.

MR. SZABO: Individual views are always not subject to these requirements. And you can even take the comments, informational questions that are asked, let's say they're talking and asking questions and what not, that's still not a problem either.

DR. NAG: So like two levels. One is the

discussion that we had among the subcommittee members, that would be our individual thoughts.

MR. SZABO: That's right.

DR. NAG: And then at the end of that we could make a combined subcommittee recommendation that would go to the full committee and be acted on at a later date.

MR. SZABO: That's right. The full committee would have to act on that subcommittee's --

MS. McBURNEY: But in the meantime she could take what information and advice that individual members of the subcommittee present to use to do the licensing.

MR. SZABO: Right. As long as it's considered to be the views of that particular member.

CHAIRMAN CERQUEIRA: The individuals, okay.

MS. McBURNEY: Sounds good.

MR. ESSIG: And I would offer, I think if we had a particularly important recommendation at this pace, the subcommittee was going to make to the full committee and we needed to act on that recommendation, we could go ahead and schedule a noticed conference call of the full committee, discuss that and then use it. That's what I think I hear.

MR. SZABO: That's absolutely correct, yes.

CHAIRMAN CERQUEIRA: Just a residual question. For that kind of confirming conference call, how long in advance do you need to post it? I mean how long would it take to do that if --

DR. HOLAHAN: Ten days.

CHAIRMAN CERQUEIRA: Ten days. Okay. All right.

MR. LIETO: I have a question. For the teleconferences of the full committee, do minutes have to be maintained of those also?

MR. SZABO: Yes. Yes. They're subject to the Act.

DR. NAG: And they're open. Anyone can call in and --

MR. SZABO: You have to call in, yes. Because we said reasonable access for the public.

CHAIRMAN CERQUEIRA: That's great. Any other questions for Mr. Szabo? Well, I thank you for coming and we'll take a break. We'll reconvene at quarter to 11.

(Whereupon, the foregoing matter went off the record at 10:37 a.m. and went back on the record at 10:53 a.m.)

CHAIRMAN CERQUEIRA: All right. This session we've changed the schedule a little bit. It's going to be dose reconstruction in unplanned exposure/extremity monitoring materials facilities. And Dr. Sami Sherbini will be making the presentation.

MR. ESSIG: If I might just add, I think Dr. Sherbini is new to the Committee. I don't know that you've made a -- he's made a presentation before. Dr. Sherbini is on my staff. He's a senior level health physicist, and he is the person that we go to for most of our modeling work. And so we felt it appropriate that he lead this particular discussion.

DR. SHERBINI: Okay. Thank you. There are actually two topics that I'm going to talk about today, and they're not really related except that both deal with dose assessment of some kind.

Okay. The purpose of the first item or topic, dose modeling, is for those concerns that were raised that NRC tends to be excessively conservative in its dose rate construction to come up with excessively high dose assessments and unrealistically conservative assumptions when it does these things. And what I'm going to try to do is show you very briefly how we do these dose reconstructions and maybe illustrate how some of these conservatisms tend to

creep them and what causes them to creep in to this.

The other topic is monitoring of the hands of workers, especially workers in the radiopharmacy industry who handle high specific activity, vials or syringes containing these materials and the difficulties we've encountered in getting a good assessment of the dose of their hands when they do these things.

I thought in the dose modeling discussion I would present this in the form of three cases that we've dealt with, and I think through the presentation of the cases we can identify the places where conservatisms enter and how they might be avoided in the future. And those are to show that really what NRC tries to do is to try whenever possible to use data rather than make assumptions. And we try to reconstruct events based on firsthand accounts. In other words, we interview the workers, we interview their supervisors and so forth to get the story directly from the people who are affected. And when it is necessary to make assumptions, we try to make them as realistic as possible.

Again, when we're uncertain, we tend to slightly overestimate or make slight conservative assumptions with the idea that it is better to

slightly overestimate the dose than underestimate it. We do not want to underestimate doses for a variety of valid reasons, I think. We also use a graded approach in dose reconstruction for cases that involve very low doses. We do approximate calculations. It's not worth the effort to do very exotic and very detailed calculations. Of course, as the dose or as the dose we think may have been received goes up, then we spend more time and we use more elaborate modeling to reconstruct the case.

The first case we have to talk about is interesting case that happened in 1995 at MIT that involved a post-doc research worker, research student who was working one of the cancer labs there. And one day when he was frisking out of his lab, as is required when he works with radioactive material, he found that he was radioactive, and it turns out that the radioactivity was internal, it wasn't surface contamination. And further assessment showed that it was caused by P-32 antibody.

The licensee did their own immediate investigations and they notified the NRC, and the NRC did special inspections. And based on the data collected, we did those assessments. Fortunately, the licensee had collected a large quantity of urine

samples and had also done whole body counting, and so we had a lot of data to work with. We used what was then the industry standard for internal dosimetry, CINDY, which is a code that uses -- that we use to calculate internal dose. We also did some hard calculations. And these are the results.

We had a consultant also working for us who did independent assessments. We got 600 microcuries,the licensee got 560, and the consultant got 580. The limits, the dose limit for occupational exposure for intake of P-32 is 600 microcuries intake limit. So our assessment was right at the limit. The licensee's was lower.

We decided to accept the licensee's assessment because they had done all the right things. They had done pretty good job in doing the assessments, and we decided that even though the number came up lower than ours and below the dose limits, we decided that it should be accepted and that's what we went with.

And the conclusions for this case is that if the licensee does a good job, we will accept their assessment without any further question, even though ours might be higher. I think in this case there are several important things that should be pointed out to

show how this case could have -- had it not been for the licensee's quick response to the situation, it could have ended up being a very conservative dose estimate and could have probably put them well above the dose limit, even though the assessment here showed it below the dose limit.

When the licensee first became aware of the contamination, they tried to pinpoint when the intake might have occurred. Incidentally, we never did find out how the P-32 was ingested. We investigated all kinds of possibilities but we never did find out how this person ingested P-32.

The point is the licensee tried to narrow down the point at which the P-32 might have been ingested. The student is required to frisk when he leaves the lab, so we know when he left the lab on that day when he was contaminated obviously the intake must have occurred before then. Unfortunately, the student hadn't worked with radioactive material for quite a few days before that, and so the other data point we had was about a week earlier. And so there was a time span of about a week or so within which the intake could have occurred. Given that P-32 is excreted fairly rapidly from the body, it's important to know very closely when the intake occurred. A span

of uncertainty of a week, especially if you have to make the assumption that the intake occurred at the beginning of that time span, which we would have done without any additional data, could have easily put the licensee over the limit.

What the licensee did, which is very interesting and very smart, I think, was realizing that P-32 appears in there almost immediately after the ingestion -- not immediately but within hours -- they went to the person's home and they went through the laundry hamper of the person's house with a frisker, and they peeled off layers of laundry and frisked the underwear, basically. And each layer was radioactive until they reached a layer that was not, and so they were able to -- and I think that was very clever -- they were able to -- this guy was very methodical and so he changed his underwear once a day at the same time every day. And so by finding the dividing line between the contaminated and not contaminated underwear, they were able to narrow down the intake interval to within 24 hours, which was a considerable improvement. And I think this was an illustration of where the licensee I think bears some of the responsibility for the conservatism that you might see in some of NRC's assessments.

If the licensee had not done that, we would have had to assume that the intake occurred may be four or five days before it had actually occurred. That makes a big difference in the intake assessments, especially for cases like P-32. And so by the time the NRC got to the site, it would have been too late to do the standard activity. We got there a week or two after the incident, and so most of that data would have been gone, and so we would not have had the benefit of this kind of reconstruction. So quick thinking on the part of the licensee to get data as quickly as possible is very important for dose reconstruction.

The other factor I think that the licensee was smart in doing was that one of the important factors in assessing intake is -- based on data is how much P-32 is excreted in a 24-hour period in the urine. Now, a lot of licensees would collect one voiding of urine, okay? But that leaves the assessor with the task of having to guess based on the consideration in this one voiding how much might have been voided during a 24-hour period. That introduces a great deal of uncertainty. The licensee instead made sure that they collected 24-hour urine samples every day for two or three weeks after the suspected

intake.

So we have 24-hour urine samples. We did not have to guess how much was the 24-hour excretion for each day. It was there in the data. There was no need to make any kind of assumptions. And so this is the kind of thing that makes dose assessor's job much easier, it makes assumptions unnecessary, and it eliminates guesswork. It eliminates the conservatisms that would have had to be introduced if this data was not available. And I think I would like to highlight the fact that, yes, we do bare some responsibility for conservatisms, but I think the licensee is in an excellent position because of proximity the incident to collect data as quickly as possible and as completely as possible to as to make it unnecessary for us to make any guesses or assumptions. And that, I think, is a very important point, as illustrated by this case. This case could have easily been -- could have easily ended up in a citation for overexposure had the licensee not acted the way they have done.

The second case involves a 1 curie cesium source that was left sitting on an oil rig in Montana for a period of about 12 hours. During that period, workers were working around the source. Nobody realized that the source was sitting out there, and

they continued working. Some of the people were exposed for the entire 12 hours, some for less time. The number of people involved was 31. These are all members of the public. They are not radiation workers, and so they were subject to the 100 millirem limit.

The licensee did an initial quick assessment, and they came up with a maximum dose of about 6 rem. They also had one of the people give blood and they did a cytogenetics analysis to determine chromosome aberrations and then estimate the dose. And the result came back at a dose of 200 rads. Now, this is something of great concern because that starts to border on a lethal dose. Some people die from 200 rads of radiation. And so we were very concerned; so was the licensee.

We quickly did just a very quick calculation. We assumed the bare 1 curie cesium source. We assumed the distance that the people were standing at, and we did a rough calculation. And our calculation showed that there was no way these people could have received 200 rads. It's just not possible. We refined the calculations, we used Microshield, which is another industry standard for external exposures, and, again, the calculations showed there

was no way the dose could approach 200 rads.

We had a special inspection go out and interview the workers, inspect the site. We also -- because we did the dose assessments based on a 1 curie cesium source, we thought, well, maybe the cesium source was mislabeled. Maybe it's not a 1 curie source. Maybe it was just mislabeled. And so we did measurements on the actual source that was on the ring to make sure that it was really 1 curie. And in fact it turns out to be it was 1 curie, and so that gave us some confidence.

We decided to repeat the blood testing, so we had ten workers volunteer for the tests, and we sent the blood out to two labs. One was in the UK, which was a well-known lab in this area. And the reason we used two labs was to eliminate the possibility that maybe the technique used by the lab that did the initial test was not correct, that they were doing some kind of systematic error that produced the wrong dose. We also got detailed drawings of the source and the reg, and we modeled it using Monte Carlo computer codes and the merge phantom to do the dose calculations.

The results of all this effort was that the calculations showed that the maximum dose could

not have exceeded 300 millirems for the most highly exposed worker. All the bloods tests that were done the second time came back negative, at least within the sensitivity of the members.

DR. NAG: Does that include the oil worker who had the high dose or not?

DR. SHERBINI: He was negative also.

DR. NAG: Okay.

DR. SHERBINI: Yes. Yes. So at least the tentative conclusion is that the first cytogenetics tests was probably an error, although we're still discussing that. But, clearly, this incident did not -- if the person had received 200 rads, he did not get it from that incident.

DR. DIAMOND: Sami, did this individual have an acute radiation syndrome?

DR. SHERBINI: No, he didn't.

DR. DIAMOND: Just from basic common sense, if you receive 200 CUI whole body over a limited number of hours, essentially a pseudo fraction, if you will, I don't know if it was two hours or six hours, you would expect very substantial acute radiation toxicities, the classic manifestations you'd expect, very typical platelet drops, and I don't know, did the patient have any of those laboratory

manifestations?

DR. SHERBINI: No. The patient did not -- luckily, it was. Luckily, it was. The patients was kind of a hypochondriac.

(Laughter.)

He was very concerned about his exposure, and so what he did was he had blood drawn every week after the exposure for a period of about three months. So we had weekly blood samples for a three-month period. And the blood samples, of course, count the lymphocytes and so forth, and we had the plot and there was no indication of any kind of radiation exposure.

DR. WILLIAMSON: So where did the 200 rem cytogenetic estimate come from?

DR. SHERBINI: It came from the first blood test that was done on this person, and we think -- it's not clear what went wrong in this test, but --

DR. SULEIMAN: Could they have radiated the blood?

DR. SHERBINI: No. We checked on that. We checked with Fed Ex, we checked with everybody but there was -- no, no, the blood was not irradiated. There was also shipping dosimeters that accompanied the blood, and these did not show any exposure.

DR. DIAMOND: I think that's an interesting question. Since I don't know how these systems work, let's say a blood sample was taken and let's say that luggage or that cargo, if you will, was irradiated in the search for explosives or whatever we look for. Could that have possibly --

DR. SULEIMAN: Not 200 rems worth.

DR. DIAMOND: I'm just asking. I mean if there's such a difference between -- there's such a disparity between the critical syndrome that this patient did not have on basic laboratory parameters and the calculations. I'm just trying to think of anything --

MS. McBURNEY: There was an error made at the lab. And it was dosimeters with the blood sample.

DR. SHERBINI: There is potential for error in cytogenetics testing. I don't know if you know the details of the process but what you have to do is look at the cells after culture and identify cells that two centimeters dicentrics.

DR. DIAMOND: Hopefully he doesn't have acute leukemia.

DR. DIAMOND: Seriously. That's a degree of cytogenetic anomalies.

DR. SHERBINI: No. Actually, there are

several conditions that can mimic dicentrics, and that's one possibility, the lab might have mistaken these conditions for true dicentrics. And what they do is they count dicentrics and then go to calibration curve and read off the dose from these curves. And so it's easy to make mistakes.

But the other piece of data is the repeat test on that person showed that the dose was negative, that's all.

The net result of this was that the NRC rejected the initial cytogenetic test, and they also rejected the licensee's dose assessments as being too conservative. We felt that the licensee made assumptions that were completely unwarranted. For example, they neglected all the shielding around the source, which of course raised the dose. They also -- they had estimated how far the people were standing from the source, let's say three feet. They used that three feet as the distance to the body, which is of course not correct, because you'd be calculating the dose to the feet, basically, which is not what you want. You want the dose to the vital organs, and so the distance up from the source is much greater than three feet. And so putting all these things together makes a big difference in the dose you assess. And

when all these assumptions were removed, we were able to drop the dose from 6 rem to 0.3 rem quite easily, and these are the numbers we finally accepted for this assessment.

I think this clearly demonstrates that NRC will go to great lengths to try and get the most reasonable assessment of the dose to the people. But, again, the fundamental underlying thing is that the data has got to be there. We don't like to make assumptions, but we will if we have to, and avoiding having to do that means that the data must be available. And usually the best person to provide it is the licensee. Yes?

MS. McBURNEY: If this is the case I'm thinking of, this was a Texas licensee and he was working in Montana.

DR. MILLER: You're right.

MS. McBURNEY: And one of the lessons that we learned from this and several other instances in which we want to get good data on cytogenetics is that the program that we had depended on for many years at Oak Ridge had lost its funding. And so we're trying to work with NRC and perhaps COE and try to get that reinstated.

DR. MILLER: Yes. What Ruth's identified

is this particular case identified a dilemma, I guess, for lack of a better word for us in getting good cytogenetic test results domestically. Sami touched on the fact that we had separate blood tests evaluated, but we had to go overseas to get that done. And getting it done in a timely manner and getting it done economically, as economically as we could, so it's Sami's currently working on an effort trying to see other -- what other capabilities are, and are there indeed other capabilities in the United States that we haven't identified?

And part of the reason that he's doing a presentation this morning and not this afternoon is he's traveling this afternoon to the University of Pittsburgh to do some further evaluation of their capabilities there. But it's identified a dilemma for us. It's rare that we or maybe the states would have the need for this, but when we do have the need for it, as Sami's pointed out, we had the need for it in a fairly timely manner. And I guess, Sami, you haven't talked about it but we made a third attempt, I guess, to go to South America to try to get some results --

DR. SHERBINI: Oh, yes.

DR. MILLER: -- and it does add to the

dilemma of having to go overseas, and because of the time delays of the samples reaching the laboratory in South America, the samples end up being, I guess, voided because of time delays.

DR. SHERBINI: Yes. They degrade it. As Charlie indicated, the problem with using overseas facilities is that we tried to send a sample to Brazil because they were the people who did the Guyana incident so they had a great deal of experience. But the difficulty we encountered was the Brazilian government does not permit blood samples into the country. And so we could not get the blood into the country to get it to the lab. Fortunately, the UK does allow this kind of shipment as we were able to do that, but this varies from country to country and of course it can change over time. And so we might lose our UK capability any time if we change their laws in that area. So it's very important to have a U.S. based facility, and that's what we're working on.

DR. MILLER: It's a challenge.

CHAIRMAN CERQUEIRA: It is, definitely. Subir, you had a comment, question?

DR. NAG: Yes. I think this also underscores that when you are making an estimate, a dose estimate, there are so many factors that you are

presuming or assuming that the dose difference can be not just a matter of two, three, four times but as much as 20 to 100 times depending on the assumptions we are making, inverse square law, biological half-life of the radioactive material and so on.

I mean just because you're getting an estimate of, say, 100 millirems may mean you went from one milligram to as much as ten grams.

DR. SHERBINI: Well, yes and no. I agree with you that this is the case, but what I'm trying to say is that, for example, in the MIT case it's true the biological half-life can vary from person to person, but there was enough data in that case for us to actually determine the biological half-life for this particular person. And so that allowed us to eliminate this source of uncertainty. And if you go -- for each factor that goes into the calculation, then they can add up, and if you have the actual data, then you can eliminate the sources.

The third case, it's a controversial one, St. Joseph's Mercy Hospital, it had to do with a patient was administered I-131.

DR. NAG: The famous one.

DR. SHERBINI: Yes. And the daughter of that patient was sitting next to her. The patient was

dying and the daughter, presumably, sat next to her bed on and off during the period July 1 to 7, 2002. When doing the dose reconstruction we found that it was not necessary to do those calculations, because the licensee had actually measured the dose every day at the place where the daughter was sitting, and so there was no need to do dose rate calculations. What was necessary was to estimate the time, the duration of exposure for each day that the daughter was sitting next to her mother.

The total dose assessed by the NRC for that period and by the licensee, unfortunately, were at variance with each other. They did not agree by a large margin. And although there was no disagreement regarding the dose rates on which the calculations were based, the disagreement centered on the estimates of stay times, how long the daughter stayed next to her mother during that period. And the licensee and the NRC disagreed quite significantly in that parameter, and so what we are doing now is we're going back to the region to ask for details and maybe even to the licensee to find out what the story is and what really is the most appropriate time to reconstruct that dose situation.

DR. SULEIMAN: Do you need to come up with

a single number? Why don't you put an upper or lower estimate?

DR. SHERBINI: We can do that. It would be nice to narrow down the range because the range is quite wide. I don't want to say what the range is because it's still -- we're still discussing it, but it is quite wide, and it would be nice to narrow it down.

DR. SULEIMAN: Let the facts speak for themselves. I mean that always fascinates me. If it's an order of magnitude, then you should -- obviously, you want to tighten that up, but --

DR. SHERBINI: Yes. Well, obviously, if we can't tighten it, then that's how it would have to stay. But you would think that, well, the stay times are basically just talking to the daughter and asking, "What did he do?" And so it's interesting that even there there is disagreements between the two groups.

DR. DIAMOND: Sami, just out of curiosity, was this woman truly ill when the 300 millicurie were delivered or did the patient have an intercurrent illness after administration of high-dose iodine in which she became extremely ill, had a massive heart attack the day after administration?

DR. SHERBINI: No, no. She was certainly

ill. I mean in fact she died on July 7. That's when the --

DR. DIAMOND: Just for the sake of this committee, nothing to do with what you're talking about, it raises a very interesting aspect of medical judgement on why in the world a physician would give high-dose I-131 to a person of this life expectancy, not only from an ethical point of view but also any time you give a radionuclide you have to consider that patient's ability to comply with regulations. Is this patient going to be able to be helpful with the nursing care? There are a whole sort of issues with this, and at first glance, not knowing the case, there are some important clinical issues at hand.

DR. MILLER: The other issue that we face, which I'm sure you would be concerned with is that human nature issue of a loved one who is next to a dying parent or a dying relative who's received that dose and the exposure of that loved one, and you -- where do you strike the balance with regard to their ability to be with their loved one in their dying days versus the radiation concerns? It strikes a balance -- it's a moral dilemma as well as --

DR. DIAMOND: But there are very, very few circumstances in which you can justify with a person

with -- let's assume, since we don't have the facts, she's dying of complications of widely metastatic thyroid cancer, differentiated thyroid cancer. Administration of 300 millicurie in this setting will have no absolutely no bearing on that person's life expectancy and only impair that final relationship, the quality of it and so forth.

CHAIRMAN CERQUEIRA: Sami, I wonder if you'd care to comment on the letter that was received from the Carol Marcus and several letters are going back and forth. This was given out to the Committee, and the Committee members got letters from -- emails from Carol and the other people.

DR. SHERBINI: I take the Fifth. First of all, I think there are things that are not clear in the letter. For example, she mentions dose calculations whereas in fact there were no dose calculations. There were measurements and so those calculations were not necessary. And the only thing that had to be estimated in fact was time, and so --

DR. NAG: And distance?

DR. SHERBINI: Pardon?

DR. NAG: Distance and time.

DR. SHERBINI: Well, even distance is not really --

DR. NAG: Because you can't be right on top of the basin 24 hours a day for so many days.

DR. SHERBINI: True, but the dose gradient close to the patient's bed was not very short. And so even if the daughter moved back and forth a little bit, it really wouldn't have such a great impact. And I don't think there is much controversy or disagreement regarding the dose rate in which the daughter was sitting. I think the disagreement was how long she sat there. And that's really it.

DR. SULEIMAN: There wasn't an issue where she embraced her mother and hugged her?

DR. SHERBINI: No. The times involved are very large. We're talking tens of hours. And so it's not a two second thing. She sat there for what some claim is the entire day, and so we're talking long time periods, and so it's --

MR. LIETO: And there's also a discrepancy as to when it started.

DR. SHERBINI: Yes.

MR. LIETO: As Sami pointed out, the NRC calculation began with the day of administration. And to answer one of Dr. Diamond's questions, the patient when administered, had renal function and was conscious and the expectation was that she was going

to be discharged. So it wasn't that she was in -- she didn't go into renal function until two or three days after, and that's when things went sour.

DR. SHERBINI: I guess the --

MR. UFFELMAN: Bill Uffelman, Society of Medicine. And not to defend Dr. Marcus but there are additional documents in the pile that you have by Dr. Royal as the President of the Society of Medicine. We had a couple meetings with at least commissioners, Commissioners McGaffigan and Merrifield, and then there are some letters relative to that. And one of the topics was not so much the specifics of this but the reality that there is expertise out in the community, sitting around this table that we as a society felt that the NRC could benefit from bringing in additional experts or calling on that expertise. And at the end of September your charter was amended, and I presume you've all seen that, to indicate that you in fact can all now be experts. And we have since written a letter to the commissioners commending them for doing that because we felt it was consistent with the discussion that was kind of summarized in the letter there.

And then Dr. Seigel and Dr. Marcus have written a monograph that at some point will be

published in the Journal of Nuclear Medicine soon. You may have all or some of you may have benefited from the emails to that effect, but I didn't feel that I could distribute that until it got published. Then I guess when you have your future meeting, that probably will be included with it.

DR. SHERBINI: Well, if I might comment on that. I think this mischaracterizes the problem and the issues really. The problem, as I see it, is not one of expertise. I think we have plenty of high-quality expertise in the agency. I think, as these cases should have illustrated, and there are a lot of other cases similar to that, is that the outcome is dependent on the quality of the data that we use to do the assessments. The expertise in terms of actually doing the calculations, running the codes and so forth is there. But as the famous computer "garbage in, garbage out" kind of thing, you have bad data in, you're going to get bad assessments out. It has nothing to do really with the expertise. It has to do with how much later do we have the quality of the data and how many assumptions we are forced to make because the data is not there.

DR. WILLIAMSON: Well, I think there is a legitimate issue that's being raised by these letters.

I certainly agree the industry standard is when you don't have the data, you make the worst possible assumption to get the highest number. But I guess maybe in these scenarios one can question whether that's really a good idea, that perhaps you should provide a range of numbers based upon different scenarios and site uncertainty and that this should probably be taken into account in the severity of the regulatory response, that if indeed the people were making reasonable efforts to protect this grieving person and someone comes along later and comes up with some different estimate, I mean this should all be considered, and maybe the individuals shouldn't have been cited.

I think this is really the issue of philosophically when there is a large amount of uncertainty in the data, this should be acknowledged, and it doesn't seem appropriate, especially when there's no issue of medical harm to anybody, this is all sort of a -- at the sort of epidemiological level we're considering even 2 rem exposure. Why do you necessarily hit the licensee with a regulatory response as if with certainty they delivered this high limit?

CHAIRMAN CERQUEIRA: Although, again, it

looks like there are several issues here. One is just a conservative approach to the dose calculations, and I think in this particular case that you had all the data, it's just a matter of the time, and that seems to be a very subjective variable that went into the calculation. And in the other cases, I think, again, the differences in that initial one between their estimate of 600 -- I mean those numbers are relatively small. So I think one thing is just the overall approach, and certainly from the three cases presented here, it seems to be a realistic approach.

DR. WILLIAMSON: I think that -- well --

CHAIRMAN CERQUEIRA: David?

DR. DIAMOND: Yes. We all understand that there are inherent difficulties in the calculations based upon those variables. I think the more important point is, Sami, in your opinion, are there truly differences between how the staff, NRC staff calculates these doses, what algorithms they use and perhaps the methodology and the algorithms that would be used by outside individuals? In your opinion, is there a difference?

DR. SHERBINI: No, there is no difference.

DR. DIAMOND: So if there's no difference, I don't understand the substance of these letters

then. If the methodology is the same, there's no difference. If there truly is a difference in methodology, then there needs to be discussion on the topic.

DR. NAG: There's not a difference in methodology of calculation, it's the difference in your estimation. For example, are one foot away or one and a half foot away. Although it doesn't sound like a big difference --

DR. DIAMOND: I understand that.

DR. NAG: -- it makes a huge difference.

DR. DIAMOND: But that's not what the letters are saying.

DR. NAG: If you add a lot of assumptions, when you add four or five different assumptions, they all add up. Two times, that's a two-fold difference with one assumption. Another two-fold difference -- and all of them are on directive sides. When you multiply them then it becomes, in a sense --

DR. DIAMOND: Right. That I agree with. It would be more useful to have ranges, as was pointed out, but as far as the actual methodologies, I mean it's radiation -- it's basic radiation calculation.

DR. SHERBINI: Yes. There's no difference. I think the point raised here was well

taken in that the most fruitful area to discuss and to consider I think is the kinds of assumptions that would be reasonable to make in each given case.

DR. SULEIMAN: Did you do any chromosome testing for the --

DR. SHERBINI: Pardon?

DR. SULEIMAN: Did they do the blood testing on the woman, on the daughter?

DR. SHERBINI: No, they did not.

DR. SULEIMAN: Because that would validate if you're -- that would clearly come in -- that would support one or the other set of --

DR. SHERBINI: The doses even with the high estimates are below the sensitivity limits. So they wouldn't really help very much.

MS. SCHWARZ: I have a question.

CHAIRMAN CERQUEIRA: Yes.

MS. SCHWARZ: Is the NRC planning to at some time in the future look into the idea of collaborating with members in the community in terms of doing these types of calculations?

DR. SHERBINI: I think what we're trying to do is to absorb the information that we've received and try to decide where to go from here. The NRC is going --has been going through what I would call a

paradigm shift. Traditionally, when we did dose calculations --

DR. NAG: Most conservative.

DR. SHERBINI: -- we always used conservative analysis, because that way if things are okay based upon conservative analysis, you had nothing to worry about; it was easy to defend. We're moving towards a realm of trying to risk inform our operations and our way of doing business. That's not a step change in the way that we do things and the way we do business. It requires what I would call a shift in the way that we think. And that shift doesn't come overnight because you're taking people who have been working in the field, in many cases, for many, many years and you're asking them to change the way that they're doing business. That takes, in some respects, a cultural change. That's the challenge, but nevertheless our challenge and what the Commission wants us to do is move towards a more risk-informed approach. To that extent I think trying to build the various thoughts that we get from groups into that helps, and to the sense that the Committee can give us counsel in that area, that also helps.

But I think what Sami's tried to point out are two things. One, to the extent that the licensee

can take immediate action to try to gather information, that goes a long way from not having to apply conservatisms where you don't need to. To the extent that that doesn't happen, well, then we're left with how do we use a risk-informed approach to try to analyze the situation.

And it's very interesting from our approach because going back to the second case that he talked about, the well logging case, I had an opportunity to go out to Montana and meet a number of people who were involved in this case. And these are plain people who work -- they're not -- and I don't mean this in any derogatory manner, for the most part they're not college-educated people, they work out in the field, they're oil rig workers. It's a community who doesn't understand medical science in any way, shape or form, and they really are looking to the NRC to try to make sense of this for them. Because they're worried about what kind of health effects, what did they read in the newspapers, what did they see on TV. Radiation is harmful, so they get very concerned about that. So we have to take our duties seriously to decide where do we draw the line. I guess that's kind of a long-winded answer, but we are trying to move towards a more risk-informed approach.

To be quite blunt, Same's too much of a gentleman to say this, but some of the letters we received were pretty, I would call, violent kinds of letters. And they go back d-- they don't go back just because of this one case, it goes back to a number of years, I think, of frustration on the part of the letter writers with regard to how they view the conservatism that's put into the NRC's calculations.

So we're trying to move towards trying to get enough information as we can so that we can move not only to a risk-informed approach but to try to get as realistic of results as we possibly can. And that's the challenge that I have, that's the challenge that I've given my staff.

DR. WILLIAMSON: Well, I mean, I guess -- I think that, you know, what a good scientist does is not just think in terms of an answer that you get with a computational methodology. You think in terms of uncertainty, there are established rules for estimating uncertainty and principles, and I think this is sort of one way to inform your regulatory responses to take into account not only that magnitude of the estimate but the uncertainty thereof.

DR. WILLIAMSON: And I think we do sometimes. I mean if you're looking at that second

case, we could have taken the first results we got with regard to the cytogenetic testing and came out with a complete overreaction.

MS. McBURNEY: Right.

DR. WILLIAMSON: But it didn't make sense to Sami, as the expert on the case. It just didn't make any sense, given there were no health effects noticed, something just -- the reconstruction given the size of the source didn't seem to make any sense. So that's where you've got to take a step back and start trying to use other logical uniques to say something's not right here.

CHAIRMAN CERQUEIRA: All right. I think we should try to wrap up the discussion. Bill, one last comment.

MR. UFFELMAN: The comment I wanted to make was one of the frustrations that Dr. Royal and others had voiced was the lack of availability of the information that you all have used so that you could independently sit down with the back of an envelope and make a calculation, that the information was not available at the time and became available after the meeting with the commissioners.

DR. MILLER: Yes. And to a certain degree we have to protect that information because of the

rights of the individuals who have been affected by this. So there's certain privacy rights that they have, and the way that we have to roll out the information has to continue to protect those privacy rights.

MR. UFFELMAN: But the results were announced but not the arithmetic -- not what went into the --

DR. MILLER: The numerology that was used to do that?

MR. UFFELMAN: Right. That was the difficulty, the lack of data.

CHAIRMAN CERQUEIRA: Sami, thank you very much.

DR. SHERBINI: There's a second part.

CHAIRMAN CERQUEIRA: Oh.

DR. SHERBINI: I'll try to go through this very quickly.

MR. ESSIG: Angela does not need 45 minutes.

CHAIRMAN CERQUEIRA: Okay. Well, she's going to have about ten. Okay. Nicki, go ahead.

MS. HOBSON: Well, you know from listening to me five and a half years that access to quality medical care delivered by competent physicians in a

safe environment is a major issue for patients. And to the extent that the application of the regulations interferes with that process, that's also a concern to patients. We want good health care to be available easily, and if the regulations drive providers out of the business of giving these treatments or diagnostic tests of whatever, then that's bad for patients.

Now, I don't have any opinion on who's right and who's wrong on this particular issue, but it looks to me in my simple way of looking at things that you have two groups of very highly qualified people who are disagreeing over something. Maybe it's the methodology or I don't know what it is. But what harm would come from getting those groups together to see where are the differences, where are the points of disagreement, who could we resolve that? Seems to me that some benefit would come out of a process like that, informal or formal, however you would structure it. I would encourage you to do it.

MS. SCHWARZ: It seems to me also that actual collaboration with individuals in the community certainly would be a positive thing to pursue, because there is expertise in the agency as well as certainly in the community. And it wouldn't have to be that it would be a violation of the individual's trust either.

I mean this doesn't have to be announced in the newspaper, but it could be certainly calculations performed to assure both sides of this issue that the right approach is being taken and that the ranges are being looked at, not just the actual number.

DR. SHERBINI: Okay. I'll whiz through this second one in five minutes, hopefully, because we're running short of time. What I'll do is just present the problem just to make you aware of what's going on.

This has to do with monitoring of the hands of people working with radiopharmaceuticals. The problem is this: People usually monitor the dose to the hand using finger badges, which are worn like a ring on the base of the finger, and people are handing things with the tips of the fingers in many cases. Our regulation requires that the dose be monitored at the location that receives the highest dose. Now, the place where the dosimeter is located and the place where the dose is being received are not the same. And the question is should there be some kind of correction factor that is added to the dosimeter reading to get a dose that would be used to show compliance? And that is really the issue that we are struggling with.

To complicate this is the fact that the dose limit to the skin or the extremities has been changed recently. The previous dose was -- the previous limit was 50 rems to the most highly exposed one square centimeter of skin. The new limit is 50 rems to the most highly exposed ten square centimeters of skin. Now, that represents a relaxation of the dose limits, in some cases quite considerably, but it makes monitoring a bit more difficult or at least it makes deciding whether a correction factor is needed or not is more difficult.

So if you're doing -- there's a two-pronged approach going on right now. Industry is making some measurements of dose placement and dose received using multiple dosimetry and so forth to try and figure out what kind of correction factor would be appropriate in that case.

And the other effort is theoretical. We don't need -- the other effort we're working with Oak Ridge to try and do this by calculation. We are trying to calculate when somebody handles various types of geometries with various 3-D nuclides in these containers, what kind of dose would be received by fingering and what kind of dose would be received to show regulatory compliance?

And the end result we're hoping to get from this is to decide whether it is appropriate to use the fingering reading directly without any corrections or whether a correction factor is needed in order to show compliance with our dose limit. So that's where we are right now. We don't know the answer yet, but that's where we are.

MS. SCHWARZ: And you're collaborating that with Oak Ridge?

DR. SHERBINI: Yes. At least that's one part. Corrar is the industry arm that's doing the measurements of -- or supervising the measurements.

MR. LIETO: Sami, is the, I won't say the intent, but what you're thinking is that the correction factor would be a number greater than one and that would have to be applied to radiopharmaceutical handling?

DR. SHERBINI: Well, we're hoping that with the change in the dose limit to -- ten square centimeters is basically the area of the entire finger, and so we're hoping that with this change the appropriate correction factor might be so close to one that we don't need a correction factor. This would be the best outcome really to make things a lot simpler than having to use a correction factor. Especially,

if you have to use a correction factor, it will probably be different depending on the kinds of manipulations that you are doing, and so it kind of complicates things a little bit. So, yes, we're hoping that the correction factor would come out to be nearly one, but we don't know yet.

MS. SCHWARZ: And I have one other question. When do you anticipate this work would be completed?

DR. SHERBINI: It will probably take close to a year, I would think. It's a complex set of calculations, and so it will take some time.

DR. WILLIAMSON: Do you plan to publish this as a technical report or NUREG or something? That sounds like it would be a very interesting study to summarize in some detail, in writing for the benefit of the community.

DR. SHERBINI: We're hoping to publish this in the open literature once we get all the data, yes. Thank you.

CHAIRMAN CERQUEIRA: Thank you, Sami. While Angela's coming up, she's just informed that after lunch the Ron Zelac update on interpretation of 10 CFR 35.61 will be given first, and then the other things will follow after that. And now Angela is

going to be talking about radioiodine activity threshold for treatment of hyperthyroidism.

MS. WILLIAMSON: Good afternoon. I'll try to make this very quick. I probably never really needed the 45 minutes. It kind of depends on how many questions this issue raises, but we actually might be in good shape despite how things look right now.

I know that the ACMUI, that everyone sitting around the table this morning knows who I am, but for the benefit of the audience my name is Angela Williamson, and I work in NMSS, the Office of Nuclear Material Safety and Safeguards. And one of my primary functions is coordinator for this Advisory Committee, and I'm here today to bring an issue to the ACMUI to get their input on an issue that the regions have recently identified. And that issue, as the title states, is should there be an activity, a radioiodine activity threshold for the treatment of hyperthyroidism. So let's go on ahead and get started.

What brought this issue -- let me give you a little bit of background to put this all into context. Under the previous regulation, the previous medical regulation, 10 CFR 35, the regions were not listing an iodine activity limit on the licenses of

licensees for the treatment of hyperthyroidism, and the reason why they didn't is because it was assumed that no one would use more than 33 millicuries. Well, now we're operating under the new Part 35, which was effective as of October 2002 and there are limits that are in the new regulation. For less than or equal to 33 millicuries there are training and experience requirements, and for greater than 33 millicuries, under 35.394, there are training and experience requirements.

This has now brought up an issue within the regions because the regions are now renewing licenses for people who previously were authorized users under the new regulation but they're renewing the licenses -- they have to renew the licenses under the revised regulation now. And these very same licensees they're claiming that they have experience using greater than 33 millicuries, but we don't have any documentation because we didn't -- it was not being listed in previous licenses.

In addition, these same licensees are stating, "Not only should I be able to use greater than 33 millicuries, no documentation notwithstanding," they're also saying, "I should be able to use whatever activity I want to use." So for

I think a now obvious reason, this has become problematic in the regions. They want to accommodate the licensees but they don't quite know how to do it because they never had the initial proof in the first place that demonstrates that these people are indeed qualified.

So that brings us to the question that needs to be answered: For these particular groups of licensees, should NRC, regardless of what they claim, should we restrict their activity or restrict the activity that they are using for the treatment of hyperthyroidism or is this a practice of medicine issue and we shouldn't Get involved with restricting the activity? That's the first question. And the second question is if the activity should be restricted, then what's the upper limit?

Now, let me throw in one more qualifier as we're debating these questions. The reason why the licensees believe that they should be able to use however much activity that they feel is necessary is because they're saying for certain cases of patients they have to superdose them because of the low uptake within the thyroid. The uptake is somewhere between five and seven percent, so they have to compensate for that, and that's the general reason that they're

giving people -- the general reason why they feel they should be able to give them whatever they feel is necessary to give them. So that's the question.

CHAIRMAN CERQUEIRA: Dick?

DR. VETTER: Yes. It appears to me that within the regulation hyperthyroidism is not even mentioned and it shouldn't be, because we're not trying to tell doctors what they would prescribe the iodine for. We simply more or less, arbitrarily, based on experience, drew a line at 33 millicuries saying below this number you need a certain amount of training, above it you need additional training. And it's not referring to any medical condition at all. We're not telling a doctor he can't give 50 millicuries for hyperthyroidism, but if he wants to give 50, he's got to have more experience in handling radioactivity.

DR. WILLIAMSON: To follow, my point was the same thing. I don't see where hyperthyroidism or thyroid cancer are mentioned as the two clinical indications in this regulation. Very quickly reading 35.392 and 394, the only difference in the training and experience is that they have to show three cases of experience greater than 33 millicuries in one and three cases less than 33 millicuries in the other. So

what is wrong with applying that criterion and asking them to basically fill out a Form 313A that documents experience with three cases less than, three cases more than and license them for both?

CHAIRMAN CERQUEIRA: Ralph?

MR. LIETO: Angela, were these individuals licensed under the old Part 300?

MS. WILLIAMSON: Yes.

MR. LIETO: Well, then I would think that they would be grandfathered in.

MS. WILLIAMSON: Yes.

MR. LIETO: Okay? And so it wouldn't be an issue from that standpoint. If it's an issue of possession limit in terms of how much they could have, again, I think it would be a matter of what they felt was appropriate for their practice of medicine. The issue of being above 33 millicuries would be if the patient follow directions or comply with the restrictions for release into the general public, then they have to be hospitalized and if they're hospitalized, then you've got all those things. And that's where that 33 millicuries came in. But I think the question about whether having the authority would again I think under this renewal process would be a matter of if they were authorized for 300.

Now, the question that's come up actually is the reverse in that under 200, old 200 physicians were allowed to administer millicurie amounts of I-131 for diagnostic studies, whole body retention studies and so forth. The problem has occurred that under the new Part 35 that with the Section 392, okay, there's this gap or gray zone where they're not allowed to use the I-131 because it requires a written directive and they have no necessarily documented training that they did this. And I have questions about relating to Dick's question about preceptor. Well, how do we document this as we move into the new Part 35 for renewal? We're documenting for these physicians to allow them to continue to do the diagnostic studies with I-131, which required maybe more than 30 microcuries.

MS. WILLIAMSON: The grandfathering -- we know that these people are qualified. They were qualified under the old regulation to be AU so we know that they continue to retain that qualification, but the issue with grandfathering -- the issue with it is that they are -- we have no documentation that they have actually -- no proof that they have actually handled what they said they handled. And so we're trying to get a grasp on how we can ascertain whether

or not they really have this experience.

MR. LIETO: Well, if they were authorized, say Dr. X --

MS. WILLIAMSON: Right.

MR. LIETO: -- was approved for 35.300. Well, the training and experience had to have been there for him to get authorized under the license. So you --

MS. WILLIAMSON: True, but we assume that he was using no more than 33 millicuries, and now they're coming in --

MR. LIETO: No. No. Three hundred was any radiopharmaceutical therapy, period.

CHAIRMAN CERQUEIRA: Yes. Dick and then David.

DR. VETTER: If it's a matter of documentation, then these physicians simply need to fill out a new 313A and whoever they were working with or under sign it as the preceptor, and now they have the documentation.

CHAIRMAN CERQUEIRA: David?

DR. DIAMOND: Yes. I think that issue can be easily resolved as well. I would like just to point out that these requirements are not to my thinking in any fashion, and in fact this is exactly

the language that the endocrinologists wanted a couple years ago. I see absolutely no reason to modify this language. I don't feel there's any burden whatsoever, and I think that the grandfathering issue is easily overcomable to me. So I don't think any additional action needs to be taken on these regs.

MS. WILLIAMSON: So I think what I'm hearing is that -- for any licensee that fits into this category ask them to fill out a new 313A, get a preceptor's statement that the person is experienced handling greater than 33 millicuries, and don't be worried about restricting activity, don't worry about an upper threshold for these folks.

DR. WILLIAMSON: I think that's right, just qualify them as 94 or 92, as appropriate, for what they've asked and plan to do.

CHAIRMAN CERQUEIRA: Leon?

DR. MALMUD: There is an underlying question. Currently, radiologists are not required to have more than three months of nuclear medicine experience in the course of their residency. I think it had been six months and in the course of either three or six months they may not have had the opportunity to provide to provide radioiodine therapy in a dose greater than 30 millicuries. It may be that

during that period of time no patient was treated with over that dose of radioiodine. The question, therefore, is not having had that experience is that of concern to us for a board certified radiologist who does have the experience and who has had the experience in providing doses of less than 33 millicuries. Is that of concern to anyone here?

DR. VETTER: If I understand this correctly, the current regulations someone ABR-certified in diagnostic radiology is not automatically qualified to administer radioiodine. They must see these -- they must have additional training and additional patients even if they are board certified, because ABR in diagnostic radiology does not include this qualification.

DR. MALMUD: So that currently, from your understanding of the regs, and I'm not on top of the regs currently on this issue, a radiologist is not authorized to give I-131 therapy unless he or she has had experience, documented case -- on a case-by-case basis?

DR. VETTER: I'll clarify. A radiologist certified by ABR and diagnostic radiology is not qualified. If that person is certified by the American Board of Nuclear Medicine, then they are

qualified.

DR. MALMUD: I wasn't referring to the nuclear physician. I was referring to the radiologist. Many hospitals don't have nuclear physicians.

DR. VETTER: Well, a radiologist could be certified by American Board of Nuclear Medicine.

DR. MALMUD: Many hospitals do not have radiologists that are certified by the American Board of Nuclear Medicine. So that the question is, and I don't know the answer, but the question is a board certified radiologist who has had a rotation or rotations in nuclear medicine as part of his or her residency currently qualified to provide I-131 therapy?

DR. WILLIAMSON: Well, I think it's a complicated question. If you look at the current training and experience regulation, I believe that the ABR diagnostic radiology qualification does not conform to the requirements as currently stated for a recognized credential. So anybody in radiology through the regulations in the main part of the document would have to qualify under the alternative pathway. If you look in Subpart J, 35.92 and 94, it doesn't actually mention any residency.

MR. LIETO: Well, Dr. Malmud, to answer your question, if a physician is ABR certified in radiology, can he be authorized to administer radiopharmaceutical therapy, and the answer is, yes, providing he applies and is approved before October of 2004.

MS. McBURNEY: Right.

DR. VETTER: Excuse me?

MS. McBURNEY: Because they can use Subpart J.

DR. VETTER: You need be careful about radiology versus diagnostic radiology. Radiology is an old board that included training in therapy, but ABR and diagnostic radiology does not include that.

DR. MALMUD: I'll rephrase my question. A radiologist finishing his or her training in the year 2003 does not require much by way of nuclear medicine training in the course of the radiology residency. Currently, those individuals can be in practice or enter practice and provide I-131 therapy. Is the question on the table --

DR. DIAMOND: No. The answer is no.

DR. MALMUD: The answer to what question is no?

DR. DIAMOND: The answer is there's a

diagnostic radiologist coming out of training today who by virtue of his training -- his or her training experience has not, for whatever reason, satisfied these additional requirements. Is that individual able to go and give I-131? I believe from my understanding of the regulations the answer is no.

DR. MALMUD: Including less than 33 millicuries.

DR. VETTER: That's correct.

DR. DIAMOND: That's correct.

DR. MALMUD: Okay. So you've answered the question for me.

DR. DIAMOND: May I ask you why you were asking the question in the first place?

DR. MALMUD: Because I don't see the great significance and difference between giving 33 millicuries and giving 50 millicuries for precisely the reason that Angela raised, and that is that are some patients who may be coming back for a second treatment of I-131 whose uptake is low because the first dose reduced the uptake and yet they have still have a larger goiter, are still hyperthyroid and require a dose greater than 33 millicuries.

DR. DIAMOND: And that's precisely why two years ago, I guess, we substantially relaxed the

requirements for 35.394 at the request of the Society of Endocrinology because they made exactly that point.

DR. MALMUD: And how does that affect the answer to your question, Angela? Does that satisfy in any way the answer to -- does that satisfy you? Or the issue. It's not you we're trying to satisfy, it's the issue you're trying to help us satisfy.

MS. WILLIAMSON: Well, I think I have the answer I need for now to go forward to answer the region's questions. The question was pretty straightforward, but I guess ultimately it depends on what kind of feedback we get back from the regions.

CHAIRMAN CERQUEIRA: Then I guess if it's a question of licensing, clearly, if they had a license previously, they should be grandfathered in. And the feeling of the Committee is that 33, greater than or less than, should still be considered in the same category and not require any additional training or restrictions.

MS. WILLIAMSON: Right. It's just that newer people they have to be able to meet one or the other, so we didn't really want people sort or sliding in and giving them authority to handle a level of activity that we can't even prove that they've ever really handled.

DR. MALMUD: It is a matter of certainty that if a resident currently in training is required to take as little nuclear medicine as he or she is to satisfy the current American Board of Radiology, Diagnostic Radiology, then that individual will most likely not have had any experience in providing doses equal to or greater than 33 millicuries. Then the question arises does it matter? In other words, does it matter -- are you concerned about someone providing the dose of 50 or 60 millicuries?

DR. VETTER: Yes, it does matter. Less than 33 -- the regulations clearly spell out that relative to 35.75, and you can go to the reg guide to do all the calculations or whatever, less than 33 the patient can be treated as an out-patient. Above 33 you need to determine whether they can be treated as an out-patient or whether they have to be kept in the hospital for radiation protection purposes. So you're really in a new ball game above 33.

DR. MALMUD: Thank you. You clarified that for me, and I am reassured by your answer.

DR. NAG: The other -- usually more than 33 for thyroid cancer and not for hyperthyroidism. That's another reason why I think there was a differentiation. The major reason whether it's in-

patient or out-patient.

CHAIRMAN CERQUEIRA: Okay. Leon?

DR. MALMUD: But the issue that Angela raised was specifically for hyperthyroidism, not for cancer, and the issue is correctly raised. There are patients who are being treated for hyperthyroidism who need more than 33 millicuries, and it's not the usual but it's not uncommon either, and it's a reasonable question to have raised.

DR. SULEIMAN: I think the answer to your question is it is a practice of medicine issue. I mean regardless of what -- but I think the second part is it's a radiation safety issue. At what point do you release them outside? So I think you've got to keep those two issues segregated.

CHAIRMAN CERQUEIRA: Dick?

DR. VETTER: Just to underscore what Dr. Suleiman just said, but I would reverse those. The primary issue is a radiation safety issue, and we are not in the business of determining, of telling doctors whether they are administering the iodine for hyperthyroidism or cancer or how much to give for either of those. So it's just a radiation safety issue above and below 33 millicuries.

DR. WILLIAMSON: Yes. And the question is

do they want to be licensed for 920, 940 or both? And you have an established pathway for forms and so on that have to be filled out to establish the credentials for each.

CHAIRMAN CERQUEIRA: Okay. Does that --

MS. WILLIAMSON: I'm going to go forward with a recommendation for when the regions get this type of -- when they encounter this type of situation to request the training and experience on Form 313A and to get a preceptor's attestation that the person is capable of handling greater than 33 millicuries. And I'll also underscore the fact that we should not be concerned about an upper threshold limit of what they should be -- what is appropriate for prescribing.

CHAIRMAN CERQUEIRA: And I guess in terms of the preceptor, as we discussed yesterday, it doesn't have to be the person who originally did the training, because some of these people might be difficult to do, but somebody who is currently in the state of -- you know, in practice and understands what they're capable or not capable of doing. Leon?

DR. MALMUD: What about the situation in which the radiologist did not have experience with doses over 30 millicuries, is practicing in an area where he or she is the only person available to treat

the person with hyperthyroidism and there's a physicist in the department who can deal with the issue of the radiation exposure and wants to treat the patient with 40 millicuries. Should not that person be able to treat, given the current advice and counsel of a competent physicist? Dr. Vetter?

CHAIRMAN CERQUEIRA: Dr. Vetter says no.

DR. VETTER: Well, no simply because the regulations don't allow it. Now, if we think that that person -- that the threshold for 33 millicuries should be changed, then we'd have to make a case for that. But it really has nothing -- the regulations have nothing to do, and shouldn't have anything to do, with whether this is -- we're treating hyperthyroidism or cancer. It has to do with the radiation safety of the amount being given. And this doctor has no experience dealing with patients who have received 40 millicuries, above the 33, then based on our experience and the wisdom behind the regulations, that person should not be allowed to prescribe more than 33.

CHAIRMAN CERQUEIRA: Ralph?

MS. McBURNEY: You can go ahead, Ralph, first.

MR. LIETO: I may burn for this for

disagreeing with Dick, but I would say that if the radiologist had experience in the administration in hyperthyroids, the issue mainly becomes can by their assessment the patient follow the directions for release? And if it's basically -- the only reason is the hyperthyroidism, they're coherent, family member situations, all those factors come into play that this can be administered as an out-patient. I think in consultation and with the appropriate documentation that it would be appropriate for them to administer that 40 millicuries in that situation.

DR. VETTER: That would be in violation of the regulations.

MR. LIETO: Why would it be a violation?

DR. WILLIAMSON: Because the regulation says that they're authorized only for less than 33 millicuries and if they're not authorized --

DR. VETTER: It doesn't have to do with hyperthyroidism.

DR. WILLIAMSON: Yes.

CHAIRMAN CERQUEIRA: Comment from the back and then Ruth and then we'll come back here.

MS. FAIROBENT: Lynne Fairobent, American College of Radiology. From sitting and listening to this discussion, I think you're confusing two

different points. One of the issues, and I think the primary issue Angela was trying to deal with, is how do we deal with those individuals who are currently on a license where we did not have the separation of less than and equal to 33 and greater than 33? I think that we have a problem if we now require and to backfit the grandfathering provision -- sorry, my reactor background comes out with backfit analysis -- but under the grandfathering provision, I don't see how we can now add under that for this situation a requirement for the preceptor statement. If an individual is currently on a license to do iodine therapies and we did not in the past under the old regulations specify any limit for the amount of activity delivered in that, I think those individuals need to be or considered to be grandfathered under both 392 and 394. For anybody in the future who will be a new user under the new regulation, the regulations, I agree, are clear. The three case studies are different, the preceptor requirements are different, and I think that has to be looked at as we go forward.

Dr. Malmud, I will get an answer to your question over lunch about the Diagnostic Radiology Board, because in any case if they have a diagnostic

radiology certification, if they're certified by ABR in that, in order to do the iodines they still have to have three case studies that are done under the supervision of an authorized user. And so I believe that if they've already -- going forward in 2003 they may not have gotten it in their residency, but if they then practice at an institution and they do the three case studies under the supervision, that should be sufficient, at least the way I read the regulations from 92 and 94.

The issue during the promulgation of the draft rule was the difference between the endocrinologists who only have the 80 hours of radiation safety training versus diagnostic radiology residents who have a three-month or a four-month residency in which their radiation safety training is greater than the 80 hours. And I think that's why we had the differentiation in the ultimate final rule for both 392 and 394 and not just the caveat of everything being in 390.

CHAIRMAN CERQUEIRA: Ruth, did you want to --

MS. McBURNEY: I was just going to agree with Dick Vetter's assessment that the way the rules are written it's based on the limits and radiation

safety concerns dealing with those limits rather than what the material is going to be used for.

MS. WILLIAMSON: So the issue of the preceptor that Lynne brought up, do you still agree that it's appropriate for us to go back and ask for a preceptor statement?

CHAIRMAN CERQUEIRA: Dick?

DR. VETTER: I think Lynne brings up a good point, and, actually, I think it really clouds the issue, because in the new Part 35 it's strictly radiation safety -- it's strictly based on safety. And in Subpart J, it differentiates between hyperthyroidism and cancer and does not refer to activity.

MS. McBURNEY: Right.

DR. VETTER: So someone who has been -- perhaps someone has been treating patients with hyperthyroidism but if it's always been below 33 millicuries, now when Subpart J expires, will you be able to treat someone with more than 33 millicuries? think maybe counsel needs to look at that.

CHAIRMAN CERQUEIRA: Jeffrey?

DR. WILLIAMSON: Well, would it be acceptable to request from these individuals who want under the grandfathering provision to have both 394

and 392 to provide a filled out 313A form to document that they have been doing this under their old license minus the preceptor statement since they may indeed by a solo authorized user with no other authorized user that could sign on their behalf? It would seem to me reasonable evidence or you could ask even a radiation safety officer to sign as a witness to these records.

MS. WILLIAMSON: What's the difference between a witness and a preceptor.

DR. WILLIAMSON: Well, the preceptor is legally defined as somebody who has to be an authorized user for that category on an agreement state or NRC license --

MS. WILLIAMSON: But I mean in the mind of the licensee what would be the difference.

DR. WILLIAMSON: You could ask for a reasonable level of evidence that that's been their proactive pattern that they could comply with but falls short of -- it may be very difficult to satisfy legal requirement that this person have the status of being an authorized user. It seems that's the issue, but it seems a very reasonable request to document that you have this experience in your past practice pattern under the old whatever the number was, I can't remember it, the single indication use for

hyperthyroidism. That seems a reasonable request for a regulatory body as long as you don't make the standard for who can validate that impossible for these individual to meet, which I think may be underlying Lynne's point.

CHAIRMAN CERQUEIRA: Leon?

DR. MALMUD: In a practical sense, the issue is radiation safety, and I believe that as the rules are currently written, and as Angela points out, there seems to be a disconnect. If the patient has thyroid cancer, I may treat the patient for thyroid cancer with 100 millicuries. If the patient has hyperthyroidism, I may not treat the patient with 40 millicuries. Both of whom are on an out-patient basis, by the way -- unless I've proven that I had experience in treating patients with over 33 millicuries. There's a certain lack of logic to this because the issue is radiation safety, and my radiation safety standards for the population surrounding that patient are the same, whether the patient had thyroid cancer or hyperthyroidism.

DR. WILLIAMSON: Not necessarily.

DR. MALMUD: Really?

DR. WILLIAMSON: Yes. Because at 33 millicuries or less, basically the issue of whether

you can release the patient is answered with 100 percent uncertainty. And if it's over 33 millicuries, you have to go through this sort of more complex procedure of determining whether the patient is going to meet the half rem limit to members of the general public, and I think that is a safety issue. But I think that's probably the basis for why they distinguish between the two categories.

DR. MALMUD: Being back in practice, I inform every patient -- I may be exceeding the requirements, but every patient that I treat as an out-patient with radioiodine for hyperthyroidism gets the same forms from me indicating are they going to be exposed to any pregnant women, any infants? Are they are any young children living in the home? If they're going to work, will they be close to any pregnant women or any infants? And if so, I recommend they take two or three days off since my belief is the best exposure for someone who doesn't need radiation is zero, and that's regardless of whether I'm treating them with ten millicuries or with 30 or 50 millicuries. Now that may be a peculiarity of my practice rather than requirements, but whether the patient's getting five millicuries or 100 millicuries, I want to know who they're going to be exposed to.

CHAIRMAN CERQUEIRA: Right. We're going to have to wrap this up soon. We've got two comments.

DR. ZELAC: Ronald Zelac, NRC. I simply wanted to point out that the basis for the release is not any more on activity. It's based on meeting the dosage limits to those who are in the now to be exposed population. So it's not automatic that 33 means that you are okay. It means you still have to consider where that patient is going and where they're going to reside. So you could say the release criteria even applies to those patients that are receiving diagnostic amounts of materia. You know basically with certainty in almost all circumstances that you will satisfy the criteria for those people to be released, but certainly for a 33 millicurie, 35 millicurie iodine case, you can't with certainty, you still have to consider where they're going and what they're doing.

CHAIRMAN CERQUEIRA: Okay. Lynne, did you want to make a --

MS. FAIROBENT: Yes. Angela, to your question of the difference between what Jeff was proposing from a preceptor to somebody else, right now by definition of the preceptor and all the coupling to the various subsections under T&E that we're looking

at, for example it would have to be a preceptor authorized user in order to sign that. I think what Jeff was trying to get to is part of the discussion we had yesterday on whether or not a preceptor can be in a broader sense. So, for example, if it is small practice hospital where you have say a diagnostic radiologist who is the only one in town doing this, there may not be a preceptor or authorized user available to sign for him, but there -- and there may or may not be a separate RSO, but chances are there would be a consulting physicist in fact the physician was serving as the RSO.

I'll throw out that Bill Uffelman and I will go back and look in the nuclear medicine community with this question, and we'll provide something back to staff and the ACMUI as to what we think the extent of the problem is.

CHAIRMAN CERQUEIRA: David?

DR. DIAMOND: I've enjoyed the discussion. I don't see any problem. What are we talking about? What's the problem?

DR. MALMUD: The problem, as I understand it, and I may have a misunderstanding but I don't think that I do, as I understand it, currently a radiologist -- a licensee who has not proven

experience with a greater than 33 millicuries of I-131 for hyperthyroidism is not approved to treat a patient with 40 millicuries of I-131 on an out-patient basis; is that correct?

MR. LIETO: No. That's not my understanding.

DR. MALMUD: Oh. What's your understanding.

MR. LIETO: What we have is our physicians who have been approved under 300, which is approval for radiopharmaceutical therapies -- all. They are now renewing their license. There's no -- they are now applying for either 392 and/or 394. And the answer is does that previous training and experience and approval process authorize them to be approved under those two categories? And --

MS. WILLIAMSON: Well, particularly the higher one.

MR. LIETO: And my answer --

MS. WILLIAMSON: Because we don't have any proof.

MR. LIETO: My answer would be, yes, and that -- CHAIRMAN CERQUEIRA:

DR. MALMUD: Yes.

DR. WILLIAMSON: Yes.

DR. DIAMOND: There's the answer; we're done. I don't think there is a big problem.

MS. WILLIAMSON: Okay.

MR. LIETO: The thing is is that -- the other question that she had was should there be some documentation, and my answer is no, because the assumption that they have been ongoing --

DR. DIAMOND: A de facto assumption.

MS. WILLIAMSON: Okay.

MR. LIETO: Otherwise every license renewal is going to require that approved physicians are going to have to submit preceptors, and it's not going to just be for radiopharmaceutical therapy, it's going to be for radiation oncologists who want to get approved for HDR, I mean because of the different categories. So that would be my recommendation.

MS. WILLIAMSON: So am I hearing now that we don't need the 313A? They just come in, they say, "Look, I was approved previously."

CHAIRMAN CERQUEIRA: "You had approved me before."

MS. WILLIAMSON: "I want to use whatever activity I feel is necessary," and we just say, "Okay." Is that what I'm hearing?

MS. SCHWARZ: I have a question. In terms

of grandfathering, does that expire when Subpart J expires?

DR. VETTER: No.

MS. SCHWARZ: So then it will continue to be grandfathered. So it seems to me that it should be acceptable.

DR. WILLIAMSON: I guess I would say I generally agree with this. I think the grandfathering has -- there's no talk of having to have preceptors and so on to demonstrate that you've actually been doing this. And while it might be reasonable to ask for some kind of evidence that you indeed had this practice pattern, I think that the standard should be much lower than for somebody that's trying to establish -- let me finish -- that's trying to establish qualifications for a practice de novo as a new practitioner. There the law is clear, you have to have a preceptor statement. But for this the standard should be greatly relaxed.

MS. WILLIAMSON: Well, I'm not sure I have a grasp on what the Committee is recommending.

CHAIRMAN CERQUEIRA: I think the Committee -- well, the defray was -- you want to make a motion?

MR. LIETO: Yes, make a motion. That will force the issue.

CHAIRMAN CERQUEIRA: I hope I make it right. My motion is that physicians currently authorized under 35.300 --

MS. McBURNEY: Which is?

CHAIRMAN CERQUEIRA: Radiopharmaceutical therapy -- are authorized for 35.392 and 35.394.

DR. WILLIAMSON: But that's not the issue. The issue is practitioners who were qualified to practice hyperthyroid therapy, single indication therapy --

MS. McBURNEY: Like endocrinologists.

DR. WILLIAMSON: -- can they be authorized automatically?

MR. LIETO: Excuse me. Thirty-five.three hundred addresses if you're approved under that, you're approved for all the radiopharmaceutical therapies that are FDA approved.

DR. WILLIAMSON: That's right, but that's not the issue we're discussing.

MS. FAIROBENT: Just for clarification, Ralph, I think that what the party of people that we're trying to assist are those physicians who are only approved under what is now 932, Subpart J 932, which was hyperthyroidism, are those who are currently on a license under 934 for therapy -- thyroid therapy.

And because those were written as disease-specific, if I may use that term, in the new Part 392 and 394 is not written disease-specific but activity-limited. Someone under 932 currently had no upper bound or lower bound limit on how much iodine he or she could administer for hyperthyroidism. So should they be grandfathered now and able to practice under both 392 and 394? And if not, then what other additional documentation therefore you have no grandfathering of these folks because we changed the structure of the regulation for these individuals. And if routine doses of hyperthyroidism today can go 30, 40 or even higher, as Dr. Malmud was stating, they probably don't have much documentation to show what they had been routinely delivered. And under the new regulation now we have the split for the added requirements. It's that body of authorized users.

MR. LIETO: I guess I'm thoroughly confused because I guess the basic premise under which this is coming in is changing. Let me re-ask the question again. Were they approved under 35.300, period?

MS. WILLIAMSON: No.

MR. LIETO: Or was it 35.300 with license condition disease-specific?

MS. WILLIAMSON: Yes. Yes.

MR. LIETO: Okay.

CHAIRMAN CERQUEIRA: Some are saying no and some --

MR. LIETO: Angela, please.

MS. WILLIAMSON: The license is written as disease-specific. Training and experience is 35.300 with limitation of what they can do.

CHAIRMAN CERQUEIRA: So that's why the thyroid comes into the -- Dr. Howe?

DR. HOWE: I think Trish answered it. And the problem is that the licenses for the endocrinologists were written very specifically. It was for hyperthyroidism only, and there is not a one-to-one correlation between the old 932 and the new 392 and the old 934 and the new 394, and so we cannot make a direct assumption that someone that was authorized under 392 now can get both. We have the same problem with diagnostic nuclear medicine because diagnostic nuclear medicine in the old Part 35 included the diagnostic treatment for people that had cancer, had already had their thyroid removed. And so we're having to write specific license conditions in order to grandfather these people that already had experience with that, because the new regulation is

not one to one with the old regulation.

CHAIRMAN CERQUEIRA: David and then --

DR. DIAMOND: Given that the whole rationale for making these regulatory changes was to accommodate the wishes of the endocrinology community to make sure they had maximum flexibility in the administration of I-131, in this spirit I would like to make a motion: Individuals authorized to use -- authorization to use I-131 under the extant regulations, those individuals also be considered to be authorized to delivery I-131 under the new 35.392 and 35.394 without a specific requirement for a preceptor statement nor for requirement to have a documentation of cases, period. That's what the endocrinologists wanted; that's what we gave them.

CHAIRMAN CERQUEIRA: Do we have a second on that?

DR. MALMUD: Second.

CHAIRMAN CERQUEIRA: Okay. Now, we've had a lot of discussion. Do we need any more discussion or should we just take a vote?

DR. WILLIAMSON: I would speak against the motion because the current Part 35 the reason -- I agree we wanted to take into account the needs of the endocrinology community, but the current Part 35 is

constructed around radiation safety, not disease. And, therefore, I think this particular solution -- the solution to this particular problem is simply to ask them to provide documentation that they have in fact treated patients above 33. That would eliminate them the problem of all endocrinologists perhaps who had only prescribed ten millicuries in the past from being able to suddenly administer 100 millicuries.

DR. DIAMOND: I have no problem with the basic premise of your point. I would like to remind the Committee that if you are a physician who would like to go and use these higher activities, that you also -- that every credentialing committee that I think of will ask you to document a number of cases so that you can go and provide that service at a hospital. So from my personal viewpoint where I still feel that credentialing committees do have some value, I think that your concern would be addressed. If the Committee, however, feels that it is useful or important to have these endocrinologists go back and just write down the name of three patients they've done, that will not be a major problem to me.

DR. WILLIAMSON: I would support it with that addition.

CHAIRMAN CERQUEIRA: So how do you want to

modify your motion so we can move forward?

DR. DIAMOND: Any other strong feelings on either side regarding the documentation of the three cases under, what is it, 313?

MS. McBURNEY: I think that since we've switched to a more radiation safety based rule, that allowing them to do that would open the door for them to go ahead and treat for carcinoma and so forth, because it's not specified in the rule what they're going to use that material for.

DR. DIAMOND: But you're missing my point that if you wanted to treat for thyroid cancer at my institution, at Manny's and Subir's, you need to also be credentialed to do that. And if you've never done that before, I would assume your credentialing committee would not approve you to do that.

MS. McBURNEY: Unless you're wanting to do it in a freestanding --

CHAIRMAN CERQUEIRA: In a facility, in an office.

MS. McBURNEY: And we have had those situations where someone --

DR. DIAMOND: You need to have it approved in an office?

MS. McBURNEY: We have had requests for

that. I mean we denied it, but --

CHAIRMAN CERQUEIRA: What do you think about the amendment for the endocrinologists to require the three cases?

DR. MALMUD: I would agree with it.

CHAIRMAN CERQUEIRA: All right.

DR. DIAMOND: Then I would like to amend my motion that those individuals who are applying, those individuals who were authorized solely to use I-131 for hyperthyroidism under the new 35.392 and the new 35.394 that those individuals do not require a preceptor statement but they must submit at least three cases documenting that they have used greater than 33 millicurie of I-131 in the past.

CHAIRMAN CERQUEIRA: Okay. Do we have a second on the --

DR. MALMUD: Second.

DR. WILLIAMSON: Second.

CHAIRMAN CERQUEIRA: Could we call the question? Okay.

All those in favor? Opposed?

(Committee votes.)

CHAIRMAN CERQUEIRA: Okay. So the motion is carried, and I think that deals with it. If we're going to have lunch, we should break now. And then we

should come back at 1:15 at which point Dr. Malmud will be running the meeting, so thank you.

(Whereupon, the foregoing matter went off the record at 12:36 p.m. and went back on the record at 1:19 p.m.)

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

1:19 p.m.

DR. MALMUD: Do you have slides?

DR. ZELAC: No. Good afternoon. I've gotten the call. Apparently we are resuming to try to stay on schedule. I'm speaking briefly, presumably briefly, simply to close a loop. At the last meeting of the Advisory Committee in May, I gave a presentation called, "Interpretation of 10 CFR 35.61(b): Conditions for Use of Survey Instruments." That particular section of the rule reads as follows: "A licensee may not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is more than 20 percent."

There was good advice given from the Advisory Committee at the last meeting as to where those particular words applied. Did they apply strictly and only to the calibration procedure or did they actually apply to the usage of the instrument in the field? We, I have to say, from an appropriate, perhaps, healths physics, point of view, we're looking at it based on usage of the instrument in the field. However, on reconsideration, looking at the rule, it appeared that in fact the appropriate interpretation was that these words applied to the calibration

procedure alone, and on that basis if the licensee calibrated an instrument using, as is typically done, a high energy source and the response to the instrument was within the plus or minus 20 percent range, then that instrument was good to go for field use.

It would be expected that if an individual licensee was going to be using an instrument in a low energy field, that they might choose to calibrate the instrument as well using a low energy source, such as the brachytherapy sources that they received for clinical use. However, this is not part of the requirement, although the ANSI standard, which is the basis for survey instrument calibrations, speaks to using a low energy source if you are going to be measuring low energy fields. That is not part of the regulatory requirement.

So on that basis, the practice, the common practice of calibrating with high energy sources and using energy correction factors when appropriate and necessary is acceptable, reasonable and will be the position that the agency takes with respect to enforcement.

Ralph Lieto had been charged, I believe, or volunteered, perhaps, at the last meeting to be the

official conduit of opinion, although we had discussion at the meeting there needed to be an official transmission, if you will, of the combined views or the considered views of the Committee. He sent me a letter last July and response was provided to him in October. We, of course, had to be sure that what we said was acceptable to our legal counsel, and it was. And it basically says the following, "That the correct interpretation of the requirement of 35.61(b) is that this section applies to the outcome of the calibration process, not to the use of survey instruments after acceptable calibration." And, two, "The use of energy correction charts or graphs after acceptable calibration is permissible." And I would hope, unless there are other points of view, that that should conclude this issue.

DR. MALMUD: Are there any questions of Dr. Zelac? Shall I assume that the silence is agreement with both Dr. Zelac's statement and Dr. Lieto's comment?

DR. ZELAC: The last thing I will mention is that there is currently a Q&A on the Part 35 web site dealing with survey instrument calibration. The information there is not incorrect; however, based on this interpretation of the rule, we are revising the

wording of that Q&A. It is now in the review process now and will be put up on the web as a revision as soon as it's completed that process and whatever adjustments are required.

DR. MALMUD: Thank you, Dr. Zelac --

DR. ZELAC: Thank you.

DR. MALMUD: -- and thank you for bringing us back to our agenda and the next item, which is to begin at 1:30. May we begin the 1:30 item early or is that in violation of the rules? Didn't you switch, Dr. Zelac with someone else or is Dr. Essig next?

MS. WILLIAMSON: Tom Essig is next.

DR. ZELAC: I simply moved up in the schedule.

DR. MALMUD: Oh, okay.

MS. McBURNEY: Right. So it's Tom.

MR. ESSIG: I'll be short too.

DR. MALMUD: Thank you.

MR. ESSIG: There should be a one-page addition to your notebooks under the tab, "Access to -- ACMUI Access to NMED." Oh, it hasn't been added then. Angela, is that handout --

MS. WILLIAMSON: Oh, I guess I forgot to pass it by --

MR. ESSIG: Oh. The public has it but you

don't have it. Sorry about that.

MS. McBURNEY: The last to know.

MS. WILLIAMSON: I put it out but I forgot to give it to the Committee.

MR. ESSIG: Okay. The issue was because of the fact that we're asking the Committee to be more involved in evaluation of medical events, it's incumbent on us to then provide the Committee members with the appropriate data. We looked at two options to do this. One is to provide the Committee on some periodic basis, maybe quarterly or so, a download of medical events from NMED on the CD, this would be sent out by our contractor to each of you, and then the user, each of you, would sort the data via the Access software.

We felt the advantage to that would be that it would be -- you would be sent only the data that had been reviewed by the staff and determined to meet the criteria for medical events, and so in that way it would be a focused data set, and the extraneous information would be excluded. The downside of that, of course, is that the data may not be totally current. It's a function of when the latest batch was processed, the quarterly batch, and the search engine to sort the data was not available. That is, you'd

have to rely on an Access database to sort the data or process the data.

The other option that we looked at was to provide what amounts to real-time access to NMED database for each member. And the advantages of that, of course, more flexible unfettered access to the data by all members. The NMED has a search engine that can sort the data. The downside is that for some of you that may be somewhat daunting because it includes all events. I mean medical events are only a subset of the database. And it also includes those events which have not been reviewed by the staff, some of which fall by the wayside because they don't meet the -- they later prove to be non-reportable. And considering those two options, we feel it's -- that our proposed approach is going to be to select Option 2, that is to provide each of you access to NMED.

We can do this as early as next week. We have all of your email addresses, and so it's just a question of our notifying our contract at the Idaho National Environmental Engineering Lab to add you to the -- provide you that access. Your access will be limited to your term on the Committee, and that of course it's to be accessed and used only really in the performance of your duties on the Committee, and we of

course are available to provide initial orientation and handle any technical questions that you may have in going into the database. That's pretty much my spiel.

I have our NMED Project Manager, Michele Burgess, available in the audience here to help field any questions that you might have. But I thought given the two options that we have of providing you either direct access to it or providing you with digests of the data through a CD, we felt that access to the NMED database, which has records dating back to about 1990 or so, that's when it was first constituted. Of course it's read-only access. That's all anybody has.

DR. MALMUD: Thank you. Jeff?

DR. WILLIAMSON: I think that's a great idea. With regard to Option 1, I found the Access database not just daunting but totally impenetrable without some fairly thorough orientation to how you had created the data structure. So I suspect with an automated search engine it will be easier on everybody.

MR. ESSIG: Okay.

MR. ESSIG: Subir?

DR. NAG: With the second method, will

there be an easy method just to pull up the medical event or do we have to go through a lot of hoops to get to the medical events?

MR. ESSIG: I would ask Michele if you could come to a microphone and if you could help with that. This is Michele Burgess who's the Project Manager for NMED. And just address the question about the ease of searching through. And Michele herself is fairly new to this. We had Sam Pettijohn who had been the Project Manager forever retired last May or June -- was it August? Okay. And Michele has been taking his place since that time.

MS. BURGESS: Well, to answer the question about using the web site, it's very easy to use. The front end let's you choose what criteria you want to sort the data by, and it can pull up all the medical events. There's a lot of push buttons you can use, icons you can choose from. It leads you through pretty well. You can always call either me or INEEL directly if you're looking for a certain piece and you're not sure how to get that piece out of what you see on the screen. We're also upgrading the web site and we hope next spring a new one will be coming out that will have even a more user-friendly interface with more choices.

DR. MALMUD: And how may you be reached if there are calls for you?

MS. BURGESS: You can reach me -- here at the NRC it's 301-415-5868. Also, on the front page of the NMED web site, it gives contact information for both me and for the contractor. If that's what the decision is and we're going to give you access, then someone will be contacting you directly to establish your contact and at that point can give you some basics on logging in and starting to use the system.

DR. MALMUD: Thank you. Other questions? Comments? Thank you very much. Oh, I'm sorry.

DR. WILLIAMSON: I'm sorry. Not to belabor this but how narrowly is performance of official ACMUI duties to be defined? Is it like only we're to use it when we're given a specific request to evaluate something like the Novoste event or can we have more latitude as to when we think it might be useful? I just ask you to explain what you mean so we don't transgress any boundaries and all wind up in jail or something.

MR. ESSIG: Well, let me give you a for instance. I could probably -- no, it's not -- I don't believe it's a jailable offense. The for instance would be to cover two extremes. Obviously, the

Novoste would be -- or something similar, which would have been a tasking from us, would clearly fit that description. Something that might not fit the description is if you're wanting to research events to write a REFRI journal article that has really no connection to your ACMUI duties at all. That would probably be the other extreme. And that we would probably say would not fit that definition of access. And, obviously, there are a lot of things in between, but if those examples help illustrate the thing. We don't have any real hard and fast rules here, but encourage or I should say discourage the use of it for those tasks which a reasonable person would come to the conclusion this isn't really related to my ACMUI duties.

DR. MALMUD: Thank you. Any other questions? Ralph?

MR. LIETO: When we met with the commissioners, one of the things that they mentioned that they wanted the Committee to look at were events that occurred -- medical events that occurred for review and comment. Will this now become sort of standing agenda item with the Committee that we'll review medical events since the last meeting or something like that? I'm trying to look at where

we'll have access to this but if it's just sort of like you sit down with your morning coffee and bagel and look at what's happened over the last couple weeks in the medical use, I'm kind of trying to get a handle on what we need to do with this access.

MR. ESSIG: We're in the process of giving that further thought, and so we'll have to share that with you at the time. But, basically, what we're trying to -- what I see the Committee can fill an important niche is we used to have in a previous NRC organization it was an office for the analysis of operational events. It was AEOD was the acronym. And there was a small medical subset of that -- or materials subset of that with this Sam Pettijohn that I mentioned who was the Project Manager. He and one other staff person did perform those long-term trends and tried to glean from that lessons learned, what did we learn from these events and how do we feedback that back into the regulatory process? Well, when that office was dissolved we lost that capability.

Now, granted, the charter here is for medical events, which are a subset of the materials events, and so we're in the process currently of reevaluating how we want to approach the events, but we thought it would be very appropriate to use this

committee as a source of expertise that would help us dissect, diagnose what happened in those events and to help us with root cause analysis and that sort of thing.

DR. MILLER: Remind me of the exact words, Tom, if you can remember them, if anybody can remember them, but the Commission gave us guidance back after your meeting with them and the staff requirements memorandum and it encouraged the staff to use the Committee to help us analyze events. What they said after that was when there is a regulatory need. Okay. What's a regulatory need? I think there's a fair amount of latitude in that, but I think, as Tom pointed out, I think that if it's aimed at official duties and if it's helping frame Committee recommendations with regard to where we go in the future or helping us to determine do we have a problem in any specific area based upon the events that had been reported, clearly, I think there's a regulatory need.

What would not be a regulatory need, my personal opinion is I think a lot of us are professional enough that we know what we're doing in this area, and I didn't look at that as a particular constraint. But I guess it was to prevent -- I guess

it was to prevent any abuses of using the Committee for other purposes or personal purposes.

DR. MALMUD: So you're asking us basically to exercise our judgment with regard to the need to know with respect to the responsibilities that we have with the ACMUI.

DR. MILLER: Yes. And I guess let's use common sense. If you have a question and you're not sure --

DR. MALMUD: Thank you.

DR. MILLER: -- just call and we'll --

DR. WILLIAMSON: I think one thing that's a burning issue on -- or a current issue is prostate brachytherapy and that would certainly be a good first thing for those of us that are interested to use the event database to get that information and think about events that have led you to the quandary where you are.

DR. MALMUD: Thank you. Any other questions for either Tom or --

DR. MILLER: I guess the only thing I would say in closing is based upon the discussion I would assume this is a desirable thing --

DR. MALMUD: Yes.

DR. MILLER: -- for the Committee to have

access.

DR. MALMUD: There's full agreement.

DR. MILLER: Okay.

DR. MALMUD: Thank you. And thank you for the brevity of the presentation. This brings us back to pretty much the schedule. And the next item is the discussion of the draft information notice regarding issuance of identification cards to patients who are released after treatment with radiopharmaceuticals. Roberto Torres.

MR. ESSIG: Yes. Roberto Torres is recently, because I think this is his first appearance in front of the Committee as well, he's one of my -- I'm sorry? The third? Okay.

DR. NAG: I've seen him before.

MR. ESSIG: But his first in his new capacity as he is one of my two section chiefs. He's responsible for Part 35 implementation, among other things.

DR. MALMUD: Welcome in your new first presentation in your new capacity.

MR. ESSIG: Yes.

MR. TORRES: Thank you.

MR. ESSIG: Since August.

MR. TORRES: Good afternoon. As it was

mentioned before, the Commission has directed us through an SRM to become more engaged with the members of the ACMUI, and this is an example of engaging you.

We developed an information notice, which it's title is, "Heightened Awareness for Patients Administered Unsealed Byproduct Material or Permanent Implants." And I will go in some history what prompted the information notice.

Around March 2003 a boat load of passengers was traveling from New York to New Jersey, across the Lincoln Tunnel and there was a radiation detector at that tunnel and the alarm was triggered. There was some commotion, law enforcement responded to the event, and it was found after some time that there was a passenger who has been given ten millicuries of Iodine-131 that morning. The patient was discharged, was given written instructions, and one of the instructions in the written instructions said that the patient need not to use public transportation for at least two days.

What happened afterward was that the head of the New Jersey Radiation Control Program sent a letter to the NRC and basically was telling NRC, "Please, NRC, emphasize to your licensees the importance of patient instructions." But she also

suggested that the NRC considered issuing -- the licensee considering issuing identification cards to the patient with some sort of information like type of treatment, type of isotope that the patient received.

Dr. Lipoti's letter received media attention, it got the attention from the Commission also. There were discussions between commissioners' technical assistance and the Region 1 office, and it was agreed by the NRC that we were going to issue an information notice to address Dr. Lipoti's concerns.

The first board shows the title of the information notice, which you have a copy of it in your booklet. There were some discussions initially whether we should write this information notice to therapy patients versus diagnostic, but we are using the new terms under the revised Part 35, which is unsealed byproduct material. We don't want to use language that will reflect the old philosophy, philosophy of the old regulation which is diagnostic and therapeutic.

So we came up with this title, "Sealed Byproduct Material or Permanent Implants," meaning and that's the next bullet, the second one, there is language in the information notice that will reflect there's a high probability that therapeutic patients

will trigger an alarm, but we also have to consider that patients who receive lower dosages will also trigger an alarm. The third bullet reflects that the IN, information notice, is reminding licensees of their regulatory requirements: Sit down with the patient, discuss and go over the written instructions.

Also, the information notice is recommending two voluntary actions. The Action Number 1 is provide an explanation to all released patients that they can trigger radiation monitoring equipment, so that they'll be aware of it. And the intent of this is if they know that there's a possibility for them to trigger an alarm, that they can step forward to law authority officials and find the cause of it.

The second action is generic post-study or post-treatment part, and, initially, these are the recommended information that we wrote down in the information notice: Patient's name, date of the procedure, isotope and activity, expiration date, some language there indicating that the patient poses no danger to the public and was released under current regulations, and the physician's telephone number.

The draft IN was sent to the Advisory Committee for medical uses of isotope, all of you, for comment. It was also sent to the NSIR, our new Office

of Nuclear Security on Incidence Response for comments also.

And we received a comment mainly from Dr. Vetter and basically he agreed on the Voluntary Action Number 1, so did NSIR. And he disagreed with Voluntary Action Number 2 mainly because it looks like it is an undue burden to medical licensee, and several of the issues are will the hospital be expected to provide this card? Another issue is the implementation issue. Different hospitals will come up with different type of cards. Another issue is what's the validity of that card when a law enforcement official looks at it. And there are also concerns about HIPAA regulations which prevents decision from releasing information to third parties. You can imagine a local federal law enforcement official calling the hospital and then asking the licensee, "Did this patient receive ten millicuries of Iodine-131 this morning?" That's the issue.

If there is a need to issue a card, Dr. Vetter agreed that it should be very, very generic and that it should basically say that this patient poses no danger to the public. NSIR's comments is that they agree in Voluntary Action Number 1. They disagree in Voluntary Action Number 2 basically this is not the

right time. The Department of Homeland Security is considering implementation of a nationwide system of radiological detection, and if they're considering that system, they will also have to consider operational procedures, protocols for alarm response and determining a threshold level to screen out all those patients that are medical patients.

Also, NSIR agreed that instead of issuing a generic card with all that information that you have seen in the two or three previous slides before to issue or give the licensees a business card or the physician's business card. NSIR also recognizes the fact that the card will not be a carte blanche that will allow the patient or the local authority to tell the individual, "Go ahead and we will not search you." The card it's just some sort of information that enforcement authority will look at the patient and will try to screen out the patient and put that patient through a different search criteria.

And the example I am trying to bring here is there's an NRC employee who has a metal implant and he carries a card that says that he has a metal implant. Every time he goes to an airport he shows the card, but that card does not allow him to go through. He will undergo a different type of search

to screen out other possibilities and to verify what he is saying, what he is claiming.

So what is NRC intent for this Voluntary Action Number 1? What law enforcement officials need to hear from this patient they have in front of them that it's emitting radiation is that that radiation is safe and that it is allowed by law. Those are the key points that we want that patient to communicate to law enforcement.

This leads us to a revised Voluntary Action Number 1, which is give the patient the licensee's business card and provide written information for law enforcement use stating that the radiation that this patient is carrying is safe it is allowed by law. In other words, the second point is that a business card licensee can write behind the business card two words, "safe" and "allowed by law," for the patient to convey that information to various law enforcement authorities. And this is our proposal that we are putting here in front of the Committee. Do you agree with this revised Voluntary Action Number 1 with that language or should it be modified to reflect our intention, which is radiation is safe and it is allowed by law?

DR. MALMUD: Dr. Nag?

DR. NAG: Yes. I'm not sure what is being done at other hospitals, but I know that in our hospital any patient that has a permanent radioactive implant has two things. They have, one, a bracelet that says -- on the bracelet they've imprinted the date of the implant, the radioactive material and what the half-life date is. And we also provide them with one page that has instructions about the implant and when it is implanted and what the radioactive material was. So either of those two I'm sure would be useful in lieu of your Action Number 2. I wonder how many hospitals provide that routinely on all implant patients. Do you have a requirement for permanent implants?

DR. VETTER: They provide written instructions to the patient or written instructions and to radiopharmaceutical therapy patients as well. They do not provide written instructions to diagnostic patients, but in fact someone who just got 30 millicuries of sestimebe could set off an alarm as well. So I think there is some wisdom in this in the sense that a diagnostic patient could set off an alarm as well.

One of the things I like about this proposed change is it's still -- it's information

notice only, and it allows a hospital to provide this information to patients in any way they wish with an armband or whatever, but it does provide guidance in a rather generic sense that offers consistency. So if hospitals decided to follow this, then Homeland Security people would get used to that sort of a thing, and it might be a little bit easier for them.

DR. MALMUD: Other comments?

MS. McBURNEY: I agree with the change and this would also not violate HIPAA regulations. It's generic enough that it gives the information to the law enforcement people that they need but not so much that it would violate HIPAA probably.

DR. VETTER: Could I make one comment in HIPAA? Actually, that was a concern for me too. When law enforcement calls, if they have a legitimate need, then HIPAA doesn't really matter.

MS. McBURNEY: Right.

DR. VETTER: But if law enforcement calls, gets the Secretary of Nuclear Medicine, says, "I need to know this information and I'm in law enforcement, you've got to give it to me," the Secretary's been trained by the Compliance Officer at the hospital to not share any of that.

MS. McBURNEY: Right.

DR. VETTER: So it's going to take hours, perhaps, to sort all that out. So I think HIPAA is a valid concern. But simply for writing a business card without a lot of other information law enforcement can follow up on that if they need to. They need to recognize they might not get an immediate answer.

DR. WILLIAMSON: Well, the information is under the voluntary control of the patient. It's not like the stamped on the patient's forehead against the patient's will. The patient has the right to withhold the information from whomever they want. So how can that be a violation of HIPAA to provide the patient with some documentation? They can share?

MS. McBURNEY: That wasn't the concern. It was the way the first Action 2 is written.

DR. WILLIAMSON: Yes.

DR. MALMUD: Other comments from the table?

MR. LIETO: It relates to the licensee's business card. The expectation then is that the law enforcement officer can call that number and get an answer to his questions or is it just simply that's where the patient came from? It's just letting him know where the patient came from.

MR. TORRES: That's where the patient came

from, and I have already samples which customer official has been given the information where this patient has came from, and it's up to them whether to pursue that phone call or they just isolate and search the individual or the vehicle. So they have other means of verifying the information without the need of calling the licensee.

DR. HOLAHAN: I have a question. Do all doctors carry a business card? I'm thinking more of private practice.

DR. NAG: I think a business card wouldn't be a problem, but what may be a problem is getting a hold of that person on the weekend and after hours. That's almost very difficult at times.

DR. MALMUD: The answer to your question is that most physicians have business cards but all have prescription blanks, and either means is adequate for putting a short note. The method that I've been using with my patients is to on the back of the xeroxed sheet, which talks about the treatment of hyperthyroidism, I have a copy of my business card and then the dose of radioiodine that they received and the date. And I tell them to use that if they need it, but I also tell them that they will avoid a lot of embarrassment for themselves by no crossing a bridge

or taking a tunnel unless they have to and not entering a federal building where they know that they'll be monitored. That they're not breaking the law by doing either of these two things but they will be possibly picked up as being temporarily radioactive. And I cite the example of the amusing case that's amusing to patients about the patient who was treated in New York and took the bus to New Jersey.

There will be situations in which patients will of necessity have to cross a bridge or go through a tunnel which is monitored. The patient from New Jersey comes to New York for I-135 therapy and goes back home to New Jersey after the getting dose he or she will have to have gone either over bridge or through a tunnel and they may be picked up.

The other thing is that the cards that we give them are not proof of anything except that someone has that card. But it is a means of reducing embarrassment. I think that if we're looking for a discussion about the intent of the revised Voluntary Action 2, we can move on that as soon as we hear a comment from the floor which I think has been standing here patiently.

MR. WHITE: Gerry White from AAPM. I just

wanted to comment I agree with much of what's been said except I'd like to point out that it's really not the patient's responsibility to educate law enforcement personnel, which is what this does, by and large, nor is it the licensee's responsibility to train patients so that they can educate law enforcement personnel. I think conceptually this project is flawed.

I'd also like to follow up on the remarks we just heard that the card really cannot possibly provide additional security. It may avoid embarrassment to a patient, but an evildoer who had bad intentions with radioactive material would simply need to make a trip to Kinko's to make this all better for him, and it's really not worth that to make this a nationwide policy for all our patients.

Lastly, I'd like to say it's very poor law enforcement policy. It takes a normal activity, something that millions of Americans undergo every year, some sort of radionuclide procedure, and places it into sort of a potentially suspicious activity. It's much like vetting people for bank fraud who happen to have a checkbook in their purse. It just is wrong. And there's a much better way to do this if education is going to be had, if recommendations or

voluntary actions are going to happen, and that is to insist that law enforcement agencies that have these radiation detectors have proper radiation detectors.

One can purchase for not much money a radiation detector that has a pulsite analysis device that prints out the isotope and could be programmed in the simplest case to flash medical or non-medical after examining the patient with the device. They're not expensive, they're available, and I think that if there's going to be a burden for this, it shouldn't be on the licensees. It certainly shouldn't be on the patients. It should be on the law enforcement personnel whose job it is to make this right for us.

DR. MALMUD: Thank you for your comments. I would just point out that everything that you've said is true. Our goal is to relieve pain and -- as physicians is to relieve pain and suffering. The note in the patient's hands will reduce the embarrassment that will come to the patient since the patient will not have broken any law, and that's my only purpose in giving my patients those notes at this time.

I agree with your observations and recommendations, and they probably should go to the new Department of Homeland Security rather than to us as clinicians. And we all agree that the notes are

not proof positive. The goal is to try and make the patient as comfortable as possible.

And, lastly, as anyone who has a handicap knows, it is for the handicapped to try to educate those who should have been wiser in dealing with the handicapped, and unfortunately the burden falls to the person who's carrying the disability. In this case, the disability is decaying rapidly but it nevertheless it is a disability which is on board for a short period of time. Dr. Vetter?

DR. VETTER: Yes. I think the real value in this is the same value as Mr. Torres mentioned relative to a card that's given to a patient with a metal implant. It simply calls out to security that they can be checked in a little different manner and probably cleared quite quickly, in particular if they get a spectrometer, but that's, again, beyond our control.

DR. MALMUD: Yes, Dr. Suleiman.

DR. SULEIMAN: Yes. We have -- I mean the whole medical alert cards and everything else the patients carry, the issue came up with security screening devices at one of the FDA advisory committees. People with implants or muscle stimulators, a whole sort of electronic devices that

could be interfered with with magnetic fields and so on. So this is just one more thing that probably the patient needs to be aware of, but how many cards is a patient going to carry around?

DR. MALMUD: The other question that I had is how many incidents have there been? I'm only aware of one that's come to my attention. That that's incident in New York. Are there many more?

PARTICIPANT: There's been a number of them.

DR. MALMUD: There have been? Ruth, I think you --

MS. McBURNEY: Just coming from a regulator standpoint, it's really noble to try to require a certain type of monitor for law enforcement. But as radiation regulators, we can't do that because they're not possessing radioactive material except maybe some exempt sources or so forth. And also some of the states are providing the training for the first responders, and we're finding just a wide assortment of -- you know, they get Homeland Security money and they just go out and buy whatever type of instrument they can. And so we also provide some calibration services for them. But to require them to have a certain type of monitor I think would be under the

purview of some other agency. And what we're dealing with is the reality of there are patients being released and picked up by these monitors.

DR. MALMUD: So the question before us is do we agree with Voluntary Action Number 2? It is a voluntary action, it's not required, and it would simply be to give the patient a note with the physician's name and address and phone number indicating that they've been treated and that it's safe and allowed by law. That would be for the patient to carry. If the patient wishes to share that information with whoever stops them, he can, and if he doesn't wish to, he doesn't have to under the law. Dr. Nag?

DR. NAG: Yes. I'm wondering whether it should be the physician who may not be easily contacted or the person in charge of radiation safety, because there's always somebody who is approachable in case of radiation accident, and we provide the name of the radiation safety person.

MS. McBURNEY: Yes. It's the licensee's business card rather than the physician's.

DR. MALMUD: It's the physician who always sees the patient because it's the physician who personally oversees the administration of the

therapeutic dose for I-131. If an individual physician works out an arrangement with his or her radiation safety officer and that individual is willing to have their number, so be it. This is a voluntary system. Our main goal, I believe, is to reduce the embarrassment of being stopped for the patient, and any constructive suggestion is welcome, as is yours. Dr. Vetter?

DR. VETTER: Yes. I like the new revised statement, and I also like the use of the word, "licensee's business card," because it allows us to do -- it could be the physician, it could be radiation safety, it could be the President, whomever the licensee decides is the best contact.

DR. MALMUD: It appears that you have reached a consensus among this table.

DR. NAG: One of the few times.

(Laughter.)

DR. MALMUD: So your first motion in your role and your third time here has brought you a consensus, and we thank you for bringing it to our -- oh, is there another? I'm sorry, excuse me.

MR. LIETO: Yes. I'm a little concerned about Voluntary Action 1. I guess it's maybe some of the language. It says, "ensure that all patients."

It's almost like you're -- it's not a recommendation and when you say, "ensure all patients," it kind of takes, to me, that voluntariness, if there's such a word, out of this action.

DR. NAG: Where?

DR. HOWE: Where does it say, "ensure."

MR. LIETO: This was the draft that was distributed in our packet.

DR. NAG: Oh, not on this, right?

MS. McBURNEY: No. On the handout it just says, "provide."

MR. LIETO: This is the draft as of just a week ago -- or a month ago, last month.

DR. HOLAHAN: In your package.

MR. LIETO: It's in our packet. It has a strikeout of Voluntary Action 2 and a replacement, okay? And I guess I would like to know if we're going to talk about this or maybe there's going to be another version of this and we can maybe respond to that at that time, I don't know.

MR. TORRES: Our intent is once we make the changes we're going to resubmit the IN to the ACMUI for a final go ahead.

MR. LIETO: I would like to not have the "ensure" because it takes, as I mentioned, that

voluntariness out of it, and it says, "all diagnostic and therapeutic." I mean we're saying every patient's going to have to have -- be instructed and have a card when they leave, and I think that's a greater burden than is being recognized here in terms of commitment of time and resources in the Nuclear Medicine Department.

I guess I'd like the institution or the licensee to be left to their decision as to what groups or, I don't know, maybe we might want to just say some likely groups that might be -- I mean I can understand for therapy. Obviously, that might be appropriate. And I guess, as Dick said, maybe stress technetium studies. But I think the majority would not need this to be -- need this card or instruction when they leave.

DR. MALMUD: Dr. Vetter?

DR. VETTER: Yes. I'm not too concerned about it because of the preceding paragraph that says, "Licensees should consider the following voluntary action." So in Rochester, Minnesota where they all go back to their farm, it's not a big deal. At Sloan-Kettering, it's a little different. So I think each hospital's going to have to treat these a little differently. They will have to decide for themselves

whether or not, but it is very voluntary, so it doesn't concern me.

DR. MALMUD: Other comments? We note your concern, Ralph.

MR. LIETO: Thank you.

DR. MALMUD: I would just comment once again that I think the goal is to reduce the discomfort for the patient, and if the patient is aware that he or she may trigger a radiation monitoring device, it's to our advantage to let the patient know that, either through the technologist for diagnostic procedure or through the physician through a therapeutic procedure. Whether or not it's in writing is less important as long as the patient knows that he or she may be in an embarrassing situation if they enter a federal building or cross a bridge or tunnel that's being monitored.

DR. NAG: One question. Where are these radiation detectors? I mean are they in airports also? Because most patients will be flying in and out for the treatment.

MR. LIETO: I can tell you that they're on the borders, okay. Being from Detroit, the bridges and the tunnels from Canada to Detroit and they do -- each one of the stations have detectors, each one of

the personnel that inspect vehicles.

DR. NAG: But my question was what about airports? Do they have it all the airports or not?

MS. McBURNEY: No.

DR. MALMUD: I have no idea. I know that we had an amusing situation about 15 years ago or so in which I treated a policeman who was to be assigned as a civilian group surrounding the Secret Service who was accompanying the President. And I told him that he was temporarily radioactive, he should let his commanding officer know, perhaps they wanted to reassign him, and instead they told him to stay home for a day or two because they didn't want to trigger off any of the monitors and have trouble with the federal agency. And that was before the era of our concern about terrorism. So these things can pop up anywhere depending upon who's visiting town. So I would assume that once again my goal is to reduce the anxiety for the patient, give the patient the card or the note and from that point on it's simply a matter of fate. Until Homeland Security develops standards. That's a different department.

Once again, have we reached consensus? Is everyone --

MR. TORRES: So my action item will be I

will incorporate -- use the revised Voluntary Action Number 1. We'll take out the "ensure all language," and we'll resubmit to the ACMUI. Thank you very much.

DR. MALMUD: Thank you. Now back to the revised agenda, and the next item on the agenda is Dr. Howe. You're back on.

DR. HOWE: I'm back.

DR. MALMUD: And the subject is emerging technologies.

(Pause.)

DR. MALMUD: There are only three slides.

DR. HOWE: Yes. Yes.

DR. HOWE: We have a group that's working on implementation questions for Part 35, and we're fielding a lot of questions from a lot of different places -- stakeholders, people -- et cetera. And we got a request from the Department of Veterans' Affairs and we looked at it, and it really was kind of an interesting question we hadn't thought about.

They wanted to use a 35.1000 device. They wanted to follow the web site guidance, but they had earlier been authorized to use this device before the new 35 came into place. And the license condition that they had on their license said that intervascular brachytherapy that you had to have the authorized

user, the medical physicist and the cardiologist present for all procedures. Well, when we went to the new 35 we went to more performance base. The new 35 did not include, say, for the gamma-knife was kind of the model that we used, the gamma-knife no longer required the neurosurgeon. The old licensing guidance required the authorized user, the neurosurgeon and the physicist. The new guidance didn't. So we thought, well, the intervascular brachytherapy is pretty similar to the gamma-knife in that we've got this individual that's probably on the team -- really a radiation user and so if you didn't need the neurosurgeon to be there, he probably is there but it's not required, then in intervascular brachytherapy we should not require the cardiologist to be there, although he probably is there.

So when we developed the web site guidance we included only the authorized user and the medical physicist. But we had licensees out there that were using these devices that are now 1000 that were conditioned by license conditions before the new 35. So they had a license condition that said, "I've got to have an authorized user, I have to have a cardiologist, and I have to have an authorized medical physicist physically present."

And when we looked at the new rule, we said, okay, 35.26 allows you to change your radiation safety program with certain criteria. The change has to be in accordance with your license. Well, in this case, the change would not be in accordance with the license. They had a license condition that said three people had to be there. So they wouldn't be able to make the change at the facility. They'd have to come in with an amendment request to drop this person. Now, will we grant the amendment request? Of course.

So our answer to the question was, no, you cannot make this change under 35.26. There may be other things that you are doing if you use this device that are not tied down by license condition. In that case, it would be in agreement with your license if you made those changes, and you'd just follow the other conditions in 35.26. So the answer had to be no.

And then we thought, well, yes, the answer's no but is that really what we want to do? As we get additional experience with 35.1000 uses, they're not going to be so exotic and new. They'll become more routine. Chances are we're going to be decreasing some of the guidance that we have up on the web site today, and when we do revise that guidance,

it's going to show NRC's current philosophy on what is needed to license that particular device. And I say device because all of our 35.1000 uses are devices right now.

So we said how do we get around this problem that 35.1000 requires a licensee to submit information that's going to be tied down by license conditions so they have to be in a higher standard than other uses that are already in the regulation. The answer was to give licensees authority in their license that allowed them to make certain changes. I don't think this is it -- oh, yes, it is. Okay. I just have three of these, so they all look the same. So this was the problem. As our web site guidance gets revised, in many cases you can't use 35.26 to change your radiation safety program because you're tied down by license condition.

So our solution was to preauthorize licensees to be able to make the kind of changes that would keep them in conformance with changing web site guidance for 35.1000 uses. And that would give them the kind of flexibility they have for 35.26 for other uses. So I developed essentially a system. It's modeled after 35.26 but it is specifically for 35.1000 uses.

Now, a licensee or someone coming in and asking for one of these uses is going to have to request it because they have to be -- this particular set of criteria to the program will be tied down by license condition. So it will already be in the license. They'll essentially have a preauthorization as long as their changes to the radiation safety program meet these criteria. And the biggest criteria is instead of being based on the license it will say the revision based on NRC's current guidance for gliacyte, microspheres, intervascular brachytherapy, SeedSelectron posted on the web site. As in 35.26, the revision has to be approved by the radiation safety officer and the license management. All affected individuals have to be instructed in the change so they can all report to that program and that you retain a record for three years and then what this record is going to contain. So it will be the change that you made, the web site guidance, the signature of the licensee. So it's essentially modeled exactly after 35.26.

And OGC has blessed this, and this is currently up on the web site as like a conforming change to 36.26 for 1000 uses. It comes at the end of the licensing guidance for the gliacyte, the

microspheres, each one of the intervascular brachytherapy units, and when we do the SeedSelectron it will be up there also. So you can either -- for the SeedSelectron when they're asking for the initial use, they'll ask you this right away. Other licensees that are using intervascular brachytherapy come in and ask for an amendment for this. It will be granted and then you can follow whatever revisions we make to the web site.

And that's why I was saying this morning for the SeedSelectron you can go ahead with -- we'll get your comments back again, but before the ACMUI really takes its final stand on the SeedSelectron, we can put our licensing guidance up there and our licensees will have this flexibility to revise their program without getting an amendment if we modify the web site guidance to reduce any of the restrictions or change any of the restrictions. Yes, Jeff?

DR. WILLIAMSON: Thanks. Sounds pretty good. I guess I would suggest in Bullet Point Number 2 the revision is consistent with rather than based upon.

DR. HOWE: Okay.

DR. MALMUD: Any other comments?

DR. HOWE: Yes, Ralph?

MR. LIETO: I have I guess maybe a more fundamental is that this seems like things will never leave 1000. The intent is that 1000 would sort of be sort of this temporary holding area where things would be for maybe a year or two before they decided where they needed to go or NUREGs needed to be formulated or whatever. And there are things that are in 1000 that are -- that I believe have approached several years now, and I guess I see this as being just another mechanism that once they're put in 1000 they're going to be there until the technology or the USCA terminates or whatever, and that will always be in this guidance licensed condition type mechanism. And I can see this for new, for new things, especially as -- well, like for example, Novoste has made engineering changes and stuff come on board to maybe improve it. But I don't know.

DR. HOWE: There are some devices in the emerging technology that will never get enough use to warrant their own regulatory place. There are other devices that may be overtaken by time, and there are other devices that need to come into the regulation. But we haven't -- we don't have a schedule for when to bring those devices into the regulations. And that would be probably a fairly good size commitment on

rulemaking's part, and so this is an attempt that while things are still over there -- so far the 1000 uses that we have don't fit into any one category. So it would require a rulemaking to bring them out of 1000.

MR. LIETO: I recognize that. I guess what also is the other concern is NRC will be making changes to the guidance. Your example was in cases where it would be loosened and certain restrictions might be taken out. But I could see it going the other way is that there might be increased restrictions or added requirements that would not have the opportunity for input by the users and the licensees.

DR. HOWE: And I thought about that aspect too, and this is licensing guidance. This is the information that you would provide when you're getting authorization to use that particular device. So if the web site guidance when you're applying says A, B, C and you're given authorization for it because you met those criteria in A, B, C or alternative criteria that we felt were acceptable and then we added a D, we won't go back and unlicense you for it. It's kind of a grandfathering type of thing unless we issued something that made things applicable to everybody

like bulletins that try to get people to commit things on orders. So I think you would not be necessary hit by --

DR. HOLAHAN: Well, I'm sorry, I agree with your comment, and we need to form a process whereby we recognize certain things that are licensed under 35.1000 get into the regulations, and we'll work on that.

MR. LIETO: One other point --

DR. HOWE: But his point was backfit. In other words, if we tighten up on the licensing criteria at some later date, but you got through earlier when we didn't have those tighter restrictions, and I'm saying that I think that is the same as any other licensing action we take. Unless NRC takes some across-the-board action, like an order or a bulletin or something, then you are licensed under what you came in on.

DR. HOLAHAN: Yes, because --

DR. HOWE: And you're not backfitted.

DR. HOLAHAN: Because that's only in guidance space, and we can't put requirements -- backfit requirements. When they come in for license renewal, we'd look at the whole thing.

MR. LIETO: The correlate is that would be

an absolute nightmare for the regional inspection enforcement people, because they're going to come in and they're going to look this is what the current criteria is on the web site, and that's how they're going to be inspecting.

DR. HOWE: They have the license and they inspect against the license. They do not inspect against the web site guidance.

MR. LIETO: But the license just has references. Those tie-down conditions are referenced by the date of the application. The license itself does not have the tie-down condition specifically listed.

DR. HOWE: But our inspectors are trained that the license is the license, and the license includes all of those documents that are tied down, and they are supposed to know or have access to those documents. Because that's what tell us what the license is committed to. Otherwise we would have documents about yea thick.

DR. MALMUD: Dr. Williamson?

DR. WILLIAMSON: Yes. I want to, I guess, underscore my support for Ralph's first point and what Patricia said as well. It's not fair to the user community to allow something to sort of sit in

guidance space forever as a substitute for rulemaking and the opportunity for public comment and participation in the process that it allows. So I think a first step would be to have some kind of reasonable criteria for when something moves out of the guidance space and begins to move into the regulated/rulemaking space and kind of have a process set up for that.

DR. HOWE: Yes.

DR. WILLIAMSON: I really think it is incumbent upon you not to just sort of let this sit forever.

DR. MALMUD: Dr. Vetter?

DR. VETTER: Notwithstanding these previous comments -- the NRC likes us to use notwithstanding.

(Laughter.)

I think this is a very positive, proactive step that makes it easier for licensees to make changes in their program.

DR. MALMUD: I agree with Dr. Vetter's comment. Any other comments? Are you looking for any kind of statement or action from this Committee?

DR. HOWE: No. I just wanted to make you aware of what we've done, what's up on the web site

and the flexibility we think we've given the licensees on this particular thing.

DR. MALMUD: Thank you. I think this does add flexibility. It may create an opportunity for clarification later on with respect to how things move out of this, but, certainly, they're moving into this stratus, so we'll speed up some issues for those who may be concerned about them. And we thank you for your effort in drafting this.

MR. LIETO: Is this going to be communicated to the licensees in like an information notice or is it just going to be visit the web site if you've got this type of technology?

DR. HOWE: Yes. I think our management will tell me whether I can or not, but I do think it needs to probably go out as an information notice so that people are aware of it. We've made -- we have master materials licensees, and the master materials licensees have to issue licenses in the same manner that we do, so we put the notice out to them already, but we haven't done the message to go out to all the licensees.

MR. LIETO: Thank you.

DR. MALMUD: Next item on the agenda is Angela Williamson.

MS. WILLIAMSON: This is sort of a routine administrative exercise that we perform at every meeting. I'd briefly go over the recommendations from the last meeting and the staff's response and disposition of the recommendations. Although the last meeting was crammed full of agenda topics, only two recommendations actually came out of the meeting. And the other actions were action items that NRC management promised to follow through on.

But I'm not going to go over the recommendations in too much detail because, actually, the first one has already been addressed by Dr. Howe during her presentation, the generic listing of sources and model numbers on licenses. And everyone has -- the Committee as a whole agreed to the staff's plan to modify the notifications and the amendment section of the regulation. So I don't think we really need to go over that one in too much detail.

The next recommendation, continuous tracking of items generated during ACMUI public meetings, is a non-controversial issue as well -- well, not as well -- a non-controversial issue in and of itself. And what the staff -- well, to briefly read the recommendation, at the last meeting, the May 20 through 21 meeting, the ACMUI made a recommendation

that about two weeks after distribution of the staff's response to any recommendations that came out of ACMUI public meetings, that we will hold a conference call with the ACMUI, a public teleconference call, to review and prioritize items so that the various items, the numerous items that are generated during public meetings are not inadvertently forgotten about and not followed through.

And staff's response to this recommendation is that, well, we agree in principle that in between the bigger meetings where ACMUI assembles here at NRC headquarters, that we can meet or we should meet again with the ACMUI, but we don't want to hold to the two-week deadline. We just would like for it to be approximately midpoint between the two main public meetings. And we've already done that, as you already know, with the July 17 meeting. So that's kind of a done deal as well.

There are only about two action items that were generated from the last meeting. The first one had to -- it came out of the ACMUI's reaction to Dr. Robert Ayrs' presentation on exemption requests that were granted for those licensees who wanted to use gamma stereotactic radiosurgery. And after he gave the staff's rationale for accepting or rejecting the

exemption request, ACMUI felt pretty strongly that they should be contacted to assist with these exemption requests or at the very least staff should make a little more effort to engage the licensees to see if additional information can be brought to the surface that will enable staff to approve most of the requests.

And so the action item that was generated as a result of that discussion was that staff would explore ways to improve the application process, as I mentioned. Well, if the application process is improved, then maybe you can approve more exemption requests. What we decided to do is to -- well, we felt the best way to improve the applications is to also do another thing that ACMUI recommended which was require licensees to use NRC Form 313A. But before we can do that, we have -- the NRC Form 313A does have to be amended.

And once it is amended, we plan on to get the word out to licensees that, okay, we need you to forward these requests on this form. Please do it. We really can't process your request otherwise. So before -- well, I should after Form 313A is amended, then we plan to get the message out by preparing an article in the NMSS newsletter as one vehicle for

informing them, and then also issue a document called a regulatory issue summary and send that out to the licensees and just try to get the widest dissemination possible so that people understand that you just can't grab a piece of paper anymore and just kind of scribble a request on it and send it to the NRC offices. So that's in the works.

And the last and final action item that was generated is also a done -- it's a done deal like the recommendations are. The ACMUI -- or, excuse me, the NRC management agreed that we would explore ways to engage ACMUI more effectively or more actively, and that was done at the Commission meeting, basically. We seek approval to utilize ACMUI as more than advisors but also as consultants when necessary and appropriate, and we've already change the charter to reflect that new capacity. So, again, that's pretty much a done deal.

Also included, and I'm sure everyone has figured this out by now, but I'm reading from the table of recommendations tasks and action items, we've also engaged the two medical physicists fairly heavily during the last six months in having them assist us with approving requests from licensees for those folks that are seeking authorized medical physicist status

but they don't quite meet the training and experience requirements. And we've been successful in approving those applications using the expertise on the ACMUI.

And that's basically all that I have.

DR. MALMUD: Thank you. Are there questions for -- yes?

DR. NAG: Well, a comment. Basically, I think I want to amend the NRC officials and staff authorizing the feedback. This is something we've been looking for year after year, and now we are being provided this loop, so thank you very much.

MS. WILLIAMSON: Okay.

DR. MALMUD: Dr. Williamson?

DR. WILLIAMSON: I don't know if this is the point to bring it up but I thought the draft summary minutes were very well written and complete. And I thought this was really good.

MS. WILLIAMSON: Thank you.

DR. WILLIAMSON: This is a very nice readable summary of the meeting and obviously reflected a lot of work on the part of someone that should be commended, I think.

DR. MALMUD: I think that's a consensus from this committee.

MS. WILLIAMSON: I'll take credit.

DR. MALMUD: So you have another consensus today from the Committee and praise over the work of your offices.

MR. ESSIG: Just one question I need to -- because I was asked earlier, Angela, on the July conference call summary minutes, have those been made available to the Committee? There's was at least one member that expressed -- that thought that they had not received them.

MS. WILLIAMSON: I will have to check into that. It was my understanding that it had been made available.

DR. HOLAHAN: They're not available in the book.

MS. WILLIAMSON: Well, no, they wouldn't be available in this book, because --

DR. HOLAHAN: Oh, it was a closed meeting.

MS. WILLIAMSON: Right. Okay.

DR. MALMUD: Thank you.

MS. WILLIAMSON: Actually, that's not why, the fact that they were closed. That isn't really why. It's just that it was a time issue.

DR. MALMUD: Then we move on to the administrative conclusion.

MS. WILLIAMSON: I do have an update

there. I found out that this room will not be available around the March 2 time frame. In fact, it won't be available for that entire week. So what we're trying to do is to see if we can get the auditorium either March 1 and 2 or 2 or 3, so that another trip is not necessary for the Committee to make another trip here.

DR. MALMUD: So you'll let us know whether the two days are going to be 1 and 2 or 2 and 3.

MS. WILLIAMSON: Well -- right, right.

DR. MALMUD: We'll look forward to hearing from you about that so those who will require them can make airline reservations in advance.

MS. WILLIAMSON: I might already have an answer waiting on me. I just need to check my messages. So by the time you get back to your --

DR. MALMUD: We'll check our emails.

MS. WILLIAMSON: Yes, you might already have an answer.

DR. MALMUD: Any other issues to be covered in the administrative conclusion? Next meeting date? Agenda topics? Meeting summary? If not, may we entertain a motion for adjournment?

DR. VETTER: So moved.

MS. SCHWARZ: Second.

DR. MALMUD: Thank you all. Thank the staff for an excellent meeting. I've been asked to hit the gavel. Meeting adjourned. Thank you all.

(Whereupon, at 2:41 p.m., the ACMUI meeting was concluded.)