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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES

(ACMUI)

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FRIDAY, MAY 12, 1995

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ROCKVILLE, MARYLAND

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The Advisory Committee met at the Nuclear Regulatory Commission, Two White Flint North, 11565 Rockville Pike, Room T2B3, at 8:22 a.m., Barry A. Siegel, Chairman, presiding.

MEMBERS PRESENT:

BARRY A. SIEGEL, M.D., Chairman

DANIEL F. FLYNN, M.D., Member

JOHN GRAHAM, Member

WIL B. NELP, M.D., Member

ROBERT M. QUILLEN, Member

JUDITH ANNE STITT, M.D., Member

DENNIS SWANSON, M.S., BCNP, Member

LOUIS WAGNER, Ph.D, Member

ACMUI STAFF PRESENT:

Torre Taylor

ALSO PRESENT:

Janet Schlueter
Sally Merchant
Patricia Rathbun
John E. Glenn
Mark Rotman
Patricia Holahan
Chairman Ivan Selin
Commissioner Gail de Planque
Myron Pollycove
Steve McGuire
Stewart Schneider
Larry W. Camper
Josephine M. Piccone

I N D E X

P R O C E E D I N G S

(8:03 a.m.)

CHAIRMAN SIEGEL: We are back on the record, and we are starting this morning's meeting. The first item of business is one of the last items of business from yesterday afternoon, a discussion of dose ranges in written directives. Larry?

MR. CAMPER: Good morning. Thank you, Barry.

Well, continuing our discussion on noncontroversial topics, do we want to go through any questions on T&E before we get into this?

CHAIRMAN SIEGEL: Sure.

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MR. CAMPER: Sure. Now, seriously we do want to talk this morning about the use of or, more correctly, I should say the inability to use a range on a written directive.

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MR. CAMPER: We published an article in the September-October '94 issue of the NMSS newsletter after we learned from inspection findings that licensees in some cases were using a range on written directives. Primarily they were

using them on written directives associated with the use of sodium iodide, but in some cases also in teletherapy.

The article was fairly short and sweet. We attempted to provide clarification. And, in essence, in that article we said that you cannot use a range in a written directive with regards to a dose nor can you use a range with regards to overall treatment period in teletherapy.

Well, following that we got some inquiries, including a letter from our old colleague Dr. Marcus, who was fairly critical of the agency's position. And then there started some telephone calls as well.

As a result of that, we then prepared another article in the March '95-April '95 issue in which we attempted to be more clear as to our position, the rationale behind that position, and how we thought the community might deal with this problem or this issue. Following that, there were more phone calls, primarily from individuals involved with the use of sodium iodide, and we ended up with about 30 telephone inquires.

The biggest problem expressed from the callers was that the idea of not being able to specify a range for the use of sodium iodide on a written directive was very problematic for them because they had no way of knowing exactly how much material they would get from the radiopharmacy. If I order 30 millicuries, for example, I

might get 28 and a half. I might get 32. And, therefore, this idea that I would put down one number they felt was problematic.

The bottom line that we expressed in those newsletter articles and in those telephone conversations was that you could not use a dose or dosage range. And, as I said, there was a considerable concern about that, at least in the 30 callers.

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MR. CAMPER: All right. Now, the impact of this, then, we think is the following. We think that from a therapy standpoint it's a minimal impact because typically authorized users are actively involved in therapy applications. They are there. They help in the administration of along with the technologists. They're actively involved. And the ability, then, to sign the written directive, to have the amount specified prior to administration doesn't impose a substantial burden.

With regards to diagnostic of greater than 30 microcuries, you may require that they would review their clinical procedures manual, put some steps in the clinical procedures manual; for example, to say to their technologist staff that the dose for a clinical procedure is X microcuries for uptake and scan and that this dose may be administered

provided it doesn't exceed more than 10 percent of the assigned value.

We also made it clear that this was not a new requirement, that it was a clarification. It's bad enough that it's not a new requirement. But it was a clarification of the language in the rule. This was nothing new, nothing different.

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MR. CAMPER: Now, why did we take this posture? Well, once we learned of this problem, we conferred with the Office of General Counsel and determined through interactions with them that before we prepared the first article and our rationale from the staff perspective and in our discussions with General Counsel was that it is the responsibility of the authorized user to clearly state the amount of activity or the dose of radiation that is to be administered to the patient.

In many institutions, the authorized user is not present at the time of administration of greater than 30 microcuries of sodium iodide, even up to and including those cases where whole body scans for metastases are performed using as much as 10 millicuries of iodine. Now, I recognize that in many of your institutions, you may be there, but in some cases they're not there. So that was a problem, we thought.

And then, finally, only the authorized user should decide the actual amount to be administered to the technologist. Now, this wasn't an issue of the amount to be administered is 30.4 millicuries. It's the fact that the authorized user knows that 30 millicuries or 30.4 millicuries are being administered versus having a range in which the technologist ultimately is in the final position to know how much material is being administered to the patient. So we thought that was problematical.

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MR. CAMPER: Now some operating parameters come to mind. We recognize that when you order a dose of sodium iodide, you don't know in advance exactly how much material you're going to get.

But that doesn't preclude the authorized user from requesting the sodium iodide dose in a range. You could tell the radiopharmacy. Your chief technologist or you could call up and say "We want 25 to 30 millicuries of sodium iodide."

Then once you receive the material, it needs to be assayed prior to administration, obviously. There's a requirement in 35.53 that it be assayed prior to administration.

Once you receive the material, you become aware of what the actual amount is. You can then modify the written directive at that point. Then, of course, the authorized user would sign and date prior to the actual administration of the material.

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(Slide)

MR. CAMPER: Now, some questions to pose to the Committee. And then I'll follow those questions in our discussion with some possible solutions or options for dealing with this issue.

The first question is: Does this position pose a problem for the nuclear medicine practitioner?

MEMBER NELP: I've never really heard of this being a problem. And I guess it surfaced without my hearing about it in the nuclear medicine community.

MR. CAMPER: When you say it's not a problem --

MEMBER NELP: I mean, I would never order a range. I mean, for therapy we just don't. I've never operated that way. And I don't know of anybody else who has. But where are these people practicing that you're referring to specifically?

MR. CAMPER: Well, Sally, you took most of the phone calls. Do you have any idea? I don't think we want to

mention the institutions. I would say that it comes from large and small institutions.

CHAIRMAN SIEGEL: I can give some examples. In fact, I can give some of the examples that Carol posed, the sum of which are real, but I see it as a small problem.

An example is you see a patient today. And you work in an environment where there's no material on hand. And ordering material takes a long time because of the budgetary process in a particularly strapped institution. And you order the material to be delivered two days from now because that's how long it takes to get the purchase order issued. And you order 12 millicuries.

The patient then doesn't show up for an additional three days because the patient gets confused. And the physician is not on site. And now the dose is only 10 millicuries. It's outside of the 10 percent because it's decayed down. And the technologist is stuck and has to track down the physician, get a telephone or fax authorization for the new written directive. And it's sort of inconvenient. So that's one kind of a potential practical issue that will occur almost never, but could inconvenience some people. That's number one.

Number two is the issue of if I know what I want to do medically and I don't care what the actual amount is

within this medical range, why are you troubling me for another piece of paper? And I guess I understand that.

The truth of the matter is -- and Carol really is right -- that I may see a patient with hyperthyroidism and I may say I want to give that patient 8.9 millicuries of I-131. Buzz may see that patient, and he may say "I want to give that patient 15 millicuries because that's the way I treat the patient." And Dennis' doctor might see that patient and say "I'm going to use five millicuries."

What Carol is saying is given the biological variability of the thyroid gland in therapy, given the fact that there is such a wide range of practices, if she wants to write a prescription that says 7 to 12 millicuries, it's because she honestly believes that it doesn't make a darn bit of difference whether the patient gets 7 millicuries or 12 millicuries. And she's medically right in saying that.

Now, is that a practical problem? Is she tilting at windmills, as she often does? I don't know the answer, but I see her point.

I also thought yesterday as we listened to the brachytherapy discussion that the prostate implant stuff is a pretty good example where it would be practical to be able to say what I hope to achieve is somewhere between 12,000 and 16,000 rads and if I'm lucky, when I get all those seeds in

the right place, I'll do so and it would be nice if I could write my prescription that way.

I can't tell if this is a --

MEMBER STITT: I have a comment on that, too, Barry, because when I saw it on the agenda, I actually thought it was referring to brachytherapy. It's been traditional to talk about low-dose rate, which has been done since late 1800s.

I want to give something between 20 and 30 centigray to a particular area to treat cervix cancer, and that's standard of practice. But it's not the way the laws are written that we have to deal with.

MR. CAMPER: Well, let me pick up on that for a minute. You just said something, Dr. Stitt, that's very interesting. It's our third question. It's probably amongst my list of questions, the one that I consider to be the most important. That is: If, in fact, it is the standard of practice to order in a range; for example, in your case brachytherapy, and if it were a standard of practice within the use of sodium iodide -- I'm not sure I'm getting that signal, but I may be hearing the signal certainly in the world of brachytherapy that it is, in fact, the standard of practice.

It concerns me immensely, I must tell you, if our regulatory requirement or the interpretation of that

regulatory requirement would be contrary to the standard of practice.

And if that's the case -- and I'd like some indication from this Committee if it is because if it's the case when I explore some of the options in a few minutes, I'd like some indication from you at this point if it is standard of practice.

Then what we might do under the options because I find -- first of all, I find the arguments you've made, Dr. Siegel, compelling arguments. I think they don't occur very often. I think most times people can deal with this in a fairly straightforward fashion. But those are compelling arguments.

But, most importantly, if it's contrary to the standard of practice, that's a significant problem, I would suggest.

MEMBER NELP: And I think there's some confusion, too, from Barry's argument and your argument. We're talking about a dose range, not a millicurie range or not a -- I mean, you implant X amount of implanted material radiation expecting to get a dose in this range. I give a patient 10 millicuries of radioiodine, and I estimate this will give 10 to 12 thousand rads, this particular dose.

But I must say I've never heard anyone say "Well, I'd give them somewhere between 7 and 12 millicuries. It

doesn't make any difference to me." That seems to be very, very unusual.

MR. CAMPER: Yes. The practice of the two modalities I think is --

MEMBER NELP: And you wouldn't say "Well, I'll put 5 to 10 millicuries of these seeds in there" because you'll tell exactly the kind of seeds you want in there and anticipate a range in dose, --

CHAIRMAN SIEGEL: Buzz, let me ask you a question, though.

MEMBER NELP: -- I believe. Isn't that correct?

MR. CAMPER: That's correct

CHAIRMAN SIEGEL: Let me ask a practical question. You've got a patient in your clinic. Let's just assume for a moment that you don't keep I-131 in stock like I do. So it's never a problem.

You've got a patient in your clinic who's got to get out of there in a hurry. And you call Syncore up, and you say "I've got a patient. I want to give the patient 10 millicuries," and Syncore says "I've got 8."

You don't say "Okay. I'm not going to treat the patient." You take the eight.

MEMBER NELP: I may not. I may or may not, --

CHAIRMAN SIEGEL: No, you may not.

MEMBER NELP: -- depending on the situation.

CHAIRMAN SIEGEL: I mean, I really see this as a small issue. But I do think that this is one where the regulatory posture is probably unnecessarily constraining the reasonable practice of medicine because the fact that Dr. Marcus wants to write a range doesn't mean that Dr. Marcus is saying that the technology is picking the dose. What Dr. Marcus is saying is "I couldn't care less whether it's 6 millicuries or 12 millicuries." And that's her medical judgment. That really is her prescription.

Would I do it that way? No. Do I think it's the standard of practice? I agree with Buzz. I think people ask for 10. And if they find out it's only eight, then they'll write a written directive.

I do it a different way. I mean, I write the order, which you can view as the written directive, but we have a subsequent part of a flow sheet that we go through. And it's really the bottom line that makes this is ready to go in the patient. And if it turns out it's different than what I originally wanted, I've basically already gone through the change procedure.

But if I were the only physician in a small clinic in Montana and today I'm at the other hospital 75 miles away, it's pretty inconvenient if I get a different dose. It means I've got to fax and they've got track me down and blah blah blah.

MEMBER NELP: I have a comment. I might disagree with Dr. Stitt. Maybe she's misinterpreting what I think she meant to say. But I think in terms of the biological dose rate, she's rate. I mean, for low-dose brachytherapy, we know that a certain range -- we're aiming for a certain range.

When we write the prescription in low-dose brachytherapy, I don't know of anyone who is writing a range. Usually it's a total dose to Point A. It doesn't matter how you get there, whether it's 45 centigray per hour or 55 centigray per hour. But the prescription is a dose, not a dose rate.

And I don't know anyone in brachytherapy who is writing a dose range as a total dose to a certain area except for the misadministration in western Massachusetts where a strontium applicator treatment was written as a very large dose range, which I thought was not appropriate. But there was also misadministration associated with it.

MEMBER STITT: Let me clarify that. In typical low-dose rate and brachytherapy -- and, in fact, there's even something that we had in our pile of dead trees yesterday that described it well, where you have to make something, a specific comment, about your prescription but you actually do it as you get toward the end of treatment so that you might put applicators in place, look at the plan, see how the patient's doing. And you've got somewhere between, say, 25 or

even 20 centigray or 30 centigray leeway that you want to carry out during that treatment.

So at some point you're going to make a statement "I'm going to make a treatment decision of this particular dose," but there is quite a range of acceptable within that. And depending on how the patient is doing, the time of day, if they need to get the train to get home, that appropriate therapy could be anywhere within that range. So you will come up with the final decision.

MEMBER NELP: Oh, I agree with you. What's medically appropriate, there's a range, but you're going to have to prescribe. Eventually you're going to have to prescribe an actual dose before --

MEMBER STITT: The point is that there's quite a leeway. But if you've made a statement and it's in print, you could end up with a misadministration because of the way the laws are written or the regulations are written. And that doesn't have anything to do with --

MEMBER NELP: You can change -- the quality management rule allows you to change the prescription any time during the procedure prior to the termination of the procedure. I was involved in the discussions originally before the QM rule.

We wanted to make sure that was the case because some patients become medically unstable during the implant,

not tolerating the implant very well. You want to be able to change the prescription as necessary.

MR. CAMPER: You certainly may modify the written directive.

MEMBER FLYNN: You may modify the written directive prior to completion of the --

MR. CAMPER: Prior to completion. That's correct.

MEMBER STITT: I just want to put one little pot shot in there. I agree with you, and that's what we're told. But I do as you do and the rest of us do, consultations and on several of them I have done this year, the aura that the doctor did something a little bit no-no because they made some changes in writing to try to avoid a misadministration.

And, as I've dealt with different regions, it was very clear in their minds that they were trying to catch these people doing something that was wrong. And there's a real adversarial type of relationship there.

CHAIRMAN SIEGEL: The whole goal of the quality management program and of the written directive is to provide a high level of confidence that the medical wishes of the authorized user are carried out by the individuals who are supervised by the authorized user. Correct?

MR. CAMPER: Absolutely.

CHAIRMAN SIEGEL: That's the philosophy. And I guess the real issue is: If it's the authorized user's wish for the patient to have 6 to 12 millicuries of I-131 and the dose's within that range, why is that not a valid written directive in a purely legalistic sense, irrespective of whether it's the standard of practice?

Mark has a comment.

DR. ROTMAN: For the record, Mark Rotman.

Three things I'd like to bring up. First of all, as a practicing pharmacist, both in the traditional world and in the world of radioactive drugs, I have filled radioactive drug prescriptions that were written in ranges going all the way back to the middle '70s, when I worked at the University of Washington Hospital Centers and clinics for Dave Allen, who worked for Wil Nelp. So it happened there back in the '70s. It still happens today. It happens in my practice of radiolabeling monoclonal antibodies.

Because of the nature of radioactive drugs, the nature of the difference in assay accuracies of dose calibrators, it's virtually impossible to pin down an exact number.

Now, does it really make a difference? Because my understanding is the written directive is not a prescription. The written directive is an NRC-created term. And the prescription is something completely different that is

a legal order from the physician to the pharmacist to fill a drug.

So if the prescription has a range, so be it. The final administered dose to the patient is the written directive. Now, if you've somehow created an additional piece of paper that is burdensome because somebody has to copy down a number from what was assayed in the dose calibrator onto the written directive, then that's another issue completely. But traditionally in the practice of regular medicine, non-radioactive drugs, dose ranges are implied and explicitly asked for all of the time.

Think about the last time you had a bad acre pain and the doc wrote a prescription for a pain killer that said "one or two tablets ever four to six hours as needed for pain." I mean, those dose ranges are built in implicitly.

The difference is with traditional drugs, they come from the manufacturer as a strength and they do not decay away. So that you don't have the inventory variability problem.

With radioactive drugs, you have an inventory variability problem. Many, many, many times I have been asked "What have you got in stock? This patient needs to be treated today." And if I tell them what I've got, "That will have to do" is the answer I often get. That isn't exactly what they wanted, but they'll take it.

So we need to separate prescription order, which is a state board of medicine and pharmacy type of issue, from an NRC issue, which is the written directive. Perhaps --

MR. CAMPER: The question, Mark, that would argue, then, that clearly on a prescription -- and you've made valid arguments for the use of a range. But from the standpoint of a written directive, then, are you saying that it is appropriate to have a specified amount?

DR. ROTMAN: Well, the written directive is something the NRC created so that you can have a paper trail to know what the doctor ordered and what was actually administered. It's different from the prescription.

If the prescription was written as a range in order to order the material and get it in, what most people do is once it comes in, they assay it in the dose calibrator. And then they write on the written directive exactly what the dose calibrator said for fear that if they wrote down 28 millicuries and 31 millicuries came in and they administer 31 millicuries, somebody is going to question that as "Is that a recordable event because it's just a tiny bit over 10 percent from what I ordered?"

If those 28 millicuries were assayed on the dose calibrator at any 3 different radiopharmacies, you would not get 28 exactly in the 3. There's a variability built in that we have to live with.

So by cutting it to 10 percent and calling that a recordable event and asking people for that sort of precision with something that has as much built-in variability is getting to be unrealistic.

But there really are two issues here. What Dr. Marcus wants to order for her patients and call that a prescription is one thing. What the NRC is going to require on their written directive is another.

Now, in communication between the NRC and Carol Marcus, you guys have referred to written directive as prescriptions in writing. Now, you may have crossed over a line that got yourselves into trouble by referring to written directives as prescriptions. And unless you want to make that distinction rather clearly that it isn't a prescription, that it's just a way to record what was actually administered to the patient, you may have crossed over into the board of pharmacy's and the board of medicine's bailiwick.

MR. CAMPER: If we have in any of our communications used the terms interactively of "written directive" and "prescription," we did not intend to do that. You're absolutely right. The term "written directive," as I mentioned yesterday, was specifically developed. We avoided the use of the term "prescription" because it has its own meaning.

The written directive, though, was not prepared so that there would be a record of. It was prepared so that there would be a clear written direction to the technologist as to how much material to be administered to the patient or the radiation therefrom to the patient.

It really wasn't an after-the-fact record so the inspectors could then go look and see what you actually did. Rather, it was to be proactive.

DR. ROTMAN: Well, whatever was intended somehow has become different from reality. At my institution written directives are not put in writing until the actual dose assay is provided to the physician who is going to administer the material.

MR. CAMPER: That's consistent with the objective.

CHAIRMAN SIEGEL: There's a specific instruction before the --

MR. CAMPER: Exactly.

CHAIRMAN SIEGEL: -- administration of the radioactive material. That's a written directive.

DR. ROTMAN: That's certainly true, but if you read the quality management rule, it appears as if the intended treatment plan is written ahead of time and then it is followed and if there are deviations from the intended treatment plan, those are to be reviewed. And if you wait

until the material arrives and then write your intended treatment plan, it seems like the intended treatment plan is influenced directly by what is available, not what was intended by the doctor to begin with.

Now, I know we've gotten way away from what your original --

MR. CAMPER: I was getting ready to say we were --

DR. ROTMA: So let me back off.

MR. CAMPER: A different but related issue.

DR. ROTMAN: I just wanted to make the point dose ranges occur in nuclear pharmacy and in traditional pharmacy practice routinely. There are significant technological problems in supplying exactly what the physician ordered for a variety of reasons. And the prescription is really a different document than the written directive. Those are the three points I wanted to make. Thanks.

CHAIRMAN SIEGEL: And just a comment. Certainly in the diagnostic study issue the range is common practice. That is the standard of practice. And, in fact, you all acknowledge that in the NUREG on management of medical programs when you talk about the responsibilities of the authorized user. It says "Typically the authorized user defines acceptable ranges for patient dosages for specific studies in a diagnostic clinical procedures manual."

So it's quite acceptable to write down that for bone scintigraphy, the range of doses for MDP is 10 to 20 millicuries. And that gives the technologists a lot of leeway based on what's available.

MR. CAMPER: Right.

CHAIRMAN SIEGEL: And the reason the authorized user gives that leeway is because the authorized user really doesn't care because you'll get a passable study either way.

MR. CAMPER: So I'm sensing, then, with regards to the first question that it may be problematical, and you've given an example.

CHAIRMAN SIEGEL: For some instances.

MR. CAMPER: With regards to the third question, it sounds like it just might be the standard of practice.

CHAIRMAN SIEGEL: It could well be the standard of practice except that NRC is trying to push it from not being the standard of practice by way of the written directive.

MR. CAMPER: Okay.

MEMBER WAGNER: This is what I guess is grating at me here, the fact that it is quite clear that this is trying to direct the standard of practice in medicine, which I don't think the NRC has any business doing.

This is a matter -- look at the questions up here. Do nuclear medicine practitioners refer to prescribe

written directives with a range? They clearly are confusing these two.

And it is quite clear that the written directive is written for the NRC. It is quite clear that this whole thing is done for the NRC, not for medical practice.

MR. CAMPER: Well, I wouldn't agree with the fact that we're confusing the two. We know the difference. Now, let me make my point. We know the difference between a prescription and a written directive, and we know that we created the written directive.

I mean, for example, we could have used other words here. We could have said: Do you prefer to state the amount of activity to be administered on a written directive in a range? I mean, that's just words.

MEMBER WAGNER: Then why do you ask why it's the standard of practice?

MR. CAMPER: Because --

MEMBER WAGNER: Because the prescription's the standard of practice when you order something.

MR. CAMPER: The reason we're asking --

MEMBER WAGNER: The written directive is different. How people do a written directive is a different idea.

MR. CAMPER: The reason we're asking you if it's the standard of practice, because a problem has surfaced.

We're trying to find out how severe this problem is and what we might do to alleviate that problem.

And, therefore, if you're telling me that it is the standard of practice and our regulatory interpretation is in conflict with the standard of practice, I need to know that. That's very disconcerting and it causes me to want to do something about it, to make some suggestions how we might resolve this problem. That's why we're asking the question.

MEMBER WAGNER: Then I would agree with you because, I mean, Point Number 4 is again a question that is really difficult for me to comprehend how it can be asked: Does the ACMUI believe it to be acceptable for technologists to decide?

The implication is the technologist is deciding. The technologist is not deciding if it's within the range. The question is just inappropriate for the situation that's occurring if a range is given. The technologist is not making that decision.

MR. CAMPER: Well, the question is the technologist. If you prescribe a range, the technologist is the person who ultimately makes the decision as to how much will, in fact, be administered.

Now, I understand. Arguably, the doctor has already set the boundaries. That's your point. I understand that. But in the opinions of some, that decision as to how

much should actually be administered, the amount, should be the medical practitioner, not the technologist. That's why the question is being asked.

MEMBER WAGNER: But the practitioner made that decision. The practitioner said --

MR. CAMPER: I understand.

MEMBER WAGNER: -- "I don't care as long as it's in this range" --

MR. CAMPER: I understand.

MEMBER WAGNER: -- or "My prescribed dose is in this range."

MR. CAMPER: Well, I find the last question sort of interesting having administered a lot of sodium iodide in my time as a technologist a few years ago. Having administered therapy doses, having administered whole body scans as a technologist and actually making that decision, it's kind of interesting from my perspective to see that question being asked.

And I think your points are well-made. The technologists follow the directions of the physician. And as long as you were within the range prescribed or in this case identified in the written directive, you were confident that you were carrying out the wishes of the physician and you were okay. No one ever questioned that.

But you get into a situation when regulations exist, they have to be interpreted. And when they are interpreted, you get into tar babies sometimes, and I think this is one of those. And what we're trying to do is find out how much of a problem this is and so forth.

What I'm hearing, then, a clear sense on each of these, that, yes, in some cases it's not a tremendous burden, but, yes, it is problematical. It may well be in conflict with the standard of practice.

It seems appropriate in the mind -- is there a clear consensus from the physician that it's appropriate and acceptable that the technologists ultimately make that decision along the range? I assume there's a consensus of opinion on that.

CHAIRMAN SIEGEL: If the physician directs a range, the technologist gets within the range, then the physician's orders were followed.

MR. CAMPER: Right. Okay. We're clear. Let's move to the options or possible solutions, then.

CHAIRMAN SIEGEL: On the other hand, let me just say one thing, that there always is the potential for abuse. And I think none of us would feel very good if there were physicians out there who preprinted a bunch of written directives that said "5 to 30 millicuries" and technologists

simply zoomed in and said "Sign here" with a form all filled out that just had the patient's name.

But the goal of this whole process was to have the authorized user, especially for I-131 therapy and diagnostic imaging, either see the patient or at the minimum know something about the patient to make sure that this I-131 is being given to the right human being for the right reason.

And so one could imagine that this range could be abused. But, again, I don't think that's likely, worst-case scenario.

MR. CAMPER: Well, let me make an observation about that. If one goes back and looks at -- what brought this written directive about? I mean, acknowledging up front that the frequency of occurrence of misadministration is small, always has been, still is, even smaller now, it appears.

But in some cases -- and we do tend to be reactionary regulatory agency, sometimes even to singular events. Perhaps in the minds of some that's appropriate. In the minds of others it's overreaction. You'll get a lot of opinion across the spectrum of opinion.

But there have been cases where, as I said yesterday, things were not written down, it was in the mind of the physician, he gave verbal instruction. When queried, it was this thing "Oh, yes. I have that here." They pull this

little piece of paper out of their briefcase, and there it is. And technologists have made mistakes because of that.

Today, though, I must tell you that in some cases I've had some sense that the practice you've just described is, in fact, going on. Written directives are created in advance, and they're just signed off at the last minute. I think there may well be some of that going on.

But, again, the thing we've got to try to do is to make, on one hand, to try to meet the intent of this regulation, at the same time clearly not interfere with the practice of medicine and not be overbearing.

So with that in mind, I've heard your points. Now let's kind of explore some options for possibly doing something about this. We could, for example, revise the language for a written directive to allow a range, specifically in rule language, allow the use of a language in a written directive. That would require a rule change.

Now, the question we ask ourselves, then: Okay. On one hand, if this problem is a big enough problem that you might want to do something about it alone in rule space, you could possibly pursue that pathway.

On the other hand, given that we're headed for a major revision of Part 35 and I can predict I think with a fair degree of confidence that the quality management rule probably won't look just like it does today in Part 35, if it

survives at all, then the question becomes: Is that a worthwhile approach? Is the problem big enough to do that?

CHAIRMAN SIEGEL: No.

MR. CAMPER: And the answer I'm hearing is no. All right.

CHAIRMAN SIEGEL: That's my opinion. Would the rest of you agree?

MEMBER NELP: I think it's a non-problem.

CHAIRMAN SIEGEL: Continue.

MR. CAMPER: So we have a consensus on that?

CHAIRMAN SIEGEL: Yes, sir.

MR. CAMPER: Okay. We certainly could exercise enforcement discretion in this area. That's a fairly easy thing to accomplish. We would simply direct the regions, in a sense would direct the regions to -- if they find that cases where a range has been used in written directives, that it is a no never mind. So note it, and that is it. That might be a problem if there is a misadministration and a range is used depending upon the circumstances associated with the misadministration.

Not all misadministrations result in enforcement activities. Some do because of programmatic problems with the quality management program. Either it hasn't been developed or it's not being carried out.

I think we're now past most instances when it hasn't been developed. I mean, people have a program in place. They've adjusted them as a result of the first 1,200 letters we sent out. So now you're in the range of you might not be carrying out your own QM programs.

So conceivably you could have some enforcement issues there. But otherwise if we just simply find dose ranges used, no problems, no misadministrations, we could instruct our inspectors to "Okay. Fine. Just note it and carry on."

What's the reaction of the Committee to that option?

MEMBER NELP: Ease up.

MR. CAMPER: Ease up?

CHAIRMAN SIEGEL: It makes sense. And in a way, I suspect OGC would probably disagree. And I think they probably already have. But in a way I don't think that's inconsistent with the language of the quality management rule because it never explicitly says that the written directive can't include a range.

MR. CAMPER: Well, before we sent the newsletter out, we did confer. And their interpretation was that a number is what the rule says. That's their interpretation.

CHAIRMAN SIEGEL: I understand.

MR. CAMPER: So the feeling about enforcement discretion is generally?

CHAIRMAN SIEGEL: Sensible.

MR. CAMPER: Sensible?

MEMBER FLYNN: Can I ask a clarification now? We're talking about nuclear medicine diagnostic or nuclear medicine diagnostic in nuclear medicine therapy?

MR. CAMPER: I'm talking about any modality affected by the quality management rule. My opening position would not be to indiscriminately ignore them in sodium iodide, but pay attention to them in therapy. I would want to practice a uniform policy.

And I guess what I need to know from you: From the therapeutic end is that a problem in terms of the teletherapy and brachytherapy, is that an appropriate posture to take?

MEMBER FLYNN: I don't think it is. I think a range is not appropriate for teletherapy or radiation oncology. We're going to give between 120 and 240 centigray per day with the teletherapy? I don't understand what the range means for teletherapy.

MEMBER NELP: This is 100 seeds. Do you see that?

MEMBER FLYNN: Right.

MR. CAMPER: What I'm saying is not so much from a practice standpoint is it appropriate. I'm saying if our inspectors where to find a written directive or a range for teletherapy or brachytherapy had been specified, as opposed to an exact amount of dose to be delivered.

MEMBER FLYNN: That would be a big problem. I think that would be against the standard of practice of radiation oncology. In radiation oncology a dose is prescribed, not a range.

CHAIRMAN SIEGEL: But then it's going to be regulated in an independent way, then, because it's not the standard of care. I mean, see, here you're saying, Dan, "Oops. My God. It's not the standard of care" and then "We'd better make sure the NRC enforces the standard of care."

The NRC does not enforce the standard of care. We do. So the fact that we've got a little flexibility in NRC regulatory space doesn't change the standard of care. We set it. We determine it. And we don't need the NRC's help.

MEMBER FLYNN: Well, I think in radiation oncology -- I mean, Judith can speak up, but I think the only thing we're encouraging is there are some practitioners out there that would -- the only individuals in my opinion to then use a range would be those that would be deviating from the standard of care and would be doing so to avoid the consequences of deviating from the standard of care, being

able to use a "Well, I'm within NRC guidelines because, well, I was supposed to take the implant out at 6:00 o'clock, but I put a 12-hour range. So I decided I'd wait until the next morning and take the implant out."

I think that's foolish. That would just create confusion in the radiation oncology if you came out with a range acceptable for brachytherapy, when the implant would be taken out.

MEMBER STITT: Actually, that's how people practiced for years. I mean, I think you have to separate the regulatory business from the practice of medicine business. Flexibility just makes it easier to practice medicine.

And depending on which part of radiation oncology you look at, you're right. People aren't going to write a therapy cobalt prescription to say "Give between 100 and 240 centigray per day," but that's just because the practice of medicine is that way. When you start looking at iodine-125 seeds or even iridium seeds, the flexibility makes it easier to practice medicine.

So I don't see -- I certainly agree with what Barry said. The practice of medicine is regulated by those who are practicing medicine. And this would make it somewhat less onerous to have a regulation that's not going to be so confining.

MR. CAMPER: Well, why don't I say this for sake of time? If it turns out that we decide to pursue the enforcement discretion route, then what I would do is we would consider what's been said here today, the difference between the use of sodium iodine and the use of teletherapy or brachytherapy.

And if, for example, we were to draw a distinction between those two in terms of enforcement space, I would want to run that guidance to the regions by Drs. Stitt and Flynn before we send it out and et your specific opinion and feedback about what we said in writing about enforcement discretion policy. Okay?

But at this point I don't know whether we're going to with that option or not. We certainly have your advice on record. And it is an option of consideration. But I've heard this difference, which may or may not be so subtle.

Another possible way of looking at this would be to say "Look, this is not a big deal, guys because our regulatory threshold is greater than 10 percent." It's not equal to or greater than 10 percent. That's an error. It's greater than 10 percent, and that's the recordable event.

So if it's below the threshold or recordable event, what's the big deal? You don't need to do anything about it. It doesn't trigger the regulatory threshold.

If one looks at 35.53, you are required to assay the dose before administration. It doesn't specify the tolerance, just says you've got to measure and record what you prescribed and what you administered.

So if the difference between what you actually requested and what you actually get an administer is below 10 percent, just don't pay any attention to it. It's no big deal. It doesn't trigger our regulatory threshold.

CHAIRMAN SIEGEL: I actually think that is the standard of practice.

MR. CAMPER: Right. So, I mean, we --

CHAIRMAN SIEGEL: If I tell my pharmacist I want 10 millicuries of I-131 in a syringe and it comes out 11, I take it because it's not ALARA to force it down to 10.

MR. CAMPER: Right.

CHAIRMAN SIEGEL: It makes her exposure higher.

MR. CAMPER: I understand. And I'm simply saying you could just keep operating with that mindset where we have this 10 percent that we can work with in terms of a recordable event. As long as we stay below that, just administer the dose and it's a regulatory no never mind.

CHAIRMAN SIEGEL: Right.

MR. CAMPER: I mean, you could operate under that mindset is all I'm saying as an option, amongst the other options. By contrast, you could say: Look, we're going to

make sure there is a specific dose and the authorized user is going to be involved in every case. And you're going to go about changing your business in how you do it differently.

You will be involved. For example, under the administrative procedures idea, you could set up in your procedures that the dose will be administered provided it's within 10 percent. If you assay the dose and you find that it's greater than 10 percent, come see me, and I'll modify the written directive as an administrative procedure. You could do that.

So, I mean, in one case you're actively physically involved, you see them all, you sign them, et cetera. In the last bullet you set up a set of administrative procedures for dealing with it. So those are other options. So I've already discussed about five options, I guess.

So I think the last two or three options kind of look at this and say, you know, the burden here is not profound, and there are things that you can do about it from a practice management standpoint to deal with this problem and keep it a no never mind or there might be some things that we could do also to help alleviate what might be a burden.

Do you have much of a reaction to those last two or three options?

CHAIRMAN SIEGEL: Well, I mean, the specific dose is the status quo. And the administrative procedures are a modification on the status quo.

MR. CAMPER: That's right.

CHAIRMAN SIEGEL: No, no reaction. I mean, I really think -- you spent a lot of time on this. I really do think this is a small problem in the final analysis. And I really support the underlying philosophy of the quality management program, which is that for therapeutic procedures and for procedures that involve large doses of I-131, it's appropriate for an authorized user to be in the loop and make a decision and give the directions.

Whether you deal with this issue right this minute or whether you keep that clear target in mind as your Part 35 revision starts to roll up is I think semi-irrelevant. What's important is you want to get that accomplished without having the paper trail burden and without having the standard of care modified in the process.

And maybe with clever language the next time around, this will be less of an issue. The real issue for the directions of the authorized users that are in accordance with the standard of care, which we'll define, followed out by the people working under the supervision of the authorized user.

In Dan's case -- and I agree with him. I don't know a teletherapy physicist in the world who would write -- I

mean, physician who would write 120 to 240 centigray per day. They won't write --

MEMBER FLYNN: There was a misadministration that I looked into where the radiation oncologist, who wasn't Board-certified, gave verbal instructions and then was unclear about the dose. But of the 3,000 radiation oncologists in the United States, I don't know one --

CHAIRMAN SIEGEL: But you all are not taught to write your prescriptions and your treatment plans in a dose range. You're taught to say fractions of 200 centigray per day, and you've got machines that are capable of making those measurements to the nearest millisecond in terms of the timers. And so you do it that way.

You've got problems with brachytherapy because you don't know at the front end exactly where the sources are going to be, but the quality management rule allows you to make adjustments. And it's really only with I-131 where there really is this great therapeutic flexibility and the potential to inconvenience and occasional physician who works at two remote sites that this comes up.

So maybe enforcement discretion is the best way to deal with it for 1995, but keep that clear objective for 1998 or '7 or whatever.

MR. CAMPER: Yes. I think if in the final analysis when we revise Part 35 if you assume for the sake of

the discussion that the quality management component of Part 35 would survive, I think that the interaction with the regulated community the next time around will be a lot more focused upon: Okay. If this thing is going to be around, what should it really look like?

I mean, I think the first time around my impression was there was an opposition to the idea philosophically amongst many. I think if you get to the point where it's going to be in there for the sake of discussion -- and that will need to be discussed. I don't know that it will survive or not. But if you get to that point, then clearly the focus becomes: Okay. If you're going to have it, what should it look like? And what would not be a burden to the community?

Okay. Thank you very much.

CHAIRMAN SIEGEL: Any final comments, anyone?

(No response.)

CHAIRMAN SIEGEL: Okay. Good. Janet, talking about revisions to Regulatory Guide 10.8.

MS. SCHLUETER: Good morning. Originally we had a couple of hours blocked out for this discussion, but I don't think it will be long. And we won't go into that detailed of a review of the work that we've done thus far, but I will provide you an overview of the project. And you have received four licensing modules in draft for discussion.

For those of you who are less familiar with Regulatory Guide 10.8, this is a sample copy. And this is the book which medical use applicants use to complete their license application forms and submit to the NRC for review.

It basically contains a body portion up front full of general information, appendices in the middle to give model procedures, and exhibits at the end which are model forms to be used. The current version that we're all working from is Revision 2, which was published in August of 1987, after the rule was published in April.

You've heard us talk about the five-year medical management plan that the NRC uses to manage at least a portion of its regulatory program. I'm the project manager for the medical management plan, and it has approximately 90-some action items in the plan over a 5-year period of time. It was implemented in October of '93. The revision of Reg Guide 10.8 is one of those such action items in this five-year plan.

The scope of the current revision that we're working on now and that we have before you is fairly limited. The purpose is to consolidate licensing guidance that we have currently in internal policy and guidance directives, standard review plans, and similar types of documents so that Reg Guide 10.8 becomes a more comprehensive licensing manual, both for applicants, licensees, and the NRC staff.

The idea is to add as much information to Reg Guide 10.8 that the applicant will be able to submit a very comprehensive license application. The NRC staff will have more information on the front end for which to conduct its review. And the process of identifying deficiencies through a letter back to the applicant and so forth we hope to be increased and more efficient in that the volume of information provided to the applicant will be greater.

So what we're trying to do now is to add modules. We're referring to them "modules" for lack of a better term. We're trying to add modules to 10.8 to provide this licensing guidance for all types of medical use currently authorized.

There are three modules that we have that will be affected by the final patient release rule. Out of the total of seven licensing modules, the three that will be affected by this release criteria are: The radioactive drug therapy modules, mobile medical service module, and manual brachytherapy, for the obvious reasons.

If the limits change on when you can release a patient, therefore, the guidance will change on what radiation safety instruction is appropriate, when can you let them go, how much activity can you administer in a mobile medical service scenario and so forth. So in some ways these draft licensing modules and Reg Guide 10.8 are evolving now and will continue to do so in the next few months.

As I mentioned, the medical management plan has as part of it this major revision to Part 35 that we've been referring to over and over again. Naturally when Part 35 is revised, we'll have to turn around and overhaul Reg Guide 10.8 again to reflect the new rule.

But we needed a fix now. We needed to provide more comprehensive licensing guidance in the interim. That's what we're trying to do with this project now: beef up Reg Guide 10.8 to consolidate our licensing guidance for all types of medical use, Band-Aid fix, let Part 35 rulemaking run its course, and then overhaul 10.8 again.

In order to accomplish this, as project manager I arranged for a task force which consists of headquarters and regional staff. We have about 12-13 members or so. And we developed working groups to develop the seven different licensing modules.

There have been four developed so far, and you have received those four. Our NRC regional offices are lagging just a little behind you in the sense that you actually have all four in your book. They have received two along with the agreement states, other NRC offices here at headquarters. And the second set, the radioactive drug and mobile medical services, are en route to the regions.

So they're lagging a little bit behind you. If you were to call them about the specifics, they wouldn't have

it in front of them at this time. So you have four. You have: The manual brachytherapy; teletherapy; radioactive drug therapy, which is new; and mobile nuclear medicine.

The manual brachytherapy, as it stands now, this guidance is currently located in our standard review plan and internal licensing guidance. There really isn't a set-specific document to provide just guidance on manual brachytherapy.

The teletherapy is a current draft reg guide, 1985 I believe, pretty old. And there's really nothing much new in the teletherapy arena, as you know. So it's a matter of taking this old draft reg guide and changing its format and placing it into Reg Guide 10.8.

Also when the draft teletherapy reg guide was developed, there wasn't the specific requirements and criteria in Part 35 that there is today. So some of this information that was currently in the old draft teletherapy guide has, in fact, been superceded by the rule and can be, thus, eliminated.

Radioactive drug therapy is a new module for us. In mobile nuclear medicine, we have a current policy and guidance directive on mobile nuclear medicine. It's been out for about three years. And since then we've seen different scenarios evolve in the mobile medical service arena. And, therefore, there are things that we need to do to that module

now to reflect current practice and current licensing practice.

The ones which are still in development are the ones listed there to be issued for first-round comment. And that's remote after-loading brachytherapy, which, in fact, is a revision of the existing Policy and Guidance Directive 86-4, which we discussed yesterday. And some of that licensing guidance, as you mentioned, needs to be revised and, as we also discussed, will probably be codified in Part 35 eventually.

The gamma stereotactic radiosurgery is new. We have issued licenses for gamma stereotactic radiosurgery, and we have done that based on teletherapy guidance and also just good health physics practices and have come up with licensing guidances for the gamma knife.

We also have in parallel with this effort a research contract study that has just been completed on quality assurance, quality control in the gamma knife, which has provided us some useful information that will be incorporated into the module.

The training and experience module is going to be guidance that was based on the draft P&GD that we issued in '94, which was the center of our energetic discussion yesterday afternoon.

CHAIRMAN SIEGEL: What's it going to say?

MS. SCHLUETER: Well, it has other issues in it besides the hot one we had yesterday. So it's going to talk about things like, let's see -- I wish I had it in front of me.

CHAIRMAN SIEGEL: That's okay. I actually don't --

MS. SCHLUETER: They're a little bit more generic and administrative in nature, and maybe we won't explain that right now.

CHAIRMAN SIEGEL: It was a rhetorical question.

MS. SCHLUETER: Okay. I'll take it as such.

In order to do this interim Band-Aid fix on Reg Guide 10.8, we originally thought that we would just develop the licensing guide as modules and let it go at that. But then as we know, there have been clarifications that have been needed to Reg Guide 10.8 since it was issued in 1987, things that we felt like either were inconsistent with the rule, weren't clear enough, we could have provided additional information on and so forth.

So we thought, "Well, we can't let the licensing guidance modules go out alone. People won't really understand the project in toto and how it all fits in with Reg Guide 10.8 and so forth. So while we're doing the modules, let's overhaul the general body of Reg Guide 10.8," the information that's contained up front in Pages 1 through 16.

So what we've done thus far is to make a first-round draft of the revision of the body of Reg Guide 10.8. And now we're working on the modules as well.

The draft modules and the revised body of Reg Guide 10.8 are scheduled to be issued for public comment in accordance with the medical management plan this fall. But we need to recognize also that there are some outside forces which affect the timing of this project.

As I mentioned already, there's one rulemaking, patience release, which will have some effect on three modules. That rule is scheduled to go to the EDO for Commission approval late June of this year. If it's on track, then we can stay on our track of the September-October time frame. If that gets waylaid, we're going to be a little behind.

Also, as I think we'll hear later this morning on BPR, the business process re-engineering, there is this other parallel, much more comprehensive, effort in the licensing guidance arena and how NRC processes license applications and so forth that could affect the final product in the sense: How will we distribute this document for public comment? What will it look like? Will it be attached to other licensing guidance?

I think Dr. Cool's idea is that there be one single huge regulatory guide for all materials licensing. So

Reg Guide 10.8 could be lumped into a much more voluminous volume of information for materials licensees in general.

So we have to feel these things out and see what their impact will be on the modules in the project that we're doing thus far. But it is interesting to note that one of the major concepts of BPR is these independent management teams. We had, in fact, already begun that approach to this project a year and a half ago, when we developed these working groups, and sought regional and headquarters expertise to develop the guidance that we have thus far.

So we're working along in parallel lines, but we're cognizant of each other's efforts. And it could affect the timing of this project.

Now, in light of all of that information, as I mentioned early on, my goal this morning was not to go into a detailed review of these licensing modules. And that is because what you have before you is a version which has just gone to our regional offices, two out of the four. The other two are en route.

I have received a significant amount of comments from the regions on the manual brachytherapy and the teletherapy modules. Those need to be considered by the working groups, and the modules need to be revised. The radioactive drug and the mobile nuclear medicine they do not have.

Once those modules are revised based on regional comment and so forth, I think that that would be a better opportunity for ACMUI members to focus more intensely on each module.

We do think it's important, very important, that we have your input on these modules before they go for public comment, which is scheduled this fall.

So I might suggest to you, Mr. Chairman, that we do one of two things: We either send to you all draft licensing modules in a more final state late summer and solicit ACMUI comments through you in a written format or however you choose to do that back to us or we or you decide to convene a subcommittee of the ACMUI and actually work through the language of the draft modules late summer in a working group environment here in headquarters and so forth. That would take a good day, day and a half, I would imagine, at least, because there are seven, much less the general body up front of Reg Guide 10.8.

So we're very interested in getting the comments. I don't want to do that today. I don't think people are even prepared. I think it would be premature and a waste of your time to go into that detailed of a discussion. I am going to step through them, though, for general concepts of the modules, but not in detail.

CHAIRMAN SIEGEL: I guess there's a third option, --

MS. SCHLUETER: Sure.

CHAIRMAN SIEGEL: -- which is that any one or two of us at a given moment could come in and meet with staff as consultants, --

MS. SCHLUETER: Certainly.

CHAIRMAN SIEGEL: -- not requiring the public meeting format that a formal subcommittee meeting would require, and give you our thoughts. Then those more digested thoughts could be presented at a subsequent formal ACMUI meeting as a way of getting commentary.

So I think all three options work. My sense is that it's important enough to discuss these with staff so that people just writing their comments and sending them back to you will not be as effective as the opportunity to sit down with you.

And so I think I'll leave it to you whether you would prefer to do using groups of us as consultants, like brachytherapy, teletherapy. You could have --

MS. SCHLUETER: Right.

CHAIRMAN SIEGEL: -- Judy and Dan and if you get the brachytherapy therapists on board come in and meet with some staff for part of a day or as a subcommittee. For the

other things you may want to get a slightly different group. And we can do either one.

MR. CAMPER: Yes. Good suggestions. I think with regards to the idea of subgroups or parts of the Committee -- and it may be an administrative issue, but I want to make certain that the guides undergo the review and the opinion on record of the ACMUI. Now, your subcommittee approach would cause that to happen.

CHAIRMAN SIEGEL: Correct.

MR. CAMPER: It's not clear to me as I sit here right now, though, that two or three individuals meeting with -- how would you then translate that into the Committee's review of --

CHAIRMAN SIEGEL: If we did it that way, then the Committee would have to review it at the time of the next formal meeting. And, as I think we did with the patient release criteria, a group of individuals came in as consultants. And they provided a report of what they had discussed with the clear understanding that what they had discussed was not the actual formula process of consensus generation. It's a fine point. And I understand the FACA requirements that make the distinction.

But subcommittee meetings are fine. It's just that it puts the additional burden on you of booking a room,

noticing it in the Federal Register and all of that, but it's easy. Let's do it.

MR. CAMPER: Well, if we took the approach that you were discussing just a moment ago, you end up then with the ACMUI's comments and formal review, if you will, being on record during the public comment period, --

CHAIRMAN SIEGEL: Correct.

MR. CAMPER: -- which is okay, but --

CHAIRMAN SIEGEL: You'd rather have them first?

MR. CAMPER: I'd rather have them first. I'd rather --

CHAIRMAN SIEGEL: Then let's do subcommittee meetings. I mean, I think we'd better get moving, but I think if you want groups of three or four of us to come in as subcommittees to look at different chunks of these during the summer, we'd better start thinking about dates real soon.

MR. CAMPER: Well, last evening at about 9:00 o'clock Janet and I were discussing that very thing.

MS. SCHLUETER: 10:00, Larry.

MR. CAMPER: Was it 10:00? I'm sorry. I'm getting into the Barry Siegel syndrome. I could have sent her an E-mail, but I didn't have a computer at home.

Really, the timing would almost have to be certainly by the end of July at the latest.

CHAIRMAN SIEGEL: Let's do it. I mean, we don't have to do it right now, but --

MR. CAMPER: We could set it up.

CHAIRMAN SIEGEL: -- let's you and I go figure it out.

MR. CAMPER: Yes. And we could set up a subcommittee meeting that would occur here if we have staff access and so forth and so on.

CHAIRMAN SIEGEL: Yes. It needs to be here.

MS. SCHLUETER: Okay. So having settled that or somewhat settled that, I'll give you just a brief overview of what we were trying to do with the body of Reg Guide 10.8 and walk through the modules just briefly to let you know some of the highlights of the modules and their purpose.

The body of Reg Guide 10.8 in Rev. 2 is Pages 1 through 16. It's been expanded to about Pages 1 through 40. And when I said that to Myron, he got real excited. And he said, "Oh, my God. You're going to require even more information from them?"

And I said, "Well, the idea is to provide more information on the front end so that the licensee or the applicant has a better idea of all the information that NRC needs during the license review process." We were trying to give more comprehensive information.

The NRC has a system in place where you put out a reg guide for the public and then internally you have what you call a standard review plan, which is usually the reg guide with possibly some reviewer notes thrown in throughout to add additional guidance to the reviewer.

Well, that concept is fine, but we decided that perhaps we'd move away from that slightly and increase the body of knowledge in Reg Guide 10.8, anything that the licensee or applicant may even by chance need to know and make it more comprehensive so that our standard review plan internally will look something more like a model license and a checklist.

The kinds of things that we did under the minor administrative cleanup are minor, you know, things like our regional offices have changed addresses, moved around. We've added an NRC regional map. We're going to add an agreement state map into the body up front, conforming changes to references to the regulations, such as Part 20, that have changed, and so forth.

The new information that we've added to the body of 10.8 to make it more comprehensive and hopefully more efficient in the licensing process are things like we need to add a discussion on the need for a QM plan which somehow in all of this flurry of activity on QM I failed to put in thus

far. So it's not in the copy you have now. I don't know how we forgot about QM, but we did.

CHAIRMAN SIEGEL: I can understand why you did that.

MS. SCHLUETER: So we'll need to add something, bringing it to their attention, of course, that there is a need for certain types of use to have a quality management program.

We have enhanced a discussion on the role of executive management. This does stem out of the draft NUREG 1516 on management of radioactive material safety programs at medical facilities. This is to heighten the awareness of executive management, if you will, of their responsibility over the licensed program.

We also added new things like reference to the training and experience criteria for authorized nuclear pharmacists that didn't exist before January 1, 1995. It's important to note. And we lay out the criteria or, else, we reference it where it can be found. I can't remember which.

And we discuss a little bit about measurement of alpha and beta dosages; in other words, reliance on the manufacturer and so forth. So this is another parallel effort that I didn't mention. We've had to move along with Donna-Beth's and Sam's efforts in the radiopharmacy arena in order to have Reg Guide 10.8 reflect those changes as well.

Everything that happened to Part 35 with radiopharmacy, meaning 35.52, .53, and so forth, we need to reflect as well. So we evolve and evolve and continue to evolve. And it's got to stop somewhere this fall.

Also a reminder of air emissions control and compliance with Part 20 limits there. It wasn't there before. And we've added some information on waste management, like returning sources back to a manufacturer.

Earlier version just says "Well, you've got to have waste disposal procedures. And if it's not the normal decay in storage, tell us what you're going to do." So we've tried to provide more comprehensive guidance in options that licensees currently exercise to get rid of their radioactive waste.

Now, in order to give some credit here to the people who actually wrote these modules, it wasn't me. We had staff members in the medical and academic sections, as I mentioned, and also regional people. Trish Holahan was the primary author on the manual brachytherapy. On teletherapy it was Jim Smith. On radioactive drug therapy it was Sally Merchant. And on mobile medical services it was Torre Taylor. And they had regional components to assist them in this effort.

So I'll talk about these modules, but they deserve the credit in time and effort in writing them. That

means I don't really know anything about them and you're going to have to ask them. Right?

The manual brachytherapy module was created to do many things, one of which was to address the use of the strontium-90 eye applicator, because there is no specific licensing guidance laid out explicitly for the use of that device, although we have it in other licensing guidance documents that we're using.

It also addresses temporary implants, permanent implants, and eye plaques that use iodine-125 or palladium-103 seeds. Eye plaques are considered an interstitial treatment and are authorized under 35.400.

It also discusses topical, interstitial, and for NRC purposes the fact that inter-cavitary equal inter-luminal. There is no distinction in our minds.

There's an enhanced training program for nursing and ancillary staff and contractors. It goes into things like the awareness of the quality management program and what that means to individuals who are caring for the patient and others.

We suggest that the training be very specific for nurses caring for these patients in brachytherapy. For example, there needs to be training where dummy sources are shown to the nursing staff so that they'll be familiar with the size and appearances of these sources, emergency kinds of

drills, if you will, and in the event that a dislodged source is noted by nursing staff, what do they do, who do they call. This gets into some of the discussions that we went through yesterday as well, reacting to emergencies.

Also it discusses necessary components of the radiation safety program, such as facilities and equipment, what type of shielding do you need to have available for implant patients' rooms and remote handling devices as well, personnel monitoring if it's required by 20.1502 and how do you give them instructions on the use of that device and records that are associated with the uses of those devices, handling of sources, equipment that's necessary, training of personnel, and so forth, also implant source records.

What that really means is your use log, where did you take the sources to use, who did you implant, what room was it in, what time did you take them, who took them and so forth; and inventory. You need to have a locked safe, a trained staff, a map of the source location, verification of the sources upon receipt from the manufacturer, when you took them to the room again and when you returned, did you have the same number or do you suspect there's been one lost and so forth, the normal radiation safety protection procedures that you would have when you conduct implant therapy.

Area surveys, the quarterly surveys that are currently required and post-explant and patient prior to

patient release as well and, as I mentioned, temporary implants and permanent implants and the release of patients.

There's an important item to note under the permanent implant portion I think in the sense that we remind licensees that a patient who has undergone an implant procedure for a permanent therapy procedure, licensees are reminded that once that patient is released from confinement pursuant to 35.75, the NRC does not hold the licensee responsible for the implanted material.

However, we've had cases, had licensees come to us that had exhibited good health physics practice in the sense that if they released a patient today and that patient had a medical emergency and died on Saturday or Sunday or so forth, they would take it upon themselves to contact the embalmer, mortician, or whatever, and at least let that individual know that yes, there are iodine 125 seeds implanted in the neck and so forth and so on.

So we would expect that. And we see that licensees demonstrate this type of health physics practice. And naturally we endorse that, but we remind licensees that once the material is released, it is released from your control. We are no longer responsible for it as far as the NRC is concerned.

I did want to mention, I didn't mention before, that each module has a glossary attached to it. And that's

just to sort of help the reader, help the individual who may not be perhaps so familiar with the medical use area, maybe the management types and so forth. It's a pretty basic glossary, nothing too exciting.

The second module is teletherapy. It basically -- sorry. I guess we should open it up for comments on each module. Sorry about that.

CHAIRMAN SIEGEL: Any big picture items on the brachytherapy module?

MEMBER FLYNN: Yes. I'm really happy to see this here because I've been looking for this for four years now. The training for nursing staff is 1,000 percent better than it was in the past.

MS. SCHLUETER: Great.

MEMBER FLYNN: And I really want to compliment you on that. I had a few comments, but I'm not going to give them now.

MS. SCHLUETER: Okay.

MEMBER FLYNN: But it's excellent.

MS. SCHLUETER: Well, if you even want to mention those to Trish directly, we'd be happy to make those modifications now.

Did you have comments, Dr. Stitt?

MEMBER STITT: No. To keep it short, I won't except I agree strongly with what Dan had to say.

CHAIRMAN SIEGEL: Good.

MS. SCHLUETER: Good.

CHAIRMAN SIEGEL: All right.

MS. SCHLUETER: Great. Now, teletherapy. There's not much to say about teletherapy, really, in a sense that: Has teletherapy changed? No. Have the devices changed? No. Is its use increasing? No.

We had a draft licensing guide that was put out, as I mentioned. A lot of that information has been codified. The idea simply is to change the format of that old reg guide and dump it into Reg Guide 10.8 as a licensing module. And there's not much new there. I'll step through these items briefly if you'd like. It does discuss the T&E for physicists, but that's in the rule now, as described in 35.961.

Under facilities and equipment, it goes into things like a detailed diagram of the facility, the viewing system that we mentioned yesterday, the television monitors, warning systems, access control, shielding, interlocks, all the things that you would expect to have, emergency instructions for when the source fails to retract.

And it provides model procedures in that area as well as model procedures for operating procedures; sample survey reports to the NRC; safety checks; instrument calibration; monthly spot checks; daily QC inspection and

servicing of units; waste disposal, which again includes returning the sources to the manufacturer; and recordkeeping requirements as well as a glossary.

Radioactive drug therapy is a new one. And up until just a few months ago, we were calling it radiopharmaceutical therapy. But we're getting in line with the radiopharmacy rule jargon. We changed the title to radioactive drug therapy.

In the very beginning it references the human research requirements that are outlined now in 35.6 that were codified as part of the pharmacy rule. And it references Appendix Y, which also we discussed yesterday as well.

It, too, has a training program for nursing staff and others and is only a slight modification of that that we put in for the manual module because many of the things applied.

Obviously we don't need to know about sealed sources. So we made it relevant to drugs. But there are a lot of the same components there: QMP, posting, handling contaminated items, visitor control, patient release, and so forth.

We also describe the necessary components of the radiation safety program facilities and equipment, including shielding, the detailed diagram to indicate the shielding and

control of emissions, but this is all very dependent on the types and quantities that you're going to be using.

So it's very general guidance in the sense that we could not get very prescriptive because we expect the applicant to come in and to demonstrate to us that depending on the amount of material, types of materials and quantities that they would be handling at any one time, that they have sufficient facilities and equipment in the way of shielding and handling equipment, emissions control and so forth.

So we give this broad picture example of what we would expect, but we're not very prescriptive at all. And perhaps this is where your comments now or later would be helpful in the sense that: Is it too wide open? Is it too general? Is it too generic? Do we need to be more prescriptive?

For example, on a discussion of instrumentation calibration and measurement of alphas and betas, there's not a lot to say other than the rule allows you to rely on the manufacturer. And we think that perhaps if you're not going to do that, you're going to come up with a volumetric calculation or you need to demonstrate to us that you have some other mechanism or instrument specifically designed to measure the alphas and betas. And if so, give us that information.

We'd like to take a look at what you have because as the radiopharmacy guide I think pointed out yesterday, there's not a lot of specifics to be laid out for the measurement of alphas and betas. And this is another area that we'd like for you to think about and what kind of guidance would be appropriate to give to the licensee here.

As you know, now the appendix to Reg Guide 10.8C I think it is or D is for photon emitters. I mean, it didn't ever consider alphas and betas. So is there guidance that we can give to applicants or licensees that would be helpful in this arena?

CHAIRMAN SIEGEL: I think there's a generic answer to the question that we've given before. And that is it's premature to put specific guidance in given that there aren't any approved drugs for doing this in the United States.

And as long as specialized places like the NIH and the University of Washington are doing this with in-house products, they have a responsibility to write their licenses in a way that shows that they can do it safely.

But it would be a mistake for you to put anything terribly specific in in anticipation of the approved drugs that aren't on the street yet. The minute you know one is coming, that FDA is at that point, then it's time. It will be time to put something in.

But you might get yourself down the wrong path if you put too much specific information in at the front end.

MS. SCHLUETER: Well, we don't want to be not helpful.

MR. CAMPER: Barry, what about the betas?

CHAIRMAN SIEGEL: Which? Name one.

MR. CAMPER: Strontium-89.

CHAIRMAN SIEGEL: I mean, basically what virtually everyone is doing is relying on the manufacturer and/or using a volume measurement and not confining the patient.

MR. CAMPER: Well, I understand why you would say that. Generally I think that's true, but we did have, for example, one episode where there were seven events that initially were thought to be misadministrations where there was clearly a lack of understanding that if I removed the dose from the vial which I received and put it into a syringe, that I then face a different density situation and the geometry is different and my dose calibrator will not necessarily demonstrate what actually is in the vial.

And in the case at hand, by the way, the RSO, who is a physicist, was aware and apparently didn't either pay attention to or didn't understand some of these differences that you have and difficulties in measuring the high-energy beta emitters.

So the question then becomes you could use just general guidance like Janet was referring to or -- I mean, the volumetric part of it is fairly easy. And you could step through just a general discussion of that.

The question becomes, though: Do you get into more detail providing some specific guidelines about how to actually measure and some of the technical consequences that you need to be considered about when measuring some of these high-energy beta emitters?

CHAIRMAN SIEGEL: It wouldn't hurt to put in some clarifying information that says that "If you plan to do this, these are the things you have to consider." There also are some pretty decent NCRP documents on measurement of radioactivity that you could refer people to.

The average Part 35 licensee is not going to be getting into this business if they can avoid it any time soon.

MS. SCHLUETER: That's right.

MR. CAMPER: Well, I think what happens, though -- in this one incident, which was a university setting, there were seven of these events. But there have been -- in fact, we put an information notice out. Torre Taylor authored an information notice.

There had been a number of instances where there was not this understanding when I go into a vial and I put it into a syringe, that unless I know what I've done and account

for it, my dose calibrator is not going to measure the same with that situation. We have started adjusting the dose accordingly. And obviously there is a mismatch there.

MEMBER SWANSON: It was from a prepared manufacturer?

MR. CAMPER: Yes.

MEMBER SWANSON: They could have done a volumetric calculation?

MR. CAMPER: Yes. And they put it in the dose syringe.

MEMBER SWANSON: Following volumetric calibration, they --

MR. CAMPER: Put it in the dose calibrator. The numbers don't match up. So they started adjusting the volume of the dose because they don't understand the problems inherent in the measuring.

CHAIRMAN SIEGEL: That's a problem.

MEMBER SWANSON: That's a problem.

CHAIRMAN SIEGEL: Guidance would be helpful on that one to make sure people don't make that mistake.

MS. SCHLUETER: I think what we have there generally addresses that, but we need to enhance it; right?

It walks through personnel monitoring requirements and bioassays, the criteria used to determine the type and frequency of a bioassay that the licensee proposes is

needed. Inpatient procedures, it emphasizes the use of the private room and bath, which these are all currently required things. The patient is to the extent possible isolated in a less trafficked area, if you will, but consistent with obviously good medical care.

Radiation surveys and detection surveys, which are necessary, it discusses those in order to decontaminate the room down to a releasable level.

And confined patients who expire, we have a little bit of information on that with the respect that if you have this patient who is confined because of 35.75, you need radiation protection procedures if that patient expires to ensure that other workers, members of the public, mortician and so forth, are not likely to receive dosages in excess of the Part 20 limits. So it goes into a little bit of discussion about inpatient and patient release procedures.

Would anyone like to comment on that module?

MR. CAMPER: I want to add an administrative point for the record. We did ask Dr. Rotman to comment on this module for us.

MS. SCHLUETER: True.

MR. CAMPER: And as we continued to develop this module, we would certainly go back to him again. I think I've seen a rough draft of his comments. I expect we'll get something formal from Mark. And then we'll look at that as

well through this process and continue to keep him in that loop.

We felt that his involvement previous with the agency and as a radiopharmacist, he was in a good position to provide viable comments on radiotherapy. So we'll keep him in the loop on that.

MS. SCHLUETER: Good point.

Now, mobile medical services. As I mentioned earlier, this is superseding a current policy and guidance directive. And it in some ways provides greater flexibility to accommodate what we see as an evolving industry.

Now, to backtrack on the discussion yesterday with the coach on the HDR, this mobile medical service module does not address therapy, mobile therapy. It addresses the diagnostic use of radioactive drugs. Okay? So it is limited in its scope.

However, there appears to be an increase in the use of mobile services, obviously more than there were even two, three, five years ago. And it's important for us to reevaluate the module that we have thus far and continue to be sensitive to the licensing restrictions that we would place on this type of service because we don't want to be burdensome or restrictive on a service that obviously is needed and we could provide the flexibility that's needed by this industry to provide the needed medical services.

So we need to be very conscientious of this effort and not make the licensing guidance too burdensome and restrictive. We're already seeing slightly different scenarios than we did just a few years ago on what applicants want to do as a mobile service.

Anyone that comes to us, has a request to do therapy in any type of therapy, whether it's radioactive drug or sealed source and so forth, has to request an exemption to the current regulations because it is prohibited in Subpart J. It only allows the diagnostic use of radioactive drugs in a mobile service.

The things that the mobile module discusses are the locations of use. There can be different locations. When we say institution, we mean a medical facility that has three or more medical disciplines, several authorized users, hospitals, some clinics, universities, and so forth. The non-institution, what we're calling a non-institution, is your group practices, private practices, that offer a limited number of services, limited number of authorized users, and that don't constitute your full-blown medical institution. Also commercial facilities can be a location of use and client properties which are leased to service companies.

CHAIRMAN SIEGEL: Two suggestions early because I think it's important. The term "medical non-institution" is a

nonterm. I think we've got to work hard to help you come up with a better --

MS. SCHLUETER: It is. We struggled a lot when we wrote the guidance that we did last summer to provide guidance to our regionals on: How do you distinguish those private practices and group practices that are growing that start having a lot of authorized users, that start providing a lot of medical disciplines, that incorporate, that become facilities that look like clinics, hospitals, medical centers, and so forth because they're providing an analogous level of service but had historically been called private practice?

CHAIRMAN SIEGEL: But even your definition I don't think does it because I just jotted a little note to myself. Your definition of medical institution means an organization in which three or more medical disciplines are practiced and more than one physician is associated with the medical practice, regardless of the number of authorized users.

So here's a medical institution for you. We've got a group practice consisting of two doctors, one of whom is an internist who is authorized to use I-131 for uptake dilution and excretion measurements. So you now have one authorized user, and we're doing this work. And we have another doctor who claims to be both a surgeon and an obstetrician. According to this, that's a medical

institution. And that could be a little, tiny office somewhere out in the middle of Montana.

We've got to help you come up with a better definition.

MS. SCHLUETER: I agree. It's been a difficult one to resolve and to define. And we're already getting test cases, if you will. We have a couple in now from the regions, and it's putting this definition to the test.

I've already been able to identify one or two problems with the current definition. So this definition has to continue to evolve to address those types of circumstances that you just mentioned.

CHAIRMAN SIEGEL: The real issue is who you issue the license to? Is that?

MS. SCHLUETER: The real issue is who you issue the license to, but it's bigger than that in a sense that some of these programs are large enough that they should be subject to additional radiation safety requirements, like they need a radiation safety committee.

There are regulatory requirements in Part 35 that apply to medical institutions that don't apply to private practice and so forth. And when you have these private practices, which are growing, growing, growing, and, in fact, should have the management oversight structures or radiation safety committee and so forth comparable to a medical

institution, we realize that your private practices, traditional private practices, aren't necessarily so traditional any more. And perhaps there should be certain mechanisms there that aren't there today.

So it's not just: Who do we issue the license to? It's management oversight, program oversight, and so forth.

MEMBER QUILLEN: From the licensing point of view, there's also an issue that we've faced. And that is when you have this kind of an arrangement, is it really an institution or is it a private practice?

In other words, are you actually licensing an organization or are you licensing an individual? And because of the business arrangements, sometimes that becomes very unclear as to which you are actually addressing.

We've wrestled with that in several cases in our --

CHAIRMAN SIEGEL: Is that ultimately going to be legally defined by how the corporation that you're licensing defines itself? I mean, if it's Dr. Jones, PLC, then it's a private practice.

If it's University Medical Consultants and it's clear that the corporation includes multiple doctors, then it starts to sound more like an institution, starts to sound. This is a tough one.

MS. SCHLUETER: Yes. There are two kinds of pathways that the issue of incorporation, business relationship, and so forth come up, one of which is a document that we have that provides guidance on change of ownership issues when somebody sells out and so forth.

We have guidance in one of our policy and guidance directives or manual chapter or whatever that addresses what information do you need from these entities to determine their relationship to one another and who's in charge and so forth.

So it gets addressed there and then also in the licensing arena here just what requirements do these facilities need to meet in order to increase our comfort level with licensing them.

And that's what I mean by we have a test case right now, almost exactly what Bob just described. We have this group of physicians, only one of which is an authorized user. They sit in private office suites, but they have this building which they own or lease and operate under this corporate umbrella. So they start to begin to walk, talk, and look like an institution, but, in fact, are they? And it's an example we have right now.

Now, OGC did work with us on the definition that you read there. I wouldn't have walked that one alone. They worked with us carefully on that definition. And since then,

as I said, we have found problems with it. We have found holes in it that we had to go back and reevaluate that definition. But they've been involved in this process.

CHAIRMAN SIEGEL: Go ahead, Larry.

MR. CAMPER: I just want to take this opportunity in the realm of mobile to plant a couple of seeds in the minds of Committee members because this is an area where we're going to really need your help in this immediate sense as you look at this guide for us in the next few months, but also as we ultimately move to revise Part 35. This is an area where we really need your help. And we need your help in a couple of ways.

If you look at the guide, what we've done today is we've tried to construct a guide so that it's consistent with the current regulatory requirements or allowances for mobile.

Now, we just had a case recently. It involved a licensee who is in an agreement state who wanted to come into our jurisdiction for reciprocity. And in reciprocity, they can do what they can do by virtue of what's authorized in their agreement state license.

But the problem is that reciprocity, some of the conditions and provisions of reciprocity, don't recognize, are not necessarily suited for medicine, the practice of medicine, short-lived isotopes. They were really built around such

things as industrial radiographers and well loggers and so forth.

But there are some interesting things that come to bear with mobile, and that is, on one hand, for example, if you look at our regulations today in 35.29 and 35.80 about where you can receive materials where you're conducting, for example, you can't receive materials at your client's facility. You can get them delivered to your base operation. You can transport them there, but you can't have them received at your client's facility.

Now, arguably, some might think that's overly burdensome. You might be able to, for example, put in place administrative procedures and regulatory safety procedures and so forth that would allow you to do that.

Another big issue that comes up -- and so the immediate sense is take a look at this, helping us with guidance now, but as you do that begin to think ahead because I think when we revise Part 35, there will be a stand-alone component for mobile imaging.

The question of the practice of medicine, the idea that I buy my mobile unit and I'm based in Maryland but I decide to move up into Pennsylvania and do some mobile imaging, what about the practice of medicine where you're licensed and which state to practice medicine? Is that an issue? I don't know. Is it an issue?

CHAIRMAN SIEGEL: If the physician's traveling with the truck, the physician who is rendering those services in Pennsylvania had better be licensed in Pennsylvania.

MR. CAMPER: Right. Well, this is just an example of some of the kinds of issues that you're up against when you begin to move about.

Now, on one hand, we have to make sure that we protect public health and safety, obviously. On the other hand, we have to recognize the emerging technology and the changes going on in the health care industry to consolidate, change ways, the services that are provided and so forth, while also recognizing practice of medicine issues.

So I think in the immediate sense you can help us by reviewing the guidance, but it's time to begin to think for the future because this is going to be a very interesting area as we revise Part 35. And you can play a key role there.

MEMBER NELP: I'd like to ask: How many mobile diagnostic units are there under your purview in the United States?

MS. SCHLUETER: Not many. The bulk of them are in Regions 1 and 3. Less than a dozen.

MEMBER NELP: Could you give me a number?

MS. SCHLUETER: Less than a dozen.

MR. CAMPER: That's in our jurisdiction. I don't know how many are in agreement states, but certainly more than that.

MEMBER NELP: My impression is that the mobile business has --

MS. SCHLUETER: Fifty.

MEMBER NELP: -- been dying, not flourishing.

MS. SCHLUETER: Okay. Excuse me. Let me correct myself. Torre corrected me to say that under the program code that's established for mobile medical services, there are 50, may be as many as 50.

MEMBER NELP: I'm sorry? There --

MS. SCHLUETER: There may be as many as 50 in NRC jurisdiction.

MR. CAMPER: Now, with regards to whether it's driving or dying, I can't really comment with any degree of validity, but our impression is that it's not dying. Our impression is that there's some shakedown going on in the industry and certain players are emerging.

But, for example, in the mobile arena, we are going to have at our front door very shortly an application for mobile HDR. The State of California in the last year or so has licensed a mobile HDR operation for the very same company. So maybe you know something I don't know.

But we see an awful lot of movement going on in the health care industry today amongst licensees to try to find more cost-effective ways to provide services involving radiation. We had an inquiry recently from one of the agreement states that has five or six hospitals and wanted to consolidate into one license. We've had a movement by one of the large commercial radiopharmacies in this country to consolidate licenses, 27 licenses, into one. There's a lot of activity going on along these lines of which mobile is a key component.

CHAIRMAN SIEGEL: Moving right along, I think we will provide comments. And it looks like this is your next to last --

MS. SCHLUETER: Yes. This is basically it. The one thing, in response to the kind of conversation we've had right now about the flexibility and so forth, it does go into things like: Where can you put a base hot lab? We need to know the scope of activities of where it would be. If it's proposed to be in a residential location, obviously there are going to be a few more concerns and pieces of licensing information that we would need before we could license such a situation.

At temporary job sites or clients' address of use, there are really two types of mobile services that go on. It's a scan and van, if you will, where the patient actually

boards the van and has the study done on the van or the service is performed at the client's address of use. They have the imaging equipment, and you're going in with the radioactive materials and the technologists and so forth.

We go through the necessary components of the radiation safety program, including checking of that instrumentation before use at each address.

The receipt of licensed material, Larry got into this a little bit. Currently 10 CFR Part 35 limits where you can receive that material, but we think that we should allow licensees to receive the material on the mobile van if the mobile van -- or excuse me.

Let me back up and rephrase that a little bit. Licensees should be allowed to receive at the client's address of use if they are receiving the material onto the mobile van that's providing the service provided that it is attended and can be kept secure and under their constant surveillance, as required by Part 35 now.

So typically that hasn't been something that we've had applicants come in and ask for, but that's the kind of flexibility that we're saying we're willing to provide in this type of revised guidance.

Our outpatient radioactive drug therapy. As I mentioned, therapy procedures do require an exemption. Emergency procedures, transportation requirements obviously

are important to us. Typically we have not allowed overnight storage on the mobile van. It needs to go back to the base hot lab location.

And waste management. We go into a little bit of a discussion about radioactive waste material that might be incident to the use. And also we had an interesting case just recently which Torre had the luxury of handling, which was a request from a licensee about holding human excretion in a holding tank on the van and how should they release it and what requirements really apply. So that was a new twist, and we got to do something a little different with mobile service there. So it's that kind of guidance that we need to incorporate in the module because that could, in fact, occur again.

That's all I have on this project.

MEMBER WAGNER: Could you answer, that no overnight storage on the mobile van, is that a regulation? Does that fall under regulation or what's the philosophy behind that?

CHAIRMAN SIEGEL: Probably securing radioactive material --

MEMBER WAGNER: Securing.

CHAIRMAN SIEGEL: -- blah blah blah, Part 20.

MR. CAMPER: You've got two problems. You have security in storage overnight.

MEMBER WAGNER: Yes.

MR. CAMPER: You also have storage in what's so-called temporary job sites is the problem, too.

MS. SCHLUETER: It's also not supposed to be stored in a public access area like a public road sitting next to a hospital or something like that. You have other Part 20 concerns on the release of that material.

That's why I said I qualified it that we typically have not authorized overnight storage on the van, mainly because I think what we have been seeing thus far are base hot labs which are operating, going out for the day, and returning and bringing the incident waste back to the base hot lab.

That's not to say that that situation won't change and we won't get an application for something different, and we have.

MR. CAMPER: Or that you wouldn't grant an exemption.

MEMBER WAGNER: Okay.

MS. SCHLUETER: Right.

MR. CAMPER: Because we have.

MS. SCHLUETER: And, as Josie mentions, we have according to the exemption for.

MEMBER QUILLEN: I just want to comment that in Colorado a number of local fire departments have started

enforcing uniform fire code, which has brought a lot of anguish to a number of our licensees because they were unaware of the criteria of that fire code.

And you might want to put something in your 10.8 to alert people to that fact that this is another set of criteria they may have to meet.

MS. SCHLUETER: You know, we did that in the mobile module, but it might be better to put it up front because it could apply obviously to other uses. We have it somewhere. I'm not getting it right at the moment.

CHAIRMAN SIEGEL: All right.

MS. SCHLUETER: Okay? Everybody happy?

CHAIRMAN SIEGEL: Yes, we are.

MS. SCHLUETER: Great.

CHAIRMAN SIEGEL: Janet, thank you.

We have to plug in about 20 more minutes of Trish's stuff from yesterday. The consensus I think is that the PDR questions that still are hanging on from yesterday we're not going to try to deal with because doing that without the physicists would not be prudent, but that there are a couple of other medically related brachytherapy questions that we could deal with.

So why don't we deal with those? Then we'll take our break. So go for it. Is that okay? Unless everybody is dying to break quickly.

MS. HOLAHAN: Good morning. For the record again, I'm Trish Holahan of the staff. I'm going to quickly just focus on a few things that are sort of more medical related. Perhaps I'd like to get some input on those.

Janet mentioned earlier and later on today you're going to hear about the patient release rule, but that rule primarily deals with release of patients administered radiopharmaceuticals and permanent implants. A question has been raised recently, particularly in line with eye plaques, as to whether or not you can release patients with temporary implants.

Currently 35.404 only authorizes release and confinement after all sources have been removed and the patient is surveyed. We have granted exemptions on a case by case basis for patients that have eye plaques and provided the licensee commits to meeting certain requirements.

For example, the measured dose rate must be less than five millirem per hour at a meter. In terms of the eye plaques, the licensees have committed to using non-hardening bonding agents. Because the plaque is surgically sutured in place, there is less chance of the plaque falling out or becoming dislodged.

Also the licensee must provide radiation safety guidance to the patient. And when the patient returns to have the eye plaque removed, the licensee must dismantle the eye

plaque to ensure that they have recovered all seeds and then do a radiation survey of the patient.

The question is: In terms of the revision of Part 35, should NRC consider modifying the regulations to allow releases of patients in certain situations?

I'd also like to mention I've received a telephone call from a licensee that wanted to use iridium-192 low-activity seeds, which they indicated would be in the patient for two to three months and then the patient would come back in, and then they wanted to release. They were asked to provide more information, which I haven't seen.

And then the second question is: What are the minimal provisions to ensure protection of health and safety? These statement "Consideration for release of patients with temporary implants have generally considered that most temporary implants have a higher dose rate than the permanent implants." And that was the rationale for not authorizing release.

CHAIRMAN SIEGEL: Should they change the regulations to allow people with sutured-in eye plaques to walk the streets? How long are these things usually left in?

MEMBER FLYNN: I've not done the eye plaques. It's only in a few places in the country.

MS. HOLAHAN: We have typically seen licensees saying they leave therm in anywhere from three to seven days.

MEMBER STITT: I guess the one that throws me is the iridium that you were --

MEMBER FLYNN: Right. I can't imagine them using iridium.

MEMBER STITT: That's what I'm not familiar with. I guess the thing that bugs me about iridium, that it's less likely to have seeds drop out of the ribbons than the iodine-125, which can end up in all sorts of places, but certainly it would be a potential that that could happen.

Most of the eye plaques are done with a different isotope.

MS. HOLAHAN: Eye plaques are done typically with either I-125 or palladium-103, the ones that we seen used in those. And, again, the plaque is sutured in place; whereas --

MEMBER FLYNN: Do you have any specific information as to these iridium in the ribbon form? And then do you have any idea of what the activity was that they're releasing the patient with? I just don't know.

What you said previously was correct, the temporary implants, the concept is that the dose rate being generated in the target area is higher. And, therefore, that's why it's removed. It's temporary. The normal tissue wouldn't tolerate that kind of a dose rate as a permanent implant. A half-life is too long. The total dose would be too great.

So I don't have any examples that I can think of whereby iridium-192 is being used as a temporary implant and a patient is being released and has to come back. I just don't know.

MS. HOLAHAN: I think the question fame in as they were looking at it as something that they were looking to do in the future. And so they did not have a lot of specifics. And that was why I wasn't able to answer the question.

But I know that they had indicated that this was a possibility for the future, that there was potentially some research being done on it, which I'm not familiar with. Perhaps I'm hearing from the Committee, too, that you're not familiar with any --

MEMBER FLYNN: And also the difference between the iridium seed and the iodine seed is the iodine seed is putting on a very nice low-energy radiation; whereas, the iridium could be potentially more of a safety problem. But it depends on what the activity is, what is the source strength.

MEMBER STITT: I guess I'm sort of baffled because you said they were proposing to leave it in three to four months or something.

MS. HOLAHAN: Two to three months is what they told me.

MEMBER STITT: I don't have the knowledge of what that procedure is.

MEMBER FLYNN: Especially if it's temporary.

MEMBER STITT: Right. That isotope for that period of time --

MEMBER FLYN: Some of the training plants were done with low-dose iridium seeds, but temporary implant I just don't --

CHAIRMAN SIEGEL: What's being treated with these I-125 and palladium eye plaques?

MEMBER STITT: Ocular melanoma is the most common thing.

MEMBER FLYNN: Right.

CHAIRMAN SIEGEL: And they're implanted where?

MEMBER STITT: At the site of the melanoma.

CHAIRMAN SIEGEL: So they're all the way back in the choroid? So they're way back in there, not likely to fall out? They're not just --

MEMBER FLYNN: I've never seen them. They're just not common. I mean, most facilities don't do this procedure.

MEMBER STITT: This is an enormously rare disease.

CHAIRMAN SIEGEL: It takes a second surgical procedure to move the temporary implant?

MEMBER STITT: It depends on which location it is on the globe, but it can be a minor procedure. That is sedation and --

MEMBER FLYNN: But it is a procedure?

MEMBER STITT: Yes.

MS. HOLAHAN: Yes. It is being done at several -- there is a study being done at several centers. They're doing the --

MEMBER STITT: The COM study is probably what you're referring to.

MS. HOLAHAN: Right, the COM study.

MEMBER STITT: That's very tightly controlled. In fact, we've got eight rad oncologists. There's only one who's allowed to do it at our institution.

And I don't think that's the problem. The cases probably don't come from the COM.

MS. HOLAHAN: We have some from the COM.

MEMBER STITT: Do you?

MS. HOLAHAN: Yes.

MEMBER STITT: Okay.

MS. HOLAHA: Some of it's from the COM. I know of one that was not part of the COM study that requested this exemption, but the majority of them have come from facilities that are on the COM study.

CHAIRMAN SIEGEL: It sounds to me like the magnitude of the problem warrants continuing to do exemptions, rather than codifying it.

MS. HOLAHAN: Okay.

MEMBER STITT: Yes.

CHAIRMAN SIEGEL: I'm afraid that if you write a general rule, you're going to open up the opportunity for it to apply to other things that you didn't intend it to and that there will be a safety problem. And it's probably better to handle it on a case by case basis.

MEMBER STITT: And the case by --

CHAIRMAN SIEGEL: Because I just can't see 2000 Part 35 licensees wanting to do this.

MEMBER STITT: Right. And the case by case can be so -- there can be such variation from one case to the next that I think they -- and the total volume is very low. I think it should be looked at as --

CHAIRMAN SIEGEL: And given that there's process re-engineering is going to mean that license amendments will sail through in two weeks. It's not going to be that big a deal; right?

MS. HOLAHAN: Okay. This next one, this issue, was originally raised about an incident which Dr. Flynn discussed yesterday in terms of prostate implant in which the

activity of the seeds used in the implant were 10 times the activity intended.

And licensees are required in the QM rule to verify the final plans of treatment, and calculations are in accordance with the written directive. However, the question has arisen in terms of verifying the source activity.

It is currently our guidance to licensees and to regional staff as licensees can verify the source activity either by assay, physical assay, or they can confirm the activity against other documentation, such as a shipping label.

And the question is: Is either physical activity or verification of documentation an acceptable method of verification of the source activity? Is this a procedure or a policy that we should continue with?

MR. CAMPER: As you answer this question, bear in mind that there was recently a misadministration, a significant misadministration, where seeds were implanted that were off by an order of magnitude.

MEMBER STITT: That's what she's talking about.

MR. CAMPER: They were verified. That's right. They were verified by shipping and logged in correctly, interestingly enough, but not assayed.

CHAIRMAN SIEGEL: No, but they weren't verified by the authorized user.

MS. HOLAHAN: Correct, correct.

MR. CAMPER: That's correct. They were verified --

CHAIRMAN SIEGEL: They were verified by somebody else.

MS. HOLAHAN: Right. They were logged in correctly in accordance with the shipping label.

MR. CAMPER: That's right.

MEMBER NELP: You can't regulate out mistakes. I mean, that's just a mistake and a very --

MR. CAMPER: Well, no, no. What we're saying, though, is the or. Is it acceptable to do it either way or should you, --

MS. HOLAHAN: Is what we do currently acceptable?

MR. CAMPER: -- in fact, require physical assay?

CHAIRMAN SIEGEL: Buzz, in a way it's no difference than if you're running a code and you say to a nurse "Give me .25 milligrams of" such and such. The nurse draws it up and holds the vial up so that you can see that that's what you've got. You as the person who is about to inject that drug have some independent verification that you've got the right stuff.

Relying on several parties down the line on source strength is troublesome, especially --

MEMBER STITT: Well, and that's how this case occurred --

CHAIRMAN SIEGEL: Yes.

MEMBER STITT: -- because it was exactly what had been ordered. And all the documentation was exactly right. The big problem was that nobody used an ionization chamber to see what was really going on. I mean, in our practice we would never use seeds without having determined their activity through some means other than shipping documents.

CHAIRMAN SIEGEL: But the shipping document was correct here.

MEMBER STITT: Oh, it absolutely --

MR. CAMPER: The problem was --

CHAIRMAN SIEGEL: Wouldn't the ACMUI have known these were the wrong seeds?

MR. CAMPER: No.

CHAIRMAN SIEGEL: Wouldn't he have looked at the shipping document?

MEMBER STITT: No. Well --

MEMBER FLYNN: I thought if you meant that the authorized user in the operating room could look at the seeds and tell. There's no color coding.

CHAIRMAN SIEGEL: No, you can't look at the seeds.

MEMBER FLYNN: You can't tell.

CHAIRMAN SIEGEL: No. But what if he looked at the labelling that came with the shipping document and said "Oops. These are 4-millicurie seeds and not 400-microcurie seeds"?

MEMBER NELP: When I treat a patient, I have three people verify the labeling before I give it to the patient. And if I can, I'll assay it, but I may not assay it if I have a --

CHAIRMAN SIEGEL: For whatever it's worth, in my shop I'm one of the three people who verifies the labelling.

MEMBER NELP: Now, in your place do you verify your own seeds? I mean, does the therapist verify the documents that say "These are the seeds that I ordered and this is the strength"?

MEMBER STITT: No. I tend not to or we tend not to look at the documentation, but we always use an ionization chamber. And the physician's a part of that.

MEMBER NELP: You assay it yourself.

MEMBER STITT: So, I mean, we're involved in the checking process.

MEMBER NELP: Personally document it in some fashion.

MEMBER STITT: Yes because we're using the darned things.

CHAIRMAN SIEGEL: I think and either/or should be included.

MS. HOLAHAN: Okay. So you're saying that our --

CHAIRMAN SIEGEL: Physical assay or --

MS. HOLAHAN: -- current approach is acceptable?

CHAIRMAN SIEGEL: Yes, I think so. I mean, I don't think you would -- there's no reason to force a freestanding facility that doesn't have a dose calibrator to order one if verification of the shipping documents does the job.

That's what I think. Now, do you all disagree?

MEMBER FLYNN: I don't disagree. I think this problem was a problem in my personal opinion with the licensee. I think the licensee has had many problems in the past with brachytherapy and has not shown a careful to the whole safety program.

And I'm talking about sources getting lost in laundries, not having the RSO feeling that it was okay for untrained personnel to be doing the surveys of linen leaving the room, a licensee whom I believe is the only one in the United States who doesn't feel it's really necessary for a medical physicist to be present at an HDR procedure.

So I think this is a licensee problem. And I think licensee administration is totally out of touch with

what's the standard of practice in the United States for this licensee.

CHAIRMAN SIEGEL: Good.

MR. CAMPER: Let the record show he didn't mention the name of the licensee.

MS. HOLAHAN: Okay. This next one relates to source localization. And the reason we're raising this issue is that we have had a number of cases recently where applicators have shifted, where the sources have moved. And I understand from yesterday's discussion that this is to be expected in many brachytherapy applications.

I guess my question, then, as a result of that is: Are the current standards adequate now to address this? Do we need any additional guidance or does the standard of practice address this?

MEMBER STITT: Boy, that was one of your questions many months ago on that question sheet that you sent around, wasn't it?

MS. HOLAHAN: Yes.

MEMBER STITT: I think the standards are adequate. What impresses me after having practiced brachytherapy for many years and now doing consultations on misadministrations is I thought I had seen it or at least heard of it all.

And it's amazing how many ways there are that patients or staff or systems just allow something kind of quirky to occur that allows sources to change positions.

I mean, I think you can only regulate and legislate so much. We cannot control a lot of these things that are simply beyond --

MS. HOLAHAN: Now, let me ask: Is this the type of thing that the American Brachytherapy Society is looking into in terms of their programs? And are the professional societies actually addressing this type of issue?

MEMBER STITT: Let's see. I'm trying to think of 56. Task Group 56 is addressing that to some degree. I mean, what you'd like is a standard that says: You as a radioactive source will not move. I mean, you can say: You as an institution, you as a physician, you as a nurse will do certain things.

And we do say that. But those sources can still move. And there's no way that we have the power to stop them.

MS. HOLAHAN: Okay. Well, I think often what we see is sources have shifted. And then the licensee has come back and said, "Well, with corrective action, I can make sure that they're sutured in or I can put packing in or I can" --

MEMBER STITT: You can do every one of those things, and you can still get the sources --

MS. HOLAHAN: Okay.

MEMBER STITT: I could document numerous cases of that. I think the standards and procedures are adequate if they're followed.

MS. HOLAHAN: Okay. Just moving to HDR, then, again, quickly. This is my last issue. In terms of the current licensing guidance on HDR, there are specific emergency procedures. The licensee must develop emergency procedures. And the personnel must be trained in the emergency procedures. And they must include specific things, such as examples of situations requiring action, step by step actions, criteria requiring surgical intervention, and identification of emergency source recovery equipment.

My question again -- and perhaps we did hear this somewhat yesterday that the AAPM is starting to develop standards, as is -- is it ACR or ASTRO?

MR. CAMPER: ASTRO.

MS. HOLAHAN: -- ASTRO in terms of industry standards. And do those address emergency procedures and handling of emergency situations?

MEMBER STITT: The answer to that question would be yes. They are in development, and the security and safety are part of what's being developed.

MS. HOLAHAN: Okay. And then in an emergency situation, should the expectation be that if surgical intervention would be required, that the licensee would have

the appropriate facilities there to handle such a situation? Again, this is getting back to the freestanding clinics and the mobile HDR, where they would not have a full --

MEMBER STITT: Trish, I don't know. What I should do is take that particular question back and look at the document we're working on to see if that's stated and if not, bring it up.

MEMBER FLYNN: If you require the authorized user to be physically present, the radiation oncologist, during the procedure, to remove the sources doesn't require a surgeon. So if you're in a freestanding center, it requires suture removal kit. You cut a stitch. You pull out a tube. It's not a big deal.

MEMBER STITT: Well, it could require a surgeon. One of the problems would be a source that's lost in a bronchus. And I think those are the --

MEMBER FLYNN: Lost in a bronchus?

MEMBER STITT: Yes.

MEMBER FLYNN: Penetrated through the --

MEMBER STITT: No. It's come disconnected from the cable and --

MEMBER FLYNN: But still in the carrying tube, though.

MEMBER STITT: If it's a high dose rate source, it would be lost in space.

MS. HOLAHAN: Even with the closed-ended catheter?

CHAIRMAN SIEGEL: Isn't there a --

MS. HOLAHAN: Why would you be able to pull the catheter? No?

MEMBER FLYNN: HDR is a closed catheter, like the Omnitron source that was removed on December 7th, a week after Indiana, by the physicist.

MEMBER STITT: Yes.

MEMBER FLYNN: I mean, it's still inside the tube itself. The tubes I believe are always closed-ended in bronchus applications.

MEMBER STITT: Yes. I think the ones that I know of are. But somehow there was a hypothetical circumstance where somebody was discussing --

MS. HOLAHAN: I think the --

MEMBER STITT: This was the iridium.

MS. HOLAHAN: -- end of the tube possibly --

MEMBER FLYNN: And some of the iridium catheters are open-ended, in some of the ones used by a prominent brachytherapy in Southern California, for a reason that if he should hit a blood vessel, he wanted to have some indication by some return of a small amount of blood so that the -- there was a beveled end to the catheter which was opened at the end.

MEMBER STITT: Well, there's one of the systems that has a little grappling hook. Is it Omnimed or -- no. I think it's a different system. It has a little grappling hook that latches onto the bronchus.

I think that if you look at a broader spectrum, if you're a freestanding any type of facility, you need to have some statement as to how you handle medical emergencies, be it pulmonary embolism, chest pain, stuck sources.

So there's nothing that is out there right now, but that question should be part of what we're developing, too. And I'll make sure we bring them up.

MS. HOLAHAN: Okay. All right.

CHAIRMAN SIEGEL: Good.

MS. HOLAHAN: Thank you.

CHAIRMAN SIEGEL: Thanks, Trish.

MEMBER FLYNN: Thank you, Trish.

CHAIRMAN SIEGEL: Okay. We are good for a 10-minute break.

(Whereupon, the foregoing matter went off the record at 10:06 a.m. and went back on the record at 10:21 a.m.)

CHAIRMAN SIEGEL: Sally, are you set? Go for it. Sally, QMP.

MS. MERCHANT: For the record, I'm Sally Merchant. And I'm the project manager for the implementation

of the quality management program and misadministration rule that became effective in January of 1992.

Now, as part of the implementation of that rule, we provided some guidance to the regions. And some of that guidance is in 12-91 before the rule went into effect. We provided a draft standard review plan for the review of that program. That review plan was revised in August of 1993 and provided to the contractor, who reviewed the submitted quality management programs.

August of '94 we issued a temporary instruction for the inspection of implemented quality management programs. And that's being used by the inspectors right now to inspect. A part of regularly scheduled inspections they are using that TI, temporary instruction, to do those.

We are entering all of those findings from that TI into a database. We plan to use those findings to evaluate the implementation. We can also use those findings to identify those things that licensees are doing consistently and regularly. And, therefore, we don't need to put a lot of time and effort into inspecting those things. We can also identify some of the things for certain modalities that might need some further attention.

Additionally, we revised the standard review plan again. And we expect that to be issued this month or very early next month. I'd like to comment that the standard

review plan has been significantly reduced so that it only addresses just how do the licensees meet the five objectives and it's completely performance-based. Other than the five objectives, the other portions of the rule are prescriptive and aren't addressed in the licensing standard review plan.

The original QMPs, as you know, were reviewed by a contractor. And the findings were conveyed to the licensees in a very long and detailed letter.

Most of the licensees have submitted revised QMPs. And these are going to be reviewed by the license reviewers for new license applications and when a modality is added or when the inspector is preparing to go out. Otherwise, these are not going to be reviewed as they come in. So we're going under the assumption that the licensees have addressed the concerns that were issued in the first letter.

To date we have 189 inspection findings entered into our QMP database. There were 314 modalities represented. And they include: brachytherapy; teletherapy; HDR; and radiopharmaceutical therapy, including sodium iodide.

We found that 45 modalities, 34 licensees failed to meet the objectives upon inspection. Six of the licensees had multiple modalities that failed. The 34 licensees' quality management programs either failed to meet an objective upon inspection but met the objective in the written QMP or

failed to meet the objective both upon inspection and in their written QMP.

I would comment that this is a little different than what we found in the pilot program. In the pilot program, we found that a majority of the licensees had better programs than their written showed. In this case, these 34 licensees failed to implement their programs or did not have an adequate program.

CHAIRMAN SIEGEL: What are the top two reasons for not meeting the objectives?

MS. MERCHANT: What we sorted for were Objectives 3 and 4. Now, 3 does not apply in radiopharmaceutical therapy or I-131. But those are the two objectives. Objective 3 is basically that you're assuring that any calculations are correct, whether they come from a computer or whether someone is checking hand calculations, but you're assuring that the calculations are correct; and, 4, that you have some kind of procedure and it can be -- I mean, you decide what that procedure is, but that you have implemented some sort of procedure to ensure that what you're about to give is what the written directive says.

And it's the same problem that happened in brachytherapy, where the sources were 10 times what they should have been. There was no procedure to check it immediately beforehand.

CHAIRMAN SIEGEL: Okay.

MS. MERCHANT: And, as I said, that procedure is up to the licensee. We'll take any reasonable procedure. It's not prescriptive. But in these cases let me make clear that these findings are based on what the licensee is telling the inspector. Do you do something? What do you do? And if they don't do anything, then they fail to meet it.

We found that there were 26 recordable events and that 15 of those recordable events were identified by the licensee. But 11 of those recordable events were identified by the inspector and not by the licensee.

CHAIRMAN SIEGEL: Tough question, to which you may not have the answer: Are those recordable events that would be 11 that occurred outside of an audit cycle by the licensees? Do you follow my question?

MS. MERCHANT: No, I don't understand the question.

CHAIRMAN SIEGEL: Let's say a recordable event occurred three weeks ago and I'm not due to do my annual audit for six months.

MS. MERCHANT: No. These would have fallen within the period of time at which you should have found it.

CHAIRMAN SIEGEL: Okay.

MS. MERCHANT: And then for the misadministration portion of the rule, we looked at the misadministrations '92, '93, '94, and '95, which we have been doing.

I might add that for 1995, we have two listed here, and that number was correct or reasonably correct as of Thursday. It is no longer correct. There have been a possible HDR incident and an iodine incident since that time.

I might also add that these two that we have listed here, I have them -- they're under misadministrations, but they're still listed as events by us in that we have not assured that they meet the definition for misadministration. It's still under -- I guess I would like to add here, just to clarify, that all misadministrations do not have a violation associated with them.

Do I have any questions on the --

(No response.)

MS. MERCHANT: Short and sweet.

CHAIRMAN SIEGEL: What's the status of agreement state implementation of the QM rule?

MEMBER QUILLEN: Mixed.

CHAIRMAN SIEGEL: I knew the answer. I just was curious.

MS. MERCHANT: I was going to say Larry can best answer that because he gave a little talk at the agreement state meeting.

MR. CAMPER: Well, Bob's characterization is correct. It's mixed. And those who haven't seem, to be waiting to see what we're going to do about revising Part 35. And those who have are annoyed because others have not because they've spent money, time, and dealt with their state legislatures.

CHAIRMAN SIEGEL: Aren't those who haven't in violation of the law?

MR. CAMPER: Well, technically it is an item of compatibility. They had three years to become compatible on it. But we have been working with OGC in trying to find ways to provide some flexibility for the agreement states on this issue. I don't know exactly where it stands at this moment. It hasn't come to closure.

But there are some problems. In some of the states, for example, this idea that you would have licensees submit their QMPs, some states, for example, have a requirement that if the regulatory agency receives the document from the licensee, they have to review it and react to it within 30 days. And if they literally had to do that, they would have to shut down the rest of their programs so they could review, submit a QMP.

So there are some practical problems for the states, but it's a mixed bag. And we're trying to work our way through it.

MEMBER STITT: I have a question for Bob. The table that Sally showed, is there anything that's equivalent to that for the agreement states regarding misadministrations by type?

CHAIRMAN SIEGEL: That was part of the point of compatibility.

MR. CAMPER: Yes. We --

MEMBER STITT: Is that actually collected?

MR. CAMPER: That's a question that always comes to my mind whenever I look at misadministration data. Let me see if I can try to properly characterize where we are.

The definitions for misadministrations were Division I compatible. That means they would have been verbatim effective in January of '95 for the agreement states. They had three years to implement the rule. It became effective on the 27th of January 1992, which meant, then, for the first time you would have had all states and NRC calling misadministrations by the same thing in terms of definitions.

What you have right now, though, is you have some of the states have achieved compatibility and are using our definitions. Some are still relying upon the old definitions. And yet another subset is relying upon definitions for misadministrations which they have created. So obviously until such time as you get the uniform definition you won't be able to get a national perspective.

It's further compounded by the fact that it's only been recently that we've asked the agreement states to report to us misadministrations which occur, but it's voluntary reporting. It's not a mandatory reporting.

Now, if one looks at the data, you look at a matrix of all the states and the misadministrations and you track it across time, this clearly holds in the data, which tells me the states are either identifying them or reporting them with varying degrees of attention and accuracy.

But it's a problem, and there's no question about it. If you ever want to really get a handle on the total number of misadministrations, we're going to have to get a level playing field, same definitions, uniform reporting, et cetera, et cetera. And, frankly, we may never achieve that.

CHAIRMAN SIEGEL: That's okay, too.

MS. MERCHANT: Just to add to that, this database does contain what information we have as far as agreement states are concerned.

MEMBER FLYNN: It's interesting when you total the numbers that if you take all brachytherapy, -- I totalled 44 -- all nuclear medicine, diagnostic and therapy, 25, and teletherapy 15, so brachytherapy now, as we predicted before, would continue to grow in terms of potential misadministrations. Teletherapy will continue to decline. Probably nuclear medicine will decline also.

MR. CAMPER: You know, we're reluctant, obviously, to react to this data because it could only be a statistical blip which in time may normalize itself. I don't know. But, on the other hand, there may be something going on. I don't know what it is. But the results are encouraging, at least.

CHAIRMAN SIEGEL: The one part of the quality management rule that made sense, the written directive, is going on.

Okay. Thanks, Sally.

MS. MERCHANT: Thank you.

CHAIRMAN SIEGEL: Pat? We're going to give an update on the National Academy of Sciences study and hear about the business process re-engineering. I think before you came in, Pat, I said that I understood that we were going to get license amendments approved in two weeks under this new plan.

DR. RATHBUN: That long?

CHAIRMAN SIEGEL: Yes. I said that.

DR. RATHBUN: We're going to do it in 1.4 days, 1.4 days.

CHAIRMAN SIEGEL: Excellent.

DR. RATHBUN: I thought it would be better to just have an informal handout here. I want to start with the National Academy of Sciences and give you a little update on

that. And I thought it might be useful to pass out some of the slides that they used at their briefing at the Commission.

If you recall, the National Academy of Sciences briefed the Commission on March the 29th. And I just thought it might be useful if we revisited the study. We're coming down the home stretch now. And then we could take and build upon where they're going.

You recall we gave them $1.15 million to do this study. They have stayed remarkably within their budget and right on schedule. They have been extremely conscientious about this. They have a 16-member interdisciplinary committee. And I on the next page provided their names.

If you recall, they commissioned a number of papers. They have held five of their six committee meetings. They had a public hearing. They formed a special panel on quality management. And they carried out four site visits. Committee members are on the next page. I think they're all known to you.

Just in case there is anyone here who didn't ever walk through the task, we gave them three broad areas to look at: The broad policy issues underlying the regulation of the medical use of radionuclides, the overall levels of risk, and the current statutory or regulatory framework. I'm sure you know by now that the Chairman's main interest is in Item 3.

The subcommittee --

CHAIRMAN SIEGEL: That's your chairman?

DR. RATHBUN: Our Chairman, Chairman Selin, right, right. I think that Dr. Putman is equally interested in all three, as he has expressed it to me.

The committees that they set up, the subcommittees, of course, parallel the tasks we gave them, possibly with the addition of education and training, which is within the purview of the National Academy of Sciences to add and expand scopes of work if they feel that that's the best way to accomplish the task.

The site visits were to Georgia, Minnesota, Massachusetts, and California.

So that brings us up to date. I've also included in your handout what is the general outline for the paper.

CHAIRMAN SIEGEL: Exceedingly helpful.

DR. RATHBUN: Well, in case anyone is wondering why I'm sort of vague here, we don't know what the National Academy of Sciences is going to do. In fact, they met in Washington last week. And it was a full executive session, which means that no member of the NRC was able to attend.

So, in all honesty, I don't have any idea what they do. I know they spend their money properly, and I know they meet their deadlines. And I guess that's good. Certainly that's good for me since I sign their vouchers that I know that, but I have no real idea as to what they're going

to be telling us. I'm starting to look like Kate-Louise briefing the Commission. I don't know.

MEMBER NELP: Question: What is the NRC's obligation or commitment to respond to the committee's report? Is it strictly an advisory report or have they sort of made an internal commitment to modify their behavior based on the report?

DR. RATHBUN: Let me answer from a procedural standpoint. The report will arrive. The report will go to peer review in October. We have negotiated with the National Academy of Sciences that the agency can receive one copy at that time. We are committed to forming a group that will evaluate this report. And so that's the procedural answer.

MEMBER NELP: Could you answer my question?

DR. RATHBUN: Larry can answer it.

MEMBER NELP: What's the climate? Is the NRC in a position to want to respond to this report in a reactive way or is this just --

CHAIRMAN SIEGEL: Which NRC are we talking about: The one this week or the one in a month?

MEMBER NELP: -- or is this just window dressing?

MR. CAMPER: No, I don't think it's window dressing. Let me try to attempt to answer your question.

CHAIRMAN SIEGEL: A whole new ball game.

MR. CAMPER: As Dr. Rathbun says, we will have a process that we will go through. There will be a task group that will be formed to evaluating the findings. The staff in our division will do a thorough evaluation of the report. I suspect in parallel or shortly thereafter Commissioners, assistants for the Commissioners at that time will do their own evaluation.

And at some point the staff will go to the Commission with its evaluation or interpretation of the findings and what it might mean to us and how we might react to it. There will be interactions with the Commission, and the Commission will then come back with its posture and direct the staff to do certain things as a result of the NES study.

Now, no one could tell you right now what our regulations will ultimately look like or, for that matter, what NES will suggest. My feeling is I believe that the NES report will be quite a mixture of findings and/or recommendations. And so it's hard to say. But certainly when we task them to do the study and as we look at the need to revise Part 35, we certainly see the NES study as a crucial component of whatever that we do.

Now, I don't think we're going to necessarily react and do everything that NES might suggest that we would do, nor do I think that we will ignore everything that NES would suggest that we do.

We know, the staff has known, the management has known for some time that there is a need to have Part 35 undergo a major revision. There's a need to take a critical look at how we regulate the medical use of ionizing radiation and are we applying the right level of regulatory presence for the risks involved and so forth.

Clearly this industry has matured if one goes back and compress it to the statute of our regulations over the last 18 years, since '87, when it was last revised.

An NES report will undergo serious consideration and review and will be a key component in what we do. But there will be other things that will also be key components. We know, for example, that we want to hold a series of public meetings, most likely geographically disbursed across the United States. We intend to solicit public comments, obviously. We intend to publish an advance notice of proposed rulemaking to solicit comments.

We intend to interact with this Committee on several occasions during that course of the revision. We want to meet with the appropriate professional societies. We want to meet with the boards and so forth that are responsible for physician training and experience requirements and board certification.

So all of these things, including the NES report, will ultimately be key components in a major revision of Part

35. I do think it's fair to say, as I've already said on the report, I think that Part 35 when it's all said and done will look quite different than it does today. And I think the NES report will have greatly influenced that.

MEMBER NELP: Will this report be in the public domain?

DR. RATHBUN: Yes.

MEMBER NELP: As soon as it's submitted?

DR. RATHBUN: Yes. The schedule right now that they're on is hopefully to complete it in August, send it out for peer review. In October it would return from peer review and go to the printer. Usually that takes about eight weeks. But that becomes a publicly available document.

In fact, that's one of the issues. The National Academy of Sciences does not like to release their work to an agency because it gets in the public too fast or incorrectly. There's an elaborate procedure that they use.

Having walked this walk with them, they have really worked hard. They have done really an excellent job. The position that we're in that makes it uncomfortable to respond to you is that we know what they're doing is good, but we have no clue as to what it is. So it's hard to say to you "Well, we might propose rulemaking" or whatever because we don't know what they're going to tell us.

But I know that many of the agency responses to Congress and many of the times that Carl Paperiello responds to the Chairman, they're awaiting the results of the NES study to give us the guidance as to how to move forward with the Medical Program in the future. So I know there is no plan to trivialize it.

MEMBER NELP: Thank you.

DR. RATHBUN: So I put in the report review process for you because that's the strong suit of the National Academy of Sciences. You know, they pull all of this information together, and then they assemble a peer review team. It is exhaustively peer reviewed. And I have a lot of confidence in that process.

I am confident they'll meet that January deadline. We are fortunate that the agency at least fit the senior management, that the Commission will see a copy of the document in October, I will be allowed to read the copy in October and hopefully all of you about eight weeks later.

All right. The next topic I'd like to talk about is the business process re-engineering that we have been working on since September.

I have included in your briefing book the executive summary of this whole staff's report. That actually is a working document. And I'm giving you today a copy of the Commission paper. Yesterday, May 11th, Carl Paperiello

briefed the Commission. And information in the Commission paper, which I think Janet will pass out next --

MS. SCHLUETER: I'm not sure everyone wants it.

DR. RATHBUN: I would give them that because the Commission paper really contains our best and final write-up of the BPR. And then what I would like to do, have you hopefully get to read that at your leisure, but we'll walk through this very exciting project.

We are a core team composed of myself as the team leader and representatives from each region in the NRC and representatives from our Office of Information Resources Management. We have practically lived together for the past six months. We eat, sleep, breathe BPR. In fact, I left there just now to come down here to return to the BPR team, who sort of said "How could you possibly leave us on a day like this?" I mean, we're like a family now. BPR is a very intense but very rewarding process.

Let's start with what is it that we did and where does that fit in the grand scheme of things. On your first slide, I show you that we concentrated our efforts, first of all, on the licensing process. But, as we are all aware, that is tightly tied in to many other facets of NMSS and agency functioning: Inspections. It's tied in to the regulations; incident response; and, of course, the collection of

operational data. The current plans that Carl has are to begin to do a BPR of the inspection process later this year.

Okay. If you turn to the next slide, which says "The Current Eight-Step Materials Licensing process," when we began this project we naively went out and made this model of how we license. Well, turn to the next page. This is how we thought it was. But when we actually went out and examined it, we found that, instead of eight steps, each one of these had their own set of steps. These things move around. They go back and forth. They sit in people's "In" baskets.

And so turn to the next page. What actually takes 84 days to do? We found there were only 1.8 days of actual work time in issuing a license. Now, this was a great revelation to the core team and management and everybody that we talked about. And it gave us what is called in BPR lingo a compelling reason to change. Now, you all probably already knew that we had a compelling reason to change, but, you know.

The other thing that was very, very interesting is that on this Slide 6 that you're looking at, we found that there were an average of 54 handoffs per license. Now, this could be the license went from the secretary to the reviewer and back to the secretary or to the secretary to the Xerox room to wherever it went. But, nevertheless, there were 54 of them.

We believe that in the new process we can cut that down to nine. That's about the best I think we can do. And we think we can cut that time down to four days on issuing that license.

MEMBER NELP: Wow.

DR. RATHBUN: Now, these are very ambitious, stretched goals. We'll see what happens.

CHAIRMAN SIEGEL: Is that including weekends?

DR. RATHBUN: No. That's workdays.

Okay. What is it we want to do? Look to the next page. This is what in BPR talk is called our vision. The new licensing process is a three-part situation. We have -- yes, sir?

MR. CAMPER: Question?

DR. RATHBUN: Are we out of --

MR. CAMPER: On Slide 6, your 1.8 days of actual work time --

DR. RATHBUN: Yes.

MR. CAMPER: -- that includes all review time?

DR. RATHBUN: That included review time.

Okay. A three-part. There's a new way of looking at regulations. There's a new way of working in teams. And there's a new licensing process.

I'm sorry my slides got out of order. We were kind of in a scramble from yesterday. If you would shift two

slides forward to what is called Slide 14? I'd like to walk you through the highlights of the new process.

The name we have given to this concept under which we hope to deal more effectively with regulatory processing is called the virtual regulatory process design center. Now --

CHAIRMAN SIEGEL: Is that where John Glenn works now?

DR. RATHBUN: John Glenn was the first person to be sent off to it. It's virtually complete. We don't want to lose any of our old friends. We just want to grandfather them in.

The reason we called it virtual is because we do not want to imply that we're altering the regional structure of the NRC. That would be foolhardy. However, we have learned that using what they called Groupware, which is a type of computer software where you can be interlinked, we can actually work from our region and others, home, licensing site, and we can be linked together in virtual space. Now, we all --

CHAIRMAN SIEGEL: Are you using Lotus Notes for --

DR. RATHBUN: Yes. We are empowered to use Lotus Notes for this issue. The agency is not yet supporting Lotus

Notes. But we can use it for this issue. That's why I kind of backed off of that.

CHAIRMAN SIEGEL: Got it.

DR. RATHBUN: Now, I don't want to oversell this. We obviously have to also meet in real time, as we have been doing now. But we believe that using this type of process, which is like a task, an empowered, upgraded task force, that we can work together with research, with the agreement states, with even the ACMUI linked in, of course, on Lotus Notes. So it has something for everyone. BPR is like that.

CHAIRMAN SIEGEL: For whatever it's worth, just to amplify on that, the Advisory Committee on Human Radiation Experiments, which has got a short half-time committee, the staff and the whole committee are using Lotus Notes for a great majority of their work. And it is fantastic.

DR. RATHBUN: It is a wonderful product.

CHAIRMAN SIEGEL: Working well.

DR. RATHBUN: The Department of Energy using Lotus Notes for their major database efforts. Computer Science Corporation, who is our prime contractor, has installed something like 10,000 copies of Lotus Notes worldwide. So if they can handle it, we can probably handle it. But it is a wonderful new way of working. We just put up a bulletin board to be able to interact, and it's great. We're hoping to get more people on it.

But what are the kinds of things we want to work on in this regulatory product design center? In a few minutes I'll be telling you about a proposal to extend licenses. We are going to combine all of our guidance documents, including policy and guidance documents, into a single licensing manual. That activity has begun and will be worked on over the next three months.

We're also developing a safety-based expert system-aided application review process. What does this mean in English, Pat? This means that we have hired an artificial intelligence expert to help us set up scripts so that when we go through the licenses, we have a computer-assisted review.

Carl is proposing that we come up with a 50.59 equivalence for materials licenses. This, if I understand, -- John, maybe you could help me out -- might involve rulemaking. We're talking about the concept of indefinite licenses.

We're also talking about developing educational products within this center. Yesterday Dr. Jackson asked me "What are your plans for training?" Well, in the model that we're using here, a training person would be with us from day one. You do these things -- rather than waiting until it's developed and just rolling it out in the world, you actually work together to develop these things. This is what we are currently envisioning goes on in this regulatory product design center. Okay?

The next page, which is Slide 15. This is our schematic of how we believe we will be licensing in the future. I'd just kind of like to walk you through it. On the left-hand side, if a bad application came in and a bad, incomplete license came in, we'd like the ability to bounce it right away, not have it lying around costing you money and wasting our time.

We'd like all applications to come into a central point and be centrally managed. What we have found is that the regional concept, although very important for interaction with licensees, is not very efficient in this setting. So we would envision licenses coming to a central point and then being apportioned where it is most appropriate to review them.

The example that Carl has been giving is that there are not a lot of gauge users in Region 1 and it will be better to have those types of licenses reviewed elsewhere.

CHAIRMAN SIEGEL: In the model that you're using, what fraction of refusals to file, if I can use the FDA parallel, do you think you'd have in terms of bad applications?

DR. RATHBUN: I think it would be very low.

CHAIRMAN SIEGEL: So it's not just a method to make your statistics look better?

DR. RATHBUN: No.

CHAIRMAN SIEGEL: Okay.

DR. RATHBUN: I think it would be very low. And, in fact, when I talked to you about the proposal for the one-time license extension, we believe that only 300, approximately, licensees would not pass a filter to go ahead and receive that.

MR. CAMPER: Just a comment, too, to add to that, Barry. This is the point that Janet was getting at this morning when she was talking about the guidance modules.

We know that the guidance documents that we are currently developing, upgrading, and what have you will ultimately undergo big changes as well because of BPR. And the idea is to get as much information on the front end for the licensee so the applications can be as sound as possible to keep that number of poor applications as low as possible.

DR. RATHBUN: It's hard to describe this because it has to fit together. You know, if the guidance is upgraded clear, coherent, consistent, and automated, it's going to vastly speed up the way we do things. So it all fits together. Also presumably we would have put out better guidance so that the licensees would better understand how to submit. So we wouldn't have the disconnect that we get right now.

CHAIRMAN SIEGEL: Got it.

DR. RATHBUN: The middle part tends to cause a little bit of confusion. We are going to look at licenses

depending upon their degree of complexity. The example at the top is of a gas chromatograph. We believe that this is a relatively simple thing to license and does not require a huge level of technical review.

We're not implying here that it is solely going to zap to the computer like the ATM machine. We understand that a human will have to take a cut at it. But we do believe that simple licenses assisted by the artificial intelligence scripting can process fairly directly through.

What this does is it frees our technical reviewers if you look at the bottom for the more difficult, say a broad-scope, license. We can pull together a team, including whatever expertise we need, to look at that license.

In the middle I show you our tool set that we believe we will be developing over the next nine months. There's no reason why we can't have a voice response system. Everybody else has it.

Coming out the back end, I wanted to stress to you that whatever is done in this new process, be it the automated part or be it the technical review part, we will subject that to a 100 percent quality assurance review. That's going to be resource-intensive, but that is, of course, vastly important from a safety standpoint. We hope to have, then, the license coming automatically in my dream through the Internet, but that's even going too far maybe.

The final and maybe the most important thing that's going to make this work is we're saying we want a new way of working in teams. The concept I'm working in out at Shady Grove is a self-managed work team.

For all of you who attended the Commission briefing yesterday, they are a self-managed work team. We couldn't keep them from standing up. It was really funny because normally only the speaker speaks at a Commission meeting and maybe, maybe the person with them. But the team was saying "No. We've got to tell the Commission" this and that. And the Commission was very open to that. It was really quite an experience yesterday.

So what do we do in our teams? Well, we partnered. In the upcoming sessions we'll have a union representative. I think that will be very helpful. Our team decisions were team decisions. We reported out, but they were consensus-based team decisions.

We're recommending parallel concurrence. By agency-wide goals I mean a de-emphasis on regional goals. We can set them as agency goals and apportion work where the expertise lies.

Some of these I've already talked about: The single guidance document, agreement state cooperation, rapid access to centrally stored data. Hopefully the things that we focus on are the exception, not the rule.

And I think, at least based upon my experience of the past six months, it's a wonderful way to work. The team has its ups and downs, but it is a good way to work. So that's our philosophy.

And if you just -- I don't want to take too much time. I think I'm going to kind of skip on. As Carl said, -- go to Slide 17 -- we actually hit all of the functional areas of the National Program Review. But I'll just be honest, as Carl Paperiello is. We didn't mean to. It just turned out this way. We didn't sit down and say "Oh, boy. This program is going to parallel NPR." It is in working this way we did accomplish these goals. And I think it is important to point that out.

Okay. Let's move on. I'd like you to go I think all the way to the end. And I'll just take a few questions. Let me show you where we are now, Slide 11, which is really your last slide.

We have completed the paper model. We briefed the Commission. I certainly anticipate Commission approval to continue. They did some modification to our schedule in terms of public comment, workshops, more interaction with the licensees. And perhaps I could even get some guidance from you all as to what would be the best steps to take in terms of involving your constituents.

We'll go into a prototype phase next. And we hope to implement in one year.

That's my fast tour of BPR. Questions? Commission paper has a lot, of course more, in it. I'd be pleased to come back and talk to you again as to how we're doing on this.

CHAIRMAN SIEGEL: I think we'd love to have a status report a little bit further down the line. Especially after some of us have been relicensed by this mechanism, it will be interesting to see how it works.

DR. RATHBUN: It could be our first feedback session.

CHAIRMAN SIEGEL: Okay. Good. Thanks, Pat. All right.

John, et al., for status of rulemaking. John, just so you are aware, we may be interrupted by visits of one or more Commissioners while you're on.

DR. GLENN: Okay. Fine.

CHAIRMAN SIEGEL: And I told them we'd stop if they came.

DR. GLENN: Very good.

The wrong patient rule is the first one. I'm going to give you status reports on three separate rulemakings, all of which have been discussed with the ACMUI before.

Do take note -- I think most of you recognize me. However, the title is new. I am not Chief of the Radiation Protection and Health Effects Branch in the Office of Research, rather than NMSS.

I've been trying to figure out in terms of the statistics that were being shown earlier in terms of misadministrations -- '94 and '95 sort of mark the end of my term in NMSS. And, all of a sudden, misadministrations drop dramatically. The question is: Do I interpret that that I was the problem or that I solved the problem and, therefore, was allowed to leave?

(Slide)

DR. GLENN: The first slide describes what the issue is with what we're calling the wrong patient rulemaking. The question is if a medical administration of a radiopharmaceutical is given to the wrong person and, in particular, it's given to a person who is not intended to receive any kind of licensed material from the licensee, should that be treated as a Part 20 exposure of a member of the public or is it a misadministration under Part 35?

In the proposed rule that we sent out, the issue was resolved in the favor of treating it as a misadministration under Part 35 and not as an exposure to a member of the public.

We published it in January of this last year. Only four comments were received, and they were all favorable to this concept. I think in the past with this Committee the comments have been the same that it is more appropriate to consider this problem as one of medical delivery, rather than of failure to control sources of radiation and exposing the public.

We initially had some problems in terms of how to go forward with this rulemaking because we attempted to define patient and wrong patient. That got us unnecessarily involved, I think, with trying to characterize medical practice.

I think we have come up with the answer and you have seen the proposed language, but basically the approach is to modify the scope and definitions of public dose and occupational dose in Part 20 to explicitly exclude doses due to any medical misadministration the individual has received.

So the verb is receiving the administration, not the status of the person in terms of a member of the public, a patient, or whatever. If it's a medical administration, it's going to be treated under Part 35. If it's a misadministration under the definitions of Part 35, it will be treated as a misadministration.

(Slide)

DR. GLENN: Okay. Schedule. The final rule has been drafted by the staff. It is in the concurrence process, and we hope to have it up to the Commission in June.

I guess if there are any comments? I think in the past the Committee has indicated general favor with this particular approach. If there are any comments in terms of the draft language that we have passed out to you?

CHAIRMAN SIEGEL: Yes. First order, are there any comments? I mean, I reviewed it. I thought it looked pretty straightforward. I think it seems like we do have one order of business, though, John. The statements of consideration --

DR. GLENN: Yes. It says you approve of.

CHAIRMAN SIEGEL: -- says that we agreed at the meeting on May 11th. So, first of all, we do need to remember to change that to May 12th.

DR. GLENN: Yes.

CHAIRMAN SIEGEL: And can we have a motion that we agree?

MEMBER SWANSO: So moved.

CHAIRMAN SIEGEL: Is there a second?

MEMBER WAGNER: Second.

CHAIRMAN SIEGEL: All in favor?

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

CHAIRMAN SIEGEL: Any opposed?

(No response.)

CHAIRMAN SIEGEL: You got it.

DR. GLENN: Thank you. We will make that correction in the paper, and it will now be 100 percent accurate.

(Slide)

DR. GLENN: The next rulemaking I want to discuss is patient release criteria. I'll just mention that the work on these two rules is by Steve McGuire and Stewart Schneider. And if we run into any difficult questions, I will ask them to respond to them.

I think one of the areas that might be most controversial -- I think, again, you approve of the approach. The approach is that we're going to a dose-based release criteria for patients that's based on 500 millirem to members of the public as a result of release of the patient. I think where you may have some disagreement is in terms of the guidance and how we are going to implement the rule.

I think one of the issues that might be of some contention is recordkeeping. Currently as drafted and with some small changes in the language because I don't think it's clear in all cases what the recordkeeping requirement is -- but our intent is to require a record if the basis for the release of the patient is not the quantity administered -- I'm sorry -- if the quantity administered exceeds the quantity in

the default release table in the regulatory guide. What that translates into is that if it involves any assumptions other than point source, 25 percent time spent at one meet, and that it's physical decay only, then you have to document the basis on which the patient was released.

What's not explicit in the rule language but which is, I think, implicit is that it also means that if instructions are required because the patient is a breast-feeding woman, that a record would also need to be kept to demonstrate that that was done and that instructions were given.

CHAIRMAN SIEGEL: Say that again, John. You lost me.

DR. GLENN: There will be another table -- and we'll get to that later -- that discusses quantities of material that may be administered to a breast-feeding woman that would require that instructions be given in order that the child not receive a dose in excess of the public limit, which is the 500 millirem. In those cases where that is required, then a record would need to be kept.

CHAIRMAN SELIN: Can I interrupt?

DR. GLEN: Sure.

CHAIRMAN SIEGEL: Of course, you can interrupt.

CHAIRMAN SELIN: I say good morning to you all.

CHAIRMAN SIEGEL: Good morning. How are you?

CHAIRMAN SELIN: I'm sorry. I need to run off this afternoon.

CHAIRMAN SIEGEL: We wanted to have a 10-second opportunity to wish you well and to say how much we've enjoyed working with you and appreciate the spirit in which the NRC has treated the ACMUI over the last four years. What else can I say?

CHAIRMAN SELIN: That's not bad. Thank you very much. But the Committee has been extraordinarily helpful as we try to figure out what we want to do about medical work.

I guess if I were going to say one thing, which obviously I am going to say, it would be to sort of help us with some of these larger questions that we come by. As you know, the staff is trying to re-engineer a lot of the Part 35 and related items. If we get something out of the National Academy study, that will be nice, but no one is foolish to have some people go away, come back two years, and count on anything explicit coming back.

So I do hope that you will not just look at the specific pieces but do a kind of overall Gedanken experiment, you know, "If these were, in fact, the rules today, how would they work?" since you bring not only your professional knowledges, experts, but as practitioners, and to help us run through how these items would work.

This is not a Commission-level committee. So I can't give you a charge, but if I were to give you a charge, it would be to look at the overall Part 35 or the changes that we're talking about and try to see how they interconnect with each other. And as practitioners would your lives be significantly easier if we do these things? And put yourselves in the shoes of the patients. Would the patients be any better or worse off if we did this?

CHAIRMAN SIEGEL: I actually think we figured that charge out already and are eager to attack those tasks.

CHAIRMAN SELIN: Very good. So this Committee has been a lot of fun for me. I can't say that metaphor regulation has been a lot of fun. This Committee has been a lot of fun for me. And I have enjoyed it. I have enjoyed it very much.

By the way, there is one major thing that we're thinking of doing that would be very helpful. I would like to see the agency get out of the business of qualifications of professionals. I just don't see that we need to do that. I don't think we need new legislation to do that. I think that we could do with in our current piece. And that's one thing the staff is going to be looking at, which goes far afield in terms of innovation compared to the other pieces which are more mechanical or logistical pieces.

So we have three pieces. One is: Is it a good idea? I mean, do we have anything to contribute at the margin by saying who's a qualified physician if you're not Board-certified? Who's a qualified technician? And do we really let the endocrinologist tell us what a qualified cardiologist is and vice versa?

The second question is: If we don't do it, do we have to make some changes so that other people will, in fact, make responsibility for errors of omission? There's always somebody to take responsibility for errors of commission, but does somebody fall between the cracks?

And the third is to look ahead in the world of gamma knives and other new technology, is it more important or less important that we be involved in deciding what it takes for people to be qualified or who would qualify? And that would be very helpful.

You have an extraordinarily varied group. It's much more of a representational group than just five people who know a lot about reactors or waste, and I think it would be very helpful to the staff.

So I'm sorry I can't stay longer either this morning or at the NRC, but, in any event, thank you for those kind words, Barry. Thank you very much.

CHAIRMAN SELIN: What were you talking about, John?

DR. GLENN: We were talking about release of patients.

I think we have another Commissioner.

CHAIRMAN SIEGEL: We're doing very quick interviews here.

DR. GLENN: Barry, do you want her to come up now?

CHAIRMAN SIEGEL: Please, Gail.

COMMISSIONER de PLANQUE: Hi.

CHAIRMAN SIEGEL: Hi. Welcome.

COMMISSIONER de PLANQUE: How are you?

CHAIRMAN SIEGEL: Fine. We wanted to see if we could capture you for two minutes --

COMMISSIONER de PLANQUE: Sure.

CHAIRMAN SIEGEL: -- to tell you how much we've all enjoyed working with you.

COMMISSIONER de PLANQUE: Thank you.

CHAIRMAN SIEGEL: We really appreciate your special interests in the Medical Program. It has been a pleasure. We wish you well. That's really it. And we'd welcome any sage advice you want to give us in 30 seconds or less or even longer.

COMMISSIONER de PLANQUE: The sage advice would be you serve an extremely important purpose to the Commission and for our regulation in the medical arena. And sometimes

you may feel that your messages aren't being heard, but I think they are.

We do get the reports of the meetings, and we really value all your input because you are our contact with what's going on on the other side of the wall.

It's extremely important that you continue to voice your opinions, your conclusions, your advice. When there are key issues and you think we might not be getting your attention directly, well, then try to get our attention directly. But it's extremely important that you do give us your input on everything that's going on.

You know, of course, we're reevaluating the entire medical regulation. And it's not quite clear what the outcome will be. I think at this point we're -- and I'm sure staff has told you that we're waiting to see what the academy will say. And dramatic actions will occur as a result of what they might say, what we think of the result.

And, try as we might, we haven't been able to get them to spill the beans and give us some sort of preview as to where they're going. So it's really hard to tell at this point, but we're certainly looking forward to that.

By the way, there was a very interesting piece on NPR this morning about errors in the medical community. If you haven't heard that piece, you might be interested in hearing it because it did provide some perspective with other

areas of medical and what kind of errors you might expect in the endeavor of trying to make comparisons. So we sent for the text of that. We think it's of interest. If you don't see it any other way, it's just one more bit of information that might be of interest to you.

But I certainly have enjoyed very much getting the results of your meetings. I haven't met all of you personally, but I've seen many of you. And we certainly appreciate your work.

CHAIRMAN SIEGEL: Thank you.

COMMISSIONER de PLANQUE: Thank you very much. Good luck.

CHAIRMAN SIEGEL: You, too. Thank you.

DR. GLENN: Barry, did I answer your question or not?

CHAIRMAN SIEGEL: I'm not sure. If there's by the table, which is as yet incomplete in the work that we saw, --

DR. GLENN: Right.

CHAIRMAN SIEGEL: -- if you're in the range between 100 and 500 millirems if the patient is, in fact, breast-feeding, then do you need a specific record or isn't that the parallel situation to being within the 100-500-millirem range for using Table 1?

I think the distinction in the rule as it's now written is that if you're between 100 and 500 millirem, you have to give instructions and you have to keep a record if you made the judgment based on something other than the table.

DR. GLENN: Other than the table.

CHAIRMAN SIEGEL: So that if you're making the judgment that a breast-fed infant is going to get less than 500 millirems based on the table, then you shouldn't have to make a special record.

DR. GLENN: Then it should be only in those cases where it would exceed the 500 if --

CHAIRMAN SIEGEL: Unless you did it by special calculation.

DR. GLENN: Yes, yes.

CHAIRMAN SIEGEL: Do you all agree? Because this is key because otherwise we've got more paper that we don't need.

DR. GLENN: It makes sense to me. Now, I'm trying to remember in the discussions we had with NMSS yesterday --

CHAIRMAN SIEGEL: Because that's truly not clear in the text.

DR. GLENN: Yes. And, Larry, I think the question is for the breast-feeding woman where it's between

100 and 500 and where instructions would be required, would we require a record if it's in that interval?

Clearly below that we don't require a record. Above that we do require a record. But there is this gray zone.

MR. CAMPER: We were taking about written instructions being provided.

DR. GLENN: Yes.

MR. CAMPER: But I don't necessarily recall that we talked about a record be maintained of. No, I don't think we were right at that point. Frankly, it's not clear to me why we'd need to have that.

DR. GLENN: Yes. So it really should be if the criterion for release requires a recommendation of cessation that that should require a record. And I think that's appropriate.

CHAIRMAN SIEGEL: Dennis?

MEMBER SWANSON: A comment or a question. In the first point you have, you require a record of the basis for release if the quantity administered exceeds the quantity in default release tables in the regulatory guide. Is that really what you mean? Because I didn't interpret reading this as scud.

DR. GLENN: That's not what it says, but I think that is what we concluded in our discussions with NMSS earlier

this week that is wanted. In other words, if the written directive or the record of the dose administered is not in and of itself a sufficient basis for release of the patient, then there can be many simple ways to include information that supports the release. But there does need to be a written record that tells what the other factors are.

MEMBER SWANSON: But it was my understanding that you didn't have to have recordkeeping if you released the patient based upon these tables.

DR. GLENN: Table 1. That's correct.

MEMBER SWANSON: But the Table 1's are based upon the quantity of the material in the patient at the time of release, not the quantity administered.

CHAIRMAN SIEGEL: But here's --

DR. GLENN: But if you do hold the patient before you release them, then there needs to be a record that they were released one day later and that the activity had decayed. That's what we're saying, that a record of that fact needs to be there. Otherwise there's nothing to tell us that, in fact, you did hold the patient for the extra day.

CHAIRMAN SIEGEL: Here, in fact, is the problem. The problem is that 35.75(c) says that you need a record under those circumstances where the calculation was based on something other than physical half-life, 25 percent occupancy, and a meet. And that automatically puts all breast-feeding

infants into that category because it's based on considerations of things like excretes.

So I'm now wondering whether you can figure out a way to --

DR. GLENN: And we realize that wording has to be changed.

CHAIRMAN SIEGEL: You really don't want records of all of those.

DR. GLENN: We don't want all of those records. And also we didn't catch the situation that Dennis was just talking about necessarily with the way it's worded. So we realize that wording needs to be tuned up.

The two criteria I had up there before are the ones that we essentially agreed to with NMSS earlier in the week. However, I think we need some fine-tuning on the second one that it doesn't cover the 100 to 500.

And getting the wording right in (c) is going to be a challenge. We realize that.

CHAIRMAN SIEGEL: What about putting the table in the regulations? I mean, obviously it won't capture every isotope known to man that might ever be used in medical therapy, but if the tables are part of Part 35, then it's easy to refer to the table. Then you leave less up to judgment.

MR. CAMPER: As an appendix or something?

CHAIRMAN SIEGEL: Well, as an appendix to Part 35. I mean, there are plenty of other things. You've got those long tables of annual limits of --

DR. GLENN: It's something that we can take a look at. There are always problems when you put information in that may change depending upon the technology and this sort of thing.

We'd like to keep it in the guidance document, where it's easier to revise, but we'll consider that. That would make it very simple to describe --

CHAIRMAN SIEGEL: To deal with the breast-feeding problem.

DR. GLENN: Yes, right.

CHAIRMAN SIEGEL: Okay.

MEMBER FLYNN: Can I ask a question about --

DR. GLEN: Sure.

MEMBER FLYNN: I'm not sure I understand. The iodine 125 implant, the 8.7 millicuries, that's the total activity?

DR. GLENN: That would be the total activity.

MEMBER FLYNN: And if a patient has greater than that activity implanted in them, they may not be released?

DR. GLENN: No. But what it says is that if they have more than 8.7 millicuries in them, that you will need to have another basis which is documented in a record for

determining that the dose to an exposed member of the public would not exceed 500.

CHAIRMAN SIEGEL: But which actually will be consistent with what you're probably doing already because the regulatory guide has a dose rate that you can use as the basis for letting them out.

DR. GLENN: Right.

MEMBER FLYNN: Because thousands of prostate implants are being done. And the dose rate might be roughly .2 millirem per hour to meet.

DR. GLENN: And the table does, in fact, say that. But by the way we are planning to write the recordkeeping requirement, you would be required to record that you measured the dose rate and that it was below the value on the table.

Just before we remove this, one thing I'd like to note is that for most isotopes, in fact, the default release criteria in terms of activity are higher than the current restriction, which is 30 millicuries. So there are just a few isotopes where it is more restrictive, iodine 125 being the prime example.

CHAIRMAN SIEGEL: I can't imagine what it would cost to give someone 240 millicuries of gallium-67 or why I would want to do that.

DR. GLENN: One question that has come up in the concurrence process and we would like a little bit of comment from the Committee, the current wording would say "Instructions, including written instructions, on how to maintain doses to other individuals as low as reasonably achievable."

I believe at the last meeting there was a discussion. There was clear instruction to the staff not to say "only written instructions." But do you see a problem with our saying "written instructions"?

I guess in the staff in discussing it, sometimes being patients, we think that sometimes, as well as you doctors communicate, by the time we get home we may not remember everything you've told us. And, therefore, a written instruction that can be referred to either by the patient or the family member is a very reasonable thing.

CHAIRMAN SIEGEL: In fact, we agreed. And I think that language is the language I suggested. So I obviously agree with it.

MEMBER FLYNN: I agree. And that's being done for the prostate implant patients, and appropriately so.

CHAIRMAN SIEGEL: Yes. I think this is fine.

MR. CAMPER: Okay. Thank you.

CHAIRMAN SIEGEL: And this is people need something they can study, and they also need to hear it. They need both.

DR. GLENN: Okay. In the current regulations in 35.315 and 35.415, which are in sections entitled "Safety Precautions," there are requirements to provide instruction to keep exposures as well as reasonably achievable.

We have revised those sections to include language that now refers back to 35.75(b). Clearly on the face of it it is redundant. And we have two choices or three choices. We can either delete those sections as no longer being necessary since we have a requirement for instructions in 35.75. We could keep this as a way to have two sections that remind people that really ALARA is an important concept or we could leave them in there but not refer back to 35.75 but just say in general principles anyone who is undergoing a therapy implant or administration, that you should provide instructions for keeping exposures ALARA.

CHAIRMAN SIEGEL: Are they in conflict in any way?

DR. GLENN: They're not in conflict. They're redundant.

CHAIRMAN SIEGEL: Yes, especially since you're saying if required in 35.75(b).

DR. GLENN: Right.

CHAIRMAN SIEGEL: I mean, the truth of the matter is to be ALARA, you really ought to delete that phrase, but I'm not recommending you do.

DR. GLENN: You're not recommending we do it. That was one question.

CHAIRMAN SIEGEL: That's what I'd do.

DR. GLENN: Yes.

CHAIRMAN SIEGEL: But that doesn't mean it ought to be a regulation.

DR. GLENN: But it doesn't need to be a prescriptive requirement.

CHAIRMAN SIEGEL: Correct.

DR. GLENN: Do you think leaving it here might encourage people to go that extra mile, even in those cases where they wouldn't be required to?

CHAIRMAN SIEGEL: I don't see this as hurting. This is pretty neutral.

(Slide)

DR. GLENN: Okay. This is a trial balloon. This is a table that we did not include. We have had many requests, and NMSS has stressed to those of us in research the need to provide some default tables for iodine 131 as sodium iodide.

Now, we are asking for your advice on the best way to present this table. I had envisaged it as being a

table of defaults depending upon the fraction of uptake in a given patient. When I asked the staff to calculate it, there were more variables involved than I had anticipated. I had not anticipated that the biological half-life is a function of uptake and things of that nature. So the kind of table I envisaged is a little more difficult.

So what I did ask them to do is for --

CHAIRMAN SIEGEL: That still is ignoring attenuation as well.

DR. GLENN: This is ignoring attenuation. The only thing we have taken into account is the biological excretion.

CHAIRMAN SIEGEL: Right.

DR. GLENN: What I asked them to do is calculate it for a 100-millicurie dose so that essentially you can multiply it by a factor. If it's 30 millicuries, it's 30 percent. And so that it's an easy calculation to do. And this way the assumptions that we've made are transparently clear as we go across.

Now, there is another measure of conservatism, other than not accounting for attenuation. And that's that column after "Eight Hours." Because we're talking about up to hundreds of millicuries of iodine in a patient, the assumption of only 25 percent of the time being close to the patient in

the early hours before the biological excretion has taken place is not necessarily a good assumption.

So we have assumed for the first 8 hours that, in fact, it is 100 percent within one meet. So that would account for people who are in cars, being transported home, perhaps being on the metro going home. So the conservatism built in for the first 8 hours is 100 percent within one meet. From that point on it's 25 percent of the time, as in the other calculations.

I believe that for this purpose we put this table together rather quickly, that we haven't accounted for the biological elimination during the eight hours. During that eight hours it's only physical decay. Then from then on we take in the biological. So these numbers would actually decrease some.

MEMBER NELP: Your total dose is over what? What's the time base for the last?

DR. GLENN: That's to decay. Rather, that's infinity.

CHAIRMAN SIEGEL: Integrated to infinity.

MEMBER NELP: And the individual is within?

DR. GLENN: One meet.

MEMBER NELP: One meet, at one meet?

DR. GLENN: At one meet, yes.

MEMBER WAGNER: By that table, am I correct in assuming that if one used this table alone, one could then use a release criterion of 50 millicuries because your total dose never exceeds one rem? So 50 millicuries would be 500 millirem. And apparently the release criteria --

CHAIRMAN SIEGEL: You can use a release for thyroid cancer. You can use a release criteria of --

DR. GLENN: Even higher.

CHAIRMAN SIEGEL: -- 200 millicuries.

MEMBER WAGNER: Well, correct, but, I mean, the table itself would suggest that any --

DR. GLENN: That 50 would always be safe.

MEMBER WAGNER: Would always be safe.

DR. GLENN: I think that that would be a proper conclusion.

CHAIRMAN SIEGEL: But it is higher.

DR. GLENN: Yes, it is higher.

MEMBER WAGNER: Currently in the table they're only listing 33. And what I'm suggesting is that maybe Table 1 could be changed based upon this table.

CHAIRMAN SIEGEL: I think that's the whole point, whether this table would potentially go in as a substitute.

DR. GLENN: Now, the only additional requirement I would think if we used this table is that there would need to be a record of the fraction taken up in the thyroid.

MEMBER NELP: Which would be ordinarily be --

CHAIRMAN SIEGEL: Ordinarily, right.

DR. GLENN: Ordinarily, yes.

CHAIRMAN SIEGEL: Some people do treat empirically, but most do not.

MEMBER NELP: So this means that using this criteria because I sort of got in on the second act or the third act of this play, at a 150-millicurie thyroid cancer dose, you could document, record all of these things. This would indicate that ordinarily that individual could be released without hospitalization.

CHAIRMAN SIEGEL: Yes.

DR. GLENN: Again, in using this table, the important thing is that you would know that the fraction of the thyroidal component was less than five percent.

CHAIRMAN SIEGEL: And that may be a problem, Buzz, because you don't, most people don't, measure the total body retention fraction before they treat a patient with thyroid cancer. Most people do a scan with 5 millicuries, see what the picture shows, and either give them 100, 150, or 200 millicuries, depending on where the metastases are.

MEMBER NELP: Yes. Most people --

CHAIRMAN SIEGEL: Few people make measurements, but most don't.

MEMBER NELP: Most people could make an assumption which would be very conservatively high.

DR. GLENN: Yes. I guess there's some guidance on what would be an equivalent establishment that it's going to be five percent or less. I guess that's my understanding that in almost every case it will be five percent.

MEMBER NELP: Very frequently it is, but there are exceptions.

DR. GLENN: Okay. In the guidance we pointed out that if a patient is in renal failure, you wouldn't be able to use this table.

MR. CAMPER: Yes, right. You would need to bring to bear specific factors and step through the analysis for that particular patient.

MEMBER NELP: Well, you do have the capability of measuring your eight-hour dose or measuring the dose from the individual with your own survey meets.

DR. GLENN: Yes. That's always an option that if you --

CHAIRMAN SIEGEL: Yes. But you can --

DR. GLENN: -- at the time the patient is walking out the door, you make a measurement that's lower than the value in Table 1.

CHAIRMAN SIEGEL: But if it's 150 millicuries, it ain't going to be below 7 millirems per hour if you just gave

the dose a few minutes ago. It's going to be higher than that.

MEMBER NELP: I'll use the table.

DR. GLENN: Okay. Now, is this an okay format for the table or would you rather see it where for a thyroidal component, fraction F_2, we actually did the calculation and said what the maximum activity could be?

MEMBER NELP: I think you could simplify the language a little bit. Instead of calling it -- more traditionally you say a thyroid uptake percent remaining in the body.

DR. GLENN: But here we are assuming you're going to do a little bit of math, you're going to take whatever administered activity you get, divide it by 100 and then multiply by that fraction.

CHAIRMAN SIEGEL: Why not just reduce the whole table to per millicurie?

DR. GLENN: Okay. Rather than do it as a percent, but --

CHAIRMAN SIEGEL: And then make the dose in millirems, rather than in rems.

DR. GLENN: Yes.

CHAIRMAN SIEGEL: Because you've also got confusing things. Right now hyperthyroidism 100 millicuries doesn't make sense. That would be a whopping dose for the

treatment of hyperthyroidism. But just thyroid ablation would be fine, and then you could just say per millicurie, but thyroid cancer you're giving --

DR. GLEN: Sort of a nominal value is what we chose to do there.

CHAIRMAN SIEGEL: Right. And that's actually a conservative value.

DR. GLENN: Yes.

MEMBER NELP: But that actual in terms of convenience if you rounded that off to 100, it would make it implicitly a little simpler to calculate. But it's not a big deal.

CHAIRMAN SIEGEL: But if it was millirem --

MEMBER NELP: I could handle --

CHAIRMAN SIEGEL: -- millirems per millicurie, instead of rems per 100 millicurie, it actually -- I mean, we're used to working in those units, millirems per millicurie or, if you will, millisieverts per mega becquerel, God forbid.

DR. GLENN: That's easy enough.

CHAIRMAN SIEGEL: I like that addition.

DR. GLENN: Okay.

CHAIRMAN SIEGEL: And I think you'll find people defaulting to that a moderate amount.

DR. GLENN: It still has a lot of conservatism into it, but I think it certainly takes care of most cases where you'd want to be related to the patient.

Now, one thing we want to raise to you: Should we in the guide raise the issue that, in fact, with these kinds of activities in patients, the potential for contamination is rather high, even though the doses that we would calculate to members of public would be small? But you do have a high potential of contamination of facilities. Should we mention the possibility that it would not be a requirement but a suggestion that for these higher activities maybe you want to hold the patient until the excretion has taken?

CHAIRMAN SIEGEL: Something in the guidance document pertaining to patients who are incontinent, nauseated, vomiting, et cetera, that ALARA considerations warrant adjustment of what you do based on the medical circumstances. And that's a true statement.

DR. GLENN: Okay. Yes.

MEMBER NELP: Under these guidelines, the only reason you'd keep a person in the hospital was if they were unable to care for themselves appropriately, but they'd be ill.

DR. GLENN: If you don't have an expectation that they can follow the instructions and that sort of thing.

CHAIRMAN SIEGEL: Buzz, do you think you'd send someone? Now, the table says you can do it. Would you send someone out the door with 150 millicuries in?

MEMBER NELP: Absolutely.

CHAIRMAN SIEGEL: You would? Would you wait --

MEMBER NELP: If they were --

CHAIRMAN SIEGEL: -- until they at least had absorbed it from the stomach and --

MEMBER NELP: Why?

CHAIRMAN SIEGEL: -- urinated once or twice?

MEMBER NELP: Why?

CHAIRMAN SIEGEL: I don't mean overnight. Just keep them around for a couple of hours.

MEMBER NELP: I would see my own -- if you want my personal answer to this, I would assure myself that they clearly understood what was going on, that they were capable, they were self-caring, they had a good living situation to go to, they weren't going to be around infants and children. But I don't keep in my office or my domain --

DR. GLEN: So we should focus on the issues where there would be some concern.

MEMBER WAGNER: There is one issue --

CHAIRMAN SIEGEL: Lou?

MEMBER NELP: There is one that I would hesitate to do this with, but --

MEMBER WAGNER: There is a major issue I think that this is going to raise. You're going to see this after this sharpens, I think. And that is we have had several problems in the State of Texas with regard to waste facilities, conventional waste facilities, that pick up radioactive diapers, radioactive diapers from adult and children-type patients, but mostly adult patients who are released from our facility.

And this is going to raise that level of concern. And it will cause a problem as to how they're going to handle that issue.

MEMBER NELP: I would hesitate to send a diapered adult home if they were --

MEMBER WAGNER: I think with this situation now you're going to have more contamination of things that might get thrown away, and it may raise that issue.

DR. GLENN: I think we have documented cases where toothbrushes have, in fact, sent the alarms off.

MR. CAMPER: We wrestled, as John pointed out, amongst ourselves a lot with this issue, this table and some of the release values associated with it. But in the final analysis this is a dose-driven rule. And you shouldn't ignore a biological half-life. And you shouldn't ignore dosimetry.

In many ways it places more responsibility upon the licensees to be certain that you're not exceeding the 500,

that you go through the proper steps, but that's probably where the responsibility belongs.

MEMBER NELP: What's the time line on this?

DR. GLEN: Soon. My last slide discusses that. The slide says July and August. I'm actually pushing the staff to get it up in June.

I would like to have this Commission have a chance to review this rule.

Okay. Next we have the table in terms of when breast-feeding should be ceased or when instruction should be given to breast-feeding women. The table is based on data that ORISE has generated for us. And, again, we have a question about the format of the table. What is the best way to present it?

And, again, this table has been generated as listing the nominal values and then saying "Instructions should be given? Yes/no. What would be the doses? Is interruption recommended? And for how long?" and that sort of thing.

So the idea here is we sort of choose what we think about the doses that people would probably be administering and giving them information as to what they should do in those cases.

We can turn it around and do it. This amount administered to the mother may result in 100 millirem. And,

therefore, instructions need to be given. This amount would result in 500. And, therefore, cessation needs to be considered.

CHAIRMAN SIEGEL: This format here, personal opinion, is very close to the format that has appeared in the published literature. It's related, the procedures at the radiopharmaceuticals to specific clinical procedures and provides quick guidance to a real procedure, rather than in this case reducing it to millirems per millicuries administered to the mother.

I actually think this format in the table is more practical and people can then extrapolate from the information in the table to the particular situation that they're dealing with. That's my opinion.

MR. CAMPER: Do you that that the 131, 150 millicuries at the top, has --

CHAIRMAN SIEGEL: I think you need more than one entry. In fact, you need three entries. They're simple. They all say the same thing: I-131, 150 millicuries; I-131, 10 millicuries; and I-131, 30 to 100 microcuries. And then all of them have the same recommendation.

DR. GLENN: Okay.

CHAIRMAN SIEGEL: You can't keep breast-feeding with that much I-131, period. Correct, Lou?

MEMBER WAGNER: Yes.

MEMBER NELP: These data all come from the literature on I guess excreted material in the milk that's been studied. Is that correct?

DR. GLENN: One thing I'll mention --

MEMBER NELP: I'm surprised that sulfur colloid is seen in breast milk. That surprises me, but --

CHAIRMAN SIEGEL: Sulfur colloid's not, but the small amount of free reduced and free pertechnetate is.

MEMBER NELP: But look at technetium red cells. That stuff is coming off of those cells very rapidly. You know, the half-life of tech on red cells is 20-hour. It dilutes off very rapidly.

CHAIRMAN SIEGEL: Not for *in vitro*. *In vivo* is a problem.

MEMBER NELP: No, no. I mean *in vitro*. Once it's labeled, then it dilutes off very rapidly.

CHAIRMAN SIEGEL: I don't think so.

MEMBER NELP: Oh, yes, I think by ALAR T 1/2. But, anyhow, I mean, that's been well-studied. But I was just curious. It's not a big deal, but it seems unusual that that would --

DR. GLENN: Let me mention one thing. We did consider simply referring to USP. Now, it's our understanding that that may not be updated very frequently and that we would have the advantage here of having ORISE give us the most

recent data that's available. However, I think in the guide we would have to say "If there's something we haven't included here, that you could refer to the USP in terms of" --

CHAIRMAN SIEGEL: And USP actually got a little funky over the last few years. USP used to include pretty specific recommendations about cessation of breast-feeding, and then they've more recently kind of dropped back to a generic statement and said the best way to be sure is to measure the activity in breast milk and became less helpful.

And I think for the guidance you need here, this table will serve the world better with the recognition that we have a responsibility to help you and you have a responsibility to keep this table as up-to-date as possible.

DR. GLENN: I will mention, I guess, that there are still some holes in here, that those are being filled, more isotopes.

MEMBER NELP: Eighty-five percent of the stuff is going to be technetium-labeled.

CHAIRMAN SIEGEL: You don't have strontium-89, but I don't think there are a whole lot of people who are breast-feeding getting strontium-89. But anything's possible.

DR. GLENN: I guess phosphorus-32 also.

CHAIRMAN SIEGEL: Thirty-two is --

MEMBER SWANSON: Both chromium and sodium phosphorus.

CHAIRMAN SIEGEL: Yes, although that's pretty straightforward what the answer is going to be.

MEMBER NELP: I think --

CHAIRMAN SIEGEL: You can't buy it in the United States anywhere.

MEMBER NELP: I think it would be a little bit overkill if you wanted to -- you know, you could go through every radiopharmaceutical that's available.

CHAIRMAN SIEGEL: The problem is you can go through a lot. You won't find published data for many more than are in this table, having looked at this quite thoroughly.

MR. CAMPER: That's right.

MEMBER NELP: You've got thallium up there. You don't have an answer. Maybe is as commonly used as thallium today or maybe more commonly used is technetium.

CHAIRMAN SIEGEL: It probably, yes --

MEMBER NELP: But I'm not sure that -- you know, thallium is rarely used in a breast-feeding woman.

CHAIRMAN SIEGEL: Well, there are at least three published cases and phenomenal data at Washington University on a case about three months ago, where we made measurements for a week and a half.

MEMBER NELP: After thallium?

CHAIRMAN SIEGEL: Yes. A patient who was breast-feeding was done at another hospital and called us to say "They found out I was breast-feeding after they did the test and told me I probably shouldn't feed for one feeding. What should I really do?" And I looked in the literature, and there was just inadequate guidance. So we got a bunch of samples.

After the first three days, it was clear that she could continue breast-feeding, but we asked her to keep sampling, which she did for another eight days. So we have a pretty complete profile.

MEMBER NELP: So you want to fill in the --

CHAIRMAN SIEGEL: I can help Stewart find the --

DR. GLENN: You can help us fill that one in.

CHAIRMAN SIEGEL: I have the references, yes.

DR. GLENN: Okay.

MEMBER WAGNER: Barry?

CHAIRMAN SIEGEL: Yes?

MEMBER WAGNER: As far as the utility of the table, would it not be preferred to list the minimum activity at which the dose to the infant would exceed the permissible dose, rather than list it the way we have it?

DR. GLEN: So you're saying add a column, not do away with this table, but add a column?

MEMBER WAGNER: Yes, that's right. That would give a lot of very useful guidance to people because then you could go right down that table and say "Well, this is above that threshold" or "isn't."

But the way it is listed now, one has to go through a calculation and try to do things. And the utility of the table is a little difficult.

MEMBER NELP: That could cause you to go down and say "Well, I just won't give" --

CHAIRMAN SIEGEL: That's fine.

MEMBER NELP: -- "the mother that much for this test."

MEMBER WAGNER: Yes.

MEMBER NELP: "I could do the test with one-third of the amount." That's a good suggestion.

CHAIRMAN SIEGEL: Okay. That's fine.

MEMBER SWANSON: I don't know if you want to hit things now. Some of the things just aren't available. Human albumin microspheres aren't available anymore. Certainly I-125, hippuran, I don't know of anybody that's using it. It's not available.

MEMBER NELP: I'm using it.

MEMBER SWANSON: I-125, hippuran?

MEMBER NELP: Oh, I'm sorry. Hippuran, no. Iothiolmate.

MEMBER SWANSON: Iothiolmate.

CHAIRMAN SIEGEL: It's not on the table.

MEMBER SWANSON: It's not on the table.

The dose for technetium white blood cells I'm assuming you're talking about the examidasine label that's 20 millicuries, rather than 5. I can give you some more.

CHAIRMAN SIEGEL: We would be happy to react to this table and feed comments back to you when it's a little further along, whenever you're ready, since we didn't have this one. And we'll get you additional literature to the extent -- I mean, Lou has collected this literature over the years, and so have I. And I have given you a lot of it, Stewart, already.

DR. GLENN: Okay. We've already mentioned schedule, July or August. That's what the staff would need in order to get I think the guide fully developed, but I think we can have the guide in its next revision and have the rule in final form in June. And that's what I'm pushing for.

CHAIRMAN SIEGEL: Okay.

MEMBER SWANSON: One comment on the guide. There are a couple of statements in here; for example, "If a radionuclide is, for example, a beta emitter, other pathways of exposure must be considered or need to be considered. The values in Table 1 do not take these other pathways into account." And, again, that leaves us kind of open-ended.

It's also the statement at the end of it "Internal doses may be ignored in the calculations if they are likely to be less than 10 percent of the external doses. They would be significantly less than the uncertainty in the external dose." But with a beta emitter you're not going to have external doses. So that would imply that you've got to take it into consideration.

All I'm saying is we probably need some table guidance.

DR. GLENN: Or at least something a little more explicit than just saying that --

MEMBER SWANSON: I would actually recommend that the NRC make some assumptions that you think are appropriate with regard to these beta emitters and come up with some calculations for the table because I think in reality most people are going to release patients based upon your table of guidance anyway. So please give them guidance on the beta emitters also.

DR. GLENN: Okay.

MEMBER SWANSON: Don't leave it open-ended is all I'm saying.

DR. GLENN: Okay. We do have some comments I guess about using ALIs, I guess, if nothing else exists, but --

CHAIRMAN SIEGEL: Okay. Can I continue on the regulatory guide?

DR. GLEN: Sure.

CHAIRMAN SIEGEL: Do you have a copy there, Stewart, or does someone? On Page 7 there is a paragraph that said "The instruction should be specific to the type of treatment given, such as" blah blah blah. "The instruction should include a contact and phone number in case the patient has any questions. Instructions should include as appropriate."

The rule actually leaves the instructions pretty open-ended. The regulatory guide is sounding kind of regulation-like in terms of what the instructions ideally have in them. It's sounding a little bit forceful, and I'm wondering whether there's any way to soften it.

There's no real rule that says you have to give a contact and phone number. So if you really think that's essential you maybe need to add that to the rule. And it can be ignored.

Are you following me?

DR. GLENN: Yes.

CHAIRMAN SIEGEL: Maybe I'm overstating my case.

DR. GLENN: Well, I guess I don't know whether my copy is different than your copy here.

CHAIRMAN SIEGEL: This is a copy of the May 2nd version that Stewart said was --

DR. GLENN: Oh, I've got the May 5th version.

CHAIRMAN SIEGEL: Okay. So you're ahead of me.

MEMBER SWANSON: Good. Maybe it's been taken out.

DR. GLENN: Okay. Yes. It's on Page 8. Okay.

CHAIRMAN SIEGEL: The "should" sort of comes across like it's part of the rule language.

DR. GLENN: In our lingo, "should" is weak, but you're saying we should take note of the fact that --

CHAIRMAN SIEGEL: Well, I don't feel strongly. I think those are reasonable things.

DR. GLENN: Yes.

CHAIRMAN SIEGEL: I'm just wondering if it will be interpreted as a requirement when it's inspected.

On what was Page 16 of the regulatory guide, you're talking about this example of the patient with thyroid cancer, and it says "In the example given above, the thyroidal fraction F_2 is 0.05, is a conservative assumption. For those individuals who have had surgery to remove thyroidal tissue, F_2 is typically smaller."

In fact, if the thyroid hadn't been removed, F_2 would be considerably higher. A .05 value assumes that the patient has had essentially a total thyroidectomy. And this

is the little bit of thyroid tissue that surgeons invariably leave behind that in the course of two weeks has hypertrophied and been stimulated by high endogenous TSH levels. So this is, in fact, not a medically correct statement.

DR. GLENN: Okay.

MEMBER SWANSON: What page?

CHAIRMAN SIEGEL: Page 16. The other example that I found bothersome also on Page 16 was the hyperthyroidism example, in which you gave 33 millicuries of I-131, so the maximum amount, but you did it to a patient who had a thyroid uptake of 55 percent. That is really blasting a patient for hyperthyroidism. You just wouldn't do it. I mean, it is conceivable that a patient with a multinodular goiter you might treat, but a typical patient with Grave's disease would not get 33 millicuries of I-131.

In order to do that, how big would the thyroid have to be? It would be a monster thyroid gland. So it's not --

DR. GLENN: It's not wrong, but it's a ridiculous example.

CHAIRMAN SIEGEL: No, it's not even ridiculous. It's an extreme example.

DR. GLENN: Okay.

CHAIRMAN SIEGEL: So you might want to come, maybe with Myron's help, a little bit closer to the --

DR. GLENN: Get some real --

CHAIRMAN SIEGEL: I mean, an average patient you could imagine this 55 percent uptake with, let's say -- an average case about an 80-gram would be big, but let's say 80-gram thyroid gland with an intended dose of 120 microcuries per gram. That's about where you would be on average. And that's going to come out more like 10 to 12 millicuries.

I'll do the calculation if you want me to, but that's off the top of my head.

DR. GLENN: I guess the thing --

MEMBER NELP: As I understand the instruction, there's no case of hyperthyroidism that would require any consideration for not releasing them immediately.

DR. GLENN: If it's less than 33 millicuries, there is no reason for doing a calculation.

CHAIRMAN SIEGEL: But I think in order for the regulatory guide to be credible, people need to be able to relate it to what they actually do for a living. And people are going to look at this and --

DR. GLENN: Yes. I agree with that.

CHAIRMAN SIEGEL: -- say "This is not my patient."

MEMBER NELP: But the point is below 33 millicuries, it's a non-issue.

DR. GLENN: Yes. The table assumes physical decay and 100 percent uptake. So it's very conservative.

CHAIRMAN SIEGEL: Okay. That's all. Those are the comments I have.

MEMBER NELP: Now, I could treat with 50 millicuries.

CHAIRMAN SIEGEL: You got it, man. Sure.

DR. GLENN: Okay. The pregnancy and breast-feeding rule I hope will go very quickly because the status is that it's on hold pending two things. One, we have some contracts with BNL and PNL. In particular, we're trying to get a fix on the placental transfer. Pertechnetate turns out to be the problem. That's the one we're working on.

CHAIRMAN SIEGEL: Right.

DR. GLENN: We won't have that report until fall. So that's one reason why it's on hold.

The other one is that we might as well wait for the National Academy study if we've waited that long.

CHAIRMAN SIEGEL: Isn't the breast-feeding rule, a component of that rule, essentially a done deal now?

DR. GLENN: Yes. It's really the embryo fetus at that point.

CHAIRMAN SIEGEL: Because, really, the issue was all that was in the breast-feeding thing was identify that the patient's at risk and provide instructions. And now you've

added, really, something that wasn't in the original breast-feeding rule: It can't go over 500 millirem.

DR. GLENN: Right. There are some unresolved issues that we might be up in a final rulemaking. We don't have a definition for a misadministration under those circumstances. Should we have a definition for a misadministration? That will wait until after the National Academy has given us some advice.

CHAIRMAN SIEGEL: All right.

DR. GLENN: Okay. In terms of the status of the contracts, BNL we expect to be completing fairly soon. One thing that I would like to get some input from you, one thing we are considering, the BNL study included literature searches and going out and visiting eight licensees and finding out what standard programs were.

But when it comes to the kind of cost-benefit study that I think we're going to be asked to do in the future, we still don't have a good sense of how many of our licensees already have voluntary programs that include either asking or assessing information in terms of pregnancy status.

We don't have a good sense of what people are actually doing and how many exposures have taken place. So we don't have a sense of both the cost and the benefit of this rule.

And one thing we're thinking about is perhaps it's worth it to go out with a mail survey, either through BNL or one of the professional societies, and actually getting that information if we're going to proceed with the rule.

CHAIRMAN SIEGEL: Sure. Let me ask another question. Your time frame for gathering that data is what?

DR. GLENN: We wouldn't be going for a final rule until next year. And so we could start the survey this fall.

CHAIRMAN SIEGEL: Now, that's fairly complicated, involves OMB approval and all that?

DR. GLENN: Right.

CHAIRMAN SIEGEL: Why not just start today and tell your inspectors to start asking 30 seconds worth of questions about what people do with pregnancy and breast-feeding and record it and send it back to headquarters? You're not inspecting them.

DR. GLENN: No.

CHAIRMAN SIEGEL: You just want to know. And maybe it won't be a random sample either, but neither will a mail survey.

MR. CAMPER: That's possible. We would want to alert the community through some informational process that we're doing that and why because I'm sure there will be some complaints otherwise.

DR. GLENN: Now, we will have the BNL study. We'll have the literature search and all of that in June. And that's probably the time to make that decision. But we have been considering a wider survey in order to get better data.

The PNL study, which is the placental transfer and we would have ORISE being the peer review group for that, we expect that in December of 1995.

CHAIRMAN SIEGEL: Okay.

DR. GLENN: Any questions on that?

CHAIRMAN SIEGEL: No.

DR. GLENN: Thank you.

CHAIRMAN SIEGEL: I love it. Well, it certainly would be useful to get the tables, but maybe if you want to polish them any further before you send them to us. Otherwise the rest of the slides I don't think we need. They'll be in the transcript anyway, won't they? You've not been adding slides to transcripts? Okay. Fine. Good.

John, thank you.

All right. We have some administrative matters.

MR. CAMPER: Yes, we have a few things to bring to your attention.

In your briefing books, we have provided some information on travel issues. From time to time some of you have had some difficulties in getting your travel vouchers and

so forth processed in a timely manner. And there is some information there for you to review.

The main thing is the idea of filling out the forms completely and preferably in a timely manner so that we can respond to them as promptly as possible. And if you'll look through the information there, we'll provide you with some instructions to hopefully help you in doing that.

We would like to wrap up your travel and your compensation as consultants, obviously, as promptly as possible. And we know you'd like that, too.

Another issue is timeliness. From time to time some of you function as consultants as well. During 1994 there was a task force established to review event evaluation follow-up by the agency. And one of the findings of the task force was that in some cases medical consultants were delayed in completing their incident reports, which holds up the subsequent enforcement action.

Dr. Paperiello was a member of that task force, and during this task force he committed that he would bring this to the attention of the ACMUI members. So if you find yourselves in the role of a consultant -- and we recognize that you're busy, too, but if you find yourselves in that role, please move as promptly as possible to complete your reports.

MEMBER NELP: I have a question. It's very straightforward. The NRC has a contract with a travel company. And I presume that's the only way I can get my ticket, to purchase it from that company. Is that correct? You won't tell me my ticket's worth 400 bucks and, therefore, you'll reimburse me that amount of that ticket? Can you just say "Your travel is worth 400 bucks. I will reimburse you to that amount"?

Like I'm on a trip now and I have other things to do. And to purchase my ticket through that agency has cost me considerably more money than it would if I had done it in an alternate fashion.

MR. CAMPER: Well, you have to use the contract carrier unless it's provided otherwise on your travel authorization.

MEMBER NELP: That's why I'm asking you.

MR. CAMPER: So what has to happen is when we prepare your travel authorization, it has to indicate that you have permission to use a non-contract carrier.

CHAIRMAN SIEGEL: Buzz, what also --

MEMBER NELP: You can give me that permission?

CHAIRMAN SIEGEL: Yes.

MR. CAMPER: Yes, sir.

CHAIRMAN SIEGEL: And what also can happen is the following, that Carlson can write the equivalent of a Seattle

to Washington to Seattle ticket that fulfills what the NRC would authorize you to do --

MEMBER NELP: I realize that.

CHAIRMAN SIEGEL: -- and then instantly turn that ticket into what you want.

MEMBER NELP: When I called and inquired about a non-authorized carrier, I didn't get that same message.

CHAIRMAN SIEGEL: When that happens, you need to call Torre and say --

MS. TAYLOR: Yes. Let me --

CHAIRMAN SIEGEL: -- "Authorize a non-contract carrier."

MEMBER NELP: That's who I called.

MS. TAYLOR: What you do need to do is --

MEMBER NELP: And also Carlson would not sell me a non-authorized ticket or a ticket of that sort until they got the authorization from them. And from the time they got the authorization from them, I'd lost my chance to get the ticket I wanted. And it cost me another three or four hundred bucks to put my own travel plans together.

CHAIRMAN SIEGEL: My only answer to you --

MEMBER NELP: Had I gotten permission to use a non-authorized carrier --

MS. TAYLOR: What helps me out is if you know you're going to be doing personal travel, --

MEMBER NELP: Yes.

MS. TAYLOR: -- let me know as soon as possible before the meeting so that we have time to do the amended travel and you can have time to make your personal travel arrangements at that cheap air fare. People will call me last week needing to do changes. It's too late when you want to get cheap air fare.

But they will verbally issue your tickets with my okay knowing that amended travel is going through if your schedule requires a non-contract carrier.

Now, this personal travel issue is a whole other story.

CHAIRMAN SIEGEL: But that's exactly what I did for this meeting. I have a nonstandard itinerary, and the ticket that they actually sold me turns out to be less than what the St. Louis to Washington ticket would have been. So the NRC is saving money on the deal. But I started doing this 10 weeks ago.

MEMBER NELP: Well, I started three months ago.

MS. TAYLOR: I never heard a word about it.

CHAIRMAN SIEGEL: The one you needed to do -- the minute Carlson gave you a roadblock, you needed to call Torre, which is what I did. And we solved it very quickly. So that's the word of advice.

MEMBER NELP: So it can be arranged?

CHAIRMAN SIEGEL: Absolutely.

MEMBER NELP: That's what I wanted to know.

MR. CAMPER: The key with the government travel is you've got get it cleared in advance. There is flexibility in ways to do things, but --

MEMBER NELP: See, the NIH will just say "This trip is worth 400 bucks. We'll reimburse you or you can buy the ticket from us. You have that option." So they sort of have a standing nonuniform --

MR. CAMPER: Okay. The other thing of an administrative nature -- any other questions on travel? Dan?

MEMBER FLYNN: The one thing about the consultants, I've had a couple of misadministrations I looked into whereby I was then given instructions where I could call the licensee. And I requested additional medical records.

Oftentimes you don't get those additional records for three or four weeks. And then I get a phone call saying "Well, we've given these records to the NRC people. Get it from them."

So there are some issues out there whereby the staff at Region 3 or Region 1 may be getting records, some records, given to them by the licensee and they're assuming that I'm in Region 1 or Region 3 to look at the records that are being obtained by the region.

I think it might be worthwhile that when the region decides to use any medical consultant they notify the licensee that a medical consultant needs to get independently all the records to look at with that patient so they won't have these delays.

The other delay with consultant reports oftentimes is you wait to see on the first follow-up what has been the effect on the patient. There was one where two weeks later there was no effect. This is a misadministration in Connecticut. And then because the patient was in contact with the source, the ulcer developed six weeks later.

MR. CAMPER: And such a delay is unavoidable.

MEMBER FLYNN: Right.

MR. CAMPER: The first type of delay we can look into, what we might do to enhance the administrative process with this records movement and see if there's something we can do to improve that.

Okay. The next issue is sort of a status report on what we're doing on the radiation therapy technologist/medical dosimetrist position. We did receive 11 nominations for this position. The nominees had been reviewed. The top three candidates were selected by the screening panel in accordance with the new procedures developed by the Commission for selecting new members of

advisory committees. And this is advisory committees across the board.

On April 13th, '95 we provided the ACMUI members with the names and resumés of the top three candidates as well as a table summarizing the qualifications of all the nominees for your independent recommendation on the screening panel's recommendation.

At this point Torre informs me that we have received I guess on the order of five or six responses from the Committee. Is that correct, Torre? And we're going to want to move pretty quickly now to bring this matter to closure.

So if any of you have not responded on the nominations or the recommendations of the panel and you wish to do so, please make it a point to do so promptly because we want to move to get that position filled.

With regards to the medical physicist position with an emphasis in therapy, the nomination period for this position closed on March 10. We received 21 nominations for this position.

In addition, three of the nominees for the radiation therapy technology/medical dosimetrist position are actually medical physicists. With their permission, we are going to review their resumés along with the resumés of the physicists that were presented for consideration.

We hope to get the screening panel together during June to review the nominations, come up with our top three recommendations, and then forward those to the Committee for your review as well. We are, like you, eager to fill that position.

For the record, I would like to show that the Committee was provided with a copy of the inspection procedures associated with the radiopharmacy rule as well. We didn't discuss those, but I just want you to be aware that they are in your packet if you want to review them. We discussed the guidance documents extensively, but we wanted you to have a copy of the inspection procedures as well. And if you have any comments at a later time on the inspection procedures themselves, please feel free to provide those to us.

One remaining administrative item, then. And that's the upcoming meeting for November. Now, Torre, you have queried the Committee. I know certainly Dr. Siegel has provided some insight. Where do we stand on the next meeting as you understand it?

CHAIRMAN SIEGEL: Well, depending on what feedback Torre has gotten from my E-mail and/or fax of the other day, I'd like to have the next meeting on October 18th and 19th. Is that correct, Torre? Those are the days I picked?

MS. TAYLOR: Right.

CHAIRMAN SIEGEL: Right.

MEMBER NELP: What days of the week?

CHAIRMAN SIEGEL: That will be a Wednesday and a Thursday. The option was 19th and 20th, but it turns out that for Larry that didn't work as well.

So you should have the calendars in your books. If you would please return those calendars to Torre as soon as possible, even before you leave if you can? And if October 18th and 19th do not appear to be a problem, then let's set that date as quickly as possible.

MR. CAMPER: Okay.

CHAIRMAN SIEGEL: Okay? Is that it?

MR. CAMPER: Now, I have just a couple of closing comments, and I know you want to make a couple of comments. Then I'll officially close the meeting.

I want to, first of all, obviously thank the Committee for your participation over the last day and a half. This is my first meeting as the Chief of the Medical Academic and Commercial Use Safety Branch. I've sat in Josie Piccone's chair for some five or six years now. But it's very enjoyable from my perspective to be in this role and to work with you.

I personally found the meeting to be very productive. I think that the Committee has grown into a true advisory committee, impacting policy and technical decisions

earlier and earlier in the process. And, frankly, I think that the value that you bring to us and the advice that you bring to us is just really very strongly valuable.

I'd like to thank Torre for putting together the meeting. She worked long and hard and all of the staff within the medical section. A tremendous amount of work goes to getting together a meeting like this. And if the size of the volume of the briefing book is an indication, you have some idea what went on.

Of course, to the presenters and our staff, they all did a great job. And I commend them for their efforts. And, although our colleagues from research have gone, they, too, worked hard to make the meeting worthwhile.

We've had some very intense meetings the last couple of days of research on the guidance document that we discussed toward the end of the meeting. I think my impression is that's beginning to finally come together.

So I again just want to thank you on behalf of myself and our division for the input over the last day and a half. It's been very worthwhile.

CHAIRMAN SIEGEL: My thanks also to Larry and Josie and always to Torre for making everything work so well and to the rest of the staff. This has been quite an interesting meeting, despite a little bit of fireworks yesterday in falling so far behind schedule yesterday.

I want the transcript to reflect the fact that we all miss Judy Brown, who sprained her ankle, I gather, and was in a wheelchair or crutches and couldn't make it, and hope she'll be back again with us at the next meeting.

And, with that, Larry, why don't you do your official thing.

MR. CAMPER: As the designated federal official for this meeting, I declare the meeting concluded.

(Whereupon, the foregoing matter was concluded at 2:15 p.m.)

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