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ANN RILEY & ASSOCIATES, LTD.
1612 K St. N.W., Suite 300
Washington, D.C. 20006
(202) 293-3950

NUCLEAR REGULATORY COMMISSION

QUALITY ASSURANCE FIELD PROGRAM

POST TRIAL WORKSHOP

Sheraton International

O'Hare Airport

6810 North Nannheim Road

Rosemont, Illinois

Friday, August 24, 1990

Whereupon, the above-entitled meeting commenced at 8:40 a.m.

WORKSHOP PARTICIPANTS:

Robert Lawalan, Harrison County Hospital
Alessandro Ricci, St. Joseph Medical Center
Robin Schaefer, St. Joseph Medical Center
Judy Bastian, Freeport Memorial Hospital
Charles Lee, St. John's Hospital
Larry Camper, Nuclear Regulatory Commission
Edward Kaplan, Brookhaven National Laboratory
Anthony Tse, Nuclear Regulatory Commission
John Telford, Nuclear Regulatory Commission
Darrel Wiedeman, Nuclear Regulatory Commission
Ed Kline, BWL
Ray Wery, Marguette General Hospital
Tracy King, Medical Physics Consultants
Thomas Stefanakos, Krause, Lubert & Associates
Rita Duffy, Marian Health Center
Terry Garner, Mt. Sinai Medical Center
Richard Clouse, Elkhart General Hospital
Bill Erickson, Mercy Hospital

PROCEEDINGS

[8:40 a.m.]

MR. TELFORD: Welcome to the second day of the workshop.

Today, we're going to go through the guide: this morning, the regulatory guide, and then, this afternoon, we're going to go through the reporting requirements. During this, you'll have ample opportunity to ask questions and make any comments you want to make for the volunteers, and at the end, we'll have further opportunity for comments.

So, at this time -- we're going to go through the guide section by section -- your suggestions on how it could be modified.

MR. TSE: Good morning.

We're going to go through the guide to learn your suggestions, comments, and modifications.

I have a few general comments I need to make first.

What we have discussed yesterday on the objectives, if it's adopted in the final rule, then those comments will be automatically carried over into the guides, because, in fact, it's supposed to match the objectives in the regulations.

Second, we heard some suggestions that we should discuss with the physicians and so on, and we are planning

to discuss with several organizations specifically in the workshop discussion. We are thinking about JACAHO. We already discussed it with them one before, but we thought that we needed a second session. And for physics portion, AAPM. So, their comments, we will specifically seek their comments and will be considered.

Then, there were comments suggested earlier of different people -- will use this guide as a regulation. In our view, this guide is just guidance for you to use in preparing your quality-assurance program. So, we would try to have discussions with states and so on, but also, to avoid those situations, we would plan to incorporate industry practices into these guides, these elements.

So, essentially, we will now have one element to fulfill certain things, and that element may have several different approaches; like A or B or C, they're all applicable, acceptable. In that case, then, it's difficult for people to use this as a regulation; there are still alternatives listed and those elements.

Then, when we go into the guide today, this morning, we will go section by section, and I will not explain, because you already know what this guide is about. So, I will just ask each of you if you have any suggestions or modifications or deletion or addition, and let us know. Okay?

We will go into the guide now.

The first couple of pages -- are the general statements, the purpose of the guide, and so on, some introductory statements. Now, does anybody have any suggestions on that one? If not, I would just go into the guide.

[No response.]

MR. TSE: Okay. Then let's go to page 4.

MR. STEFANAKOS: Tony, excuse me. I was trying to find a section in here, but I couldn't find it in the objectives and all that, where we discussed about audits and responsibilities and all that. Remember that?

MR. TSE: Yes, I think so.

MR. STEFANAKOS: Yesterday we talked about it.

MR. TSE: We did talk about that.

MR. STEFANAKOS: Yes. Remember, we talked about audits and whose management and so forth? Well, in this Responsibility, Authority, and Audit, it says somebody other than those involved in the program itself. But yesterday, we said that it was all right for the people who are running the program -- namely, the physician or something in the therapy program -- to do the audit and that. Yet, this is completely contradictory to it.

MR. TSE: Well, this -- remember, this document was prepared way back, and at the time when we prepared this

document, the importance -- but if there are some difficulties, somebody may have a difficulty, then we will accept suggestions, and we will look at them, and yesterday, we were discussing whether people could monitor themselves, and whatever the result of our consideration, it will carry over here.

Now, do you have a suggestion how to change this?

MR. STEFANAKOS: Well, the only suggestion I would make is that -- when you say audits will be conducted, where it says by qualified personnel who are not involved in or with the activity being audited, I would add the words "whenever possible" in case there is a situation that that can't be done, and as was brought out over here by someone, you hate bringing somebody else in to air your dirty laundry to somebody else when they're going to do the audit and such.

So, I would just like to see "when possible"; not involved in the activity being audited when possible, so that you give somebody the out.

MR. TSE: Okay.

MR. WERY: Also, I think you need to define it. You use "qualified" in there. That's not really defined as to what a "qualified" person would be.

MR. TSE: Well, it says in it later, that management will decide what it is.

MR. WERY: Okay. And, also, to sort of include with that is that personnel who are not involved with the activity being audited -- as long as management has to make a decision, you may have someone like QA committees that are involved in a hospital that are set up. Now, they're not directly involved with the option thing, but they are part of the hospital, and if you look at it from the broad view, they are part of the hospital. So, they are involved with people being -- with the activity being audited, because they are part of the hospital.

In many cases, you would want to use those QA people who are doing this work. In a hospital situation, at least, that framework is all set up. It might be a good one to follow.

MR. TSE: Maybe your suggestion is to add like word like "directly" involved. If I made a calculation or I did this procedure, I can't look at myself, because I always will know that this is the calculation.

MR. WERY: Sure.

MR. TSE: Maybe -- would that --

MR. WERY: Yes.

MR. TSE: Will that kind of thing resolve --

MR. WERY: Yes.

MR. TSE: But note here, we did not say "independent"; therefore, it doesn't have to be somebody

outside.

MR. WERY: Yes.

MR. TSE: Any other comments?

[No response.]

MR. TSE: If not, then we'll move on to Section 2.

Section 2 are the general elements which apply to all program areas: diagnostic, radiopharmaceutical therapy, brachytherapy, and teletherapy.

Does anybody have comments or suggestions?

Some of them were already discussed yesterday. But you can restate it if you wish.

MR. STEFANAKOS: You know, 2.4 --

MR. TSE: Yes.

MR. STEFANAKOS: Maybe I'm misreading this, but I think you're asking the technologist to play physician, because it says "Before medical use, the person administrating a byproduct material," which is, 90 percent of the time, the technologist, "will verify that medical use is in accordance with a prescription."

MR. TSE: Right.

MR. STEFANAKOS: Now, do you mean by that, "in accordance with the prescription," by what the prescription says?

MR. TSE: Yes.

MR. STEFANAKOS: Okay. Then that's fine.

MR. TSE: Make sure it's the same.

MR. STEFANAKOS: Okay. Then there is no problem with that. I misread it.

MR. TSE: Anybody else have any questions? It's okay?

MR. STEFANAKOS: Yes, if that's the way it's intended.

MR. TSE: It may not be so clear. Would you suggest making it clearer?

MR. STEFANAKOS: I don't have any way of making it clearer. That's fine. It was just my misunderstanding.

MR. TSE: Any questions?

MR. RICCI: I have a comment on 2.3.

MR. TSE: Yes.

MR. RICCI: I would object to "seek guidance," because it may not be necessary to seek guidance in order to resolve an apparent discrepancy, etcetera, etcetera, in the sense of the tech might be able to stop procedure and dedicate himself to solve the discrepancy by himself, on his own -- he would seek guidance. So, I would just drop that.

I would suggest an alternative to 2.3, which reads "The responsible individual shall withhold or stop medical use on a patient if there appears to be a discrepancy in records, observation, or physical measurements that may result in a diagnostic or therapy event, except possibly in

emergency situations. The responsible individual may resume the procedure only upon resolution of the discrepancy." And there I don't mention "seek guidance," but then, of course, if the resolution of the discrepancy requires seeking guidance, that's part of it.

MR. TSE: Yes. That may be a good suggestion, but if that's the case, with the second-to-last sentence, if we just take the three words away -- "All workers shall stop medical use if there is a discrepancy," etcetera. "The worker may resume use after resolving the discrepancy."

MR. RICCI: Certainly.

MR. TSE: If not the worker, perhaps a physician, him or herself trying to solve the problem himself. So, he may or may not have to seek the guidance.

MR. RICCI: Right.

MR. TSE: That's a good point.

Any others?

Richard, we were looking at the guide. We're finished with Section 1, and now we are looking at Section 2. But if you have some comments on Section 1 or 2, please give them to us.

MR. CLOUSE: Okay. No.

MR. TSE: Any other comments?

[No response.]

MR. TSE: If not, we will go to Section 3.

Section 3 applies specifically to radiopharmaceutical therapy and Iodine 131 and 125 for more than 30 microcuries. As we discussed yesterday -- may not be included in here. So, when you look at this item, you should keep in mind -- does not have to follow this.

But other than that, all items -- greater than 30 microcuries, we suggest the same. But again, we have to be careful. This is just a recommendation, suggestions. We suggest that these elements be used as elements to meet the objectives.

So, please, if you have any comments on this page, those five elements for therapy, radiopharmaceutical therapy, if you have any suggestions or questions --

MR. LEE: On 3.2, I just have a problem with the word "personally"; that the authorized user will personally make -- a prescription.

MR. TSE: What's your concern?

MR. LEE: Well, I just don't see why people doing that -- it usually is done by the tech after a verbal order for the pharmaceutical.

MR. TSE: Even for therapy?

MR. LEE: Well -- therapy. I don't know how I would change it. I guess if they were required to do it, they'd have to do that.

MR. TSE: Well, this goes back to the objective we

talked about yesterday. For therapy, the objective says you must have a written prescription, and a written prescription is defined. You must have a prescription in the objectives. But the prescription is defined as the written directive, containing certain information like item 31, how many milicuries, and so on, and assigned by the authorized user, and that's how we tried to put the authorized user in charge. Now, your suggestion is that maybe they don't need to do that?

We put "personally" here, because sometimes people can delegate. If it's "personally," then you cannot delegate. You cannot, say, give a verbal -- by saying you sign it for me.

For therapy -- now, this is only for therapy, plus the iodine greater than 30 microcuries, and of course, we discussed yesterday, because with 30 microcuries, it could easily mistake it to -- could be mistaken for milicuries; that's 1,000 times off, and that's why we'd be more careful in making those suggestions.

Any other comments -- suggestions or something you think should be deleted or anything that should be added?

[No response.]

MR. TSE: If not, we go to the next section, which is for brachytherapy. Brachytherapy will have about 2 pages.

So, if anyone has some questions or comments or suggestions on any of those elements you already know, please say so. Otherwise, we will take time so you could go through it to see whether you can make some suggestions.

Yes?

MR. WERY: I think at the last meeting you talked about 4.5 --

MR. TSE: Yes.

MR. WERY: -- needs to be changed.

MR. TSE: Last meeting, we discussed -- we have discussed it several times, and we did not change it yet, because this is still the same copy. After the workshops are finished, we will.

MR. WERY: Is it necessary to have an emergency caveat? We have the emergency caveat as part of the eight objectives, sort of tacked on to the bottom of that, that emergency conditions, you have 24 hours for work orders and that type of thing.

Is it necessary to have or does anyone think it's necessary to have something like that in the regulatory guide, saying basically the same thing?

MR. TELFORD: Are there any cases of brachytherapy that are emergencies?

MR. WERY: Not so much brachytherapy. I guess I'm jumping ahead to teletherapy.

MR. TSE: We do have an emergency portion.

MR. WERY: Right. I'm thinking more of a prescription. But perhaps we should wait until we get to the teletherapy portion.

MR. STEFANAKOS: I have three that I want to discuss; 4.2 is the first one: "Before administering byproduct material, the authorized user or the physician under the supervision of the authorized user will personally make and date a prescription."

Now, when we say that, I don't agree with using the word "prescription," because prescription is very, very detailed and saying sources, etcetera, and so forth, and if we're talking about a time prior to the insertion of the material or just before the insertion or prior before the insertion of the applicators, it is dependent on when the prescription is written. I don't know when you're saying the prescription is written.

I think this should be stated that the doctor should just be obligated to say how much he wants to deliver to that patient, not in what configuration or anything at the time that he writes it, because our physicians, what they do is -- like when we do an inter-uterine insertion, we'll have like 5,000 rads external. We'll deliver 2,000 rads; then we'll split the therapy, do -- or sometimes we do it at the end, but a lot of times we'll split it. We'll do

a therapy and put a block in there, and then we'll do a -- the brachy insert for 3,000 rads, come back and finish up with another 2,000 rads external, and then come back and sometimes even do a second brachy. All right?

That prescription is written in the chart as such. Okay? Do the external, 200 times 10; then come back and do a brachy. But all he states there is that it will be done that way, not how much he wants to deliver specifically, in many cases.

I think that it depends on what you're saying before administering.

MR. TSE: Okay. The idea is that before insertion, somehow the physician should transmit the information to a physicist or a technologist, how many sources, what kind of sources -- or how many doses I want to deliver.

MR. STEFANAKOS: When you say how many curies, that's the thing that disturbing. He doesn't know. That's what the physicist has to tell him. He sometimes can tell by milligram hours. But even that, that's very antiquated.

I think the physician should only be required to tell the physicist how many rads or centigrade he wants to deliver to point A or point B. Then the physicist goes in there and determines a configuration, gives him the configuration, and he approves or disapproves at that time.

MR. TSE: But he approves it before the insertion. Right?

MR. STEFANAKOS: That's correct. Okay.

MR. TSE: Then, at that point, he approves it, that becomes -- let's assume the word "prescription" as a tentative word, but it's easier to say.

So, here, before insertion, the physician must somehow say this the way I want it.

MR. STEFANAKOS: Okay. So, you're saying before the sources are actually taken up to the room and put into the patient.

MR. TSE: Right.

MR. STEFANAKOS: Okay.

MR. TSE: And then he says this is what I wanted, that's what we're going to do, and he is somehow signing a piece of paper, which now becomes the prescription. You may not like the word.

So, that's the meaning of this.

Now, the prescription -- would you suggest a word like "preplanning" or something, which may be better than the word "prescription"?

MR. STEFANAKOS: Yes, that would be better. But still, I don't want to leave from this one just yet, because --

MR. TSE: Okay.

MR. STEFANAKOS: -- I'm sure there are still people out there who don't have after-loading systems. What do you do in a case like that? You don't know what the time is, you don't know what the configuration is before that. Well, you'd know the configuration, because you're going to put it in there. But you can't do a plan, because you don't have the radiographs; you've already inserted.

Now, I don't know how many people, if anybody, has non-after-loading systems, but if they do, that's going to be a real burden on them, because they don't know how much time they're going to have to leave those sources in there.

MR. TSE: Well, you have the option.

MR. WERY: You have the option to change it. This could be just a wild estimate, if you want.

Again, trying to imagine what it would be like without after-loaders, you go out there with a pretty good idea of what the sounding is, so you're going to know what you think that you can do when you go up there.

MR. STEFANAKOS: See, I guess maybe I have a problem with writing things, saying oh that's all right; if it's not right, we'll change it, because that leads to too much leeway for somebody to say, oh, well, we really blew it, but we'll just say we're going to change it, and that's all right. That's just my own, you know, hang-up, is that I don't like it when you go in there and say that's all right,

just write whatever you want, and we can change it later, because we're allowed to change it any way we want.

MR. WERY: As I mentioned yesterday, what we did -- see, we didn't have a prescription form that sort of fit this. We sort of wrote one that fit this very nicely, and what it sort of did is the top half of the page said, okay, this is after our simulation of the patient. We've got our -- radiographs. We know what we're going in. The physician and the physicist get together regarding the loading they want -- and the physician, then, before he puts the sources in, says, okay, we'll shoot for that being a certain number of hours we'll put that in.

Usually, what happens then is the actual computer plan gets generated after that. Right before that, we have another thing, after consultation of a treatment plan. Now, a place for the loading to be changed -- sometimes the loading gets changed after you see the actual loading, and the new time is now this and a place for the physician to sign, and that sort of policy has always worked.

MR. STEFANAKOS: I can see that. But I think that is a lot of extraneous work that isn't necessary. We can do it verbally. Because you are not going to do anything until you get the treatment plan out, anyway. And you know, why fill a chart up with papers that aren't necessary, and you know 99 percent of the time are going to be changed, anyway?

MR. WERY: I think a lot of places do treatment plans after the sources are loaded.

MR. STEFANAKOS: Well, --

MR. WERY: We do. Occasionally, we will change it. Not very often. But occasionally, we will change things after we go.

MR. STEFANAKOS: We don't. We go up there and we insert the applicators, put the dummy sources in, take the radiographs, come down, then put it through the treatment plan and make our determination of the hours that we are going to have it in there. Or, in fact if, you know, how can you tell? If you have a tipped uterus, you aren't going to be able to leave it in the hours or have the loading you thought originally.

MR. WERY: Right.

MR. STEFANAKOS: Or you could go up there, and the vaginal vault is constricted, and you can't use the minis, you know you have to use the minis instead of the max. And there are too many variables involved, in my own opinion. I'm not trying to say what I'm saying in this record here to pin somebody down and say, do this before. There's just too many variables.

And the other thing is there are times that we had to go up there and abort. I mean, we can't even do it. And now you got a prescription that's in there, and that

shouldn't have been in there to begin with.

MR. WERY: No, no. Our prescriptions are not written until the afterloaders are in place. When he is talking about insertion --

MR. TSE: So let's say supposing we --

MR. WERY: When you are talking about insertion, I am assuming that you are talking about the insertion of the radioactive materials.

MR. TSE: Right.

MR. WERY: Not the insertion of the instruments.

MR. TSE: No. No.

MR. STEFANAKOS: Yes, but you just said they do it before you insert the source, I mean after you insert the sources, you do your treatment plan.

MR. WERY: We routinely will, the instruments are put down in the OR. The patient comes down, we take our radiographs.

And if the plan is as expected, in that we can tell how many sources we can put in from the radiographs and that everything is straight and relatively uncomplicated, we will then, with the physician, look at the plans, and with standard plan we will do our standard loading or a modification of the standard loading that we want to do, and put in the sources at that point.

The sources are then put in. Right after that, we

will do our treatment planning, the treatment planning. Within a couple hours we generate a treatment plan of what the distribution actually will look like in three dimensions.

The prescription is written at the time that the physician and the physicist went together and determined the loading. And that prescription has an estimate of the total time that they are going to want.

Then the sources are put in, you run the treatment plan, you review again with the physician. If there is a change, we have a bladder dose or a rectum dose, that is not acceptable, we modify the hours, if the distribution does not look as we anticipate it will look, we can even modify the loading. We can switch sources around, do another treatment plan, continue to look through that.

That is, I don't think, an unusual way of doing a treatment plan. It may not be, certainly, done everywhere that way.

MR. TSE: I think that's the way when they look at 4.2, says before administering by product, and look at the 4.6 --

MR. STEFANAKOS: You are talking about a change?

MR. TSE: Yes. 4.6. 4.6 says that you can change your prescription to reflect the actual loading, because we understand the loading may not be the same as originally

planned.

MR. STEFANAKOS: See, that's where my hangup is. Why should you have to do that? I mean, I think those charts shouldn't be complicated by adding and subtracting things, pre-plan, so to speak. Don't put something in that chart that you don't want to be a part of that chart, to be a part of that patient's record. And that's what you are asking up here. And then you are saying down here, go ahead and change it.

I think you should wait until you are ready to do the plan or you've set your plan exactly the way you want it. And then you go in there. That's where mistakes happen, is when you go in there and have to change things or you have to find where these things are and you have to go in there and make alterations, and so forth.

Like I said, that's maybe just a hangup of mine. But I don't like putting things in that chart that there is a good chance you are going to change later on down the road. Because a mistake is going to happen. Someone is either not going to read it, someone is not going to do it. And mistakes happen that way.

MR. RICCI: On the other hand, whenever an action is taken whereby sources are inserted, with potentially great consequences to patient and personnel, someone has to take the responsibility. And a signed prescription, I would

think, is a must.

MR. STEFANAKOS: I'm not disagreeing with a signed prescription. I'm saying when does that prescription take place?

MR. RICCI: Before they are inserted.

MR. STEFANAKOS: Well, I disagree. Because I'm saying that before you put it in there, you don't know what is going to happen.

Now, if you are saying before you put it in there after a treatment plan, then that's fine. But I can't agree with going in there and saying that I'm going to put a source in there for 48-1/2 hours, loading at 15, 10, 10, 15, 15 and --

MR. RICCI: It's not required to write the time. He can write the dose.

MS. KING: Yes.

MR. RICCI: He doesn't have to write the time.

MS. KING: The definition of the prescription for brachytherapy is just the total dose radioisotope treatments. Or, instead of the total dose --

MR. RICCI: Or. Right.

MS. KING: -- treatment time --

MR. RICCI: Right.

MS. KING: So it doesn't seem unreasonable to ask a physician to write down the total dose he wants to give.

MR. WERY: But the total dose where?

MR. RICCI: Total dose, eight points, from which you will calculate dimension in time from the computer plan. But the dose that he wants, he has in mind, is pretty well defined.

MS. KING: Should be written down.

MR. WERY: But he may not be able to deliver that dose, because of bladder and rectum, and he even may decide to change that total dose; and if there is a mechanism there to do it, okay.

MR. TSE: Then you go to the next changes.

MR. WERY: I don't see any particular problem. What Tom is saying is different than the way we are doing it. I'm not here saying that that is not a bad way to do it.

You know, the positive part of it is you have more data in your hand before start the treatment.

The negative part of it is it takes longer to do the plan, because the patient is sitting in her room with the instruments inserted for a period of time while you are doing the calculation, where normally, the plan would have already been started.

MR. TSE: But even here it doesn't say you have to complete the calculations.

MR. WERY: No, no. But I think Tom is suggesting

that --

MR. STEFANAKOS: That's right.

MR. WERY: -- that be included.

I guess I don't particularly see the need for that. But I don't think it's a poor idea.

MR. TSE: Do any other persons have some comments on this particular point?

MR. KLINE: I want to comment that it appears that, based on the site visits and just working in the field, that both Ray and Tom are both correct, in the sense that both methods are incorporated at various institutions. Either the treatment plan is done after the dummy sources are inserted, and prior to insertion of live sources, or the treatment plan can be done after the live sources, prior to taking out the live sources.

But the premise that a prescription is written, satisfies both requirements, in that you can change the prescription accordingly, based on what actually is the application.

Certain physicians feel they know the source configuration nine out of ten times; other physicians might not.

Also keep in mind that brachytherapy is not just a static situation. You have seeds that are applied; and I don't know anything about seeds, which usually changes quite

a bit during the actual application process. It is unusual to talk to people which have put in exactly the number of seeds which they originally thought they might use or exactly the number of strands, into a certain area.

So the flexibility in the guide is to try to take that into consideration so that you can change and modify your program without tying yourself into a set quantity or material at one time.

I don't know if that helps.

MR. TSE: Any other comments on this point or any other points?

MR. RICCI: Well, 4.5.

MR. TSE: Yes.

MR. RICCI: The comment, or the objection that we made before, a short time ago. Do you have on your register my comments I have suggested --

MR. TSE: Right.

MR. RICCI: Whenever the geometrical arrangement of each source relative to the prescription point or points and to any critical points is not otherwise known, a X-ray, you mentioned, will be taken, will be used for determining it.

MR. STEFANAKOS: There is no mention made in my version of after implanting brachytherapy sources, because the X-rays are normally now taken with dummies. And so it

is done before.

In the case of implants, the X-ray imaging should be obtained before implantation of the sources by using dummies.

MR. TSE: Okay. Thank you. We will be considering this point. It has been made previously, and you have the evaluation --

MR. RICCI: Yes.

MR. STEFANAKOS: This is going to be strange. But I think you are practicing medicine here. I think you're telling the doctor how he's got to determine point doses.

If he doesn't want to use radiographs, I don't feel that it is the responsibility of the NRC to come in there and tell him that you have to use radiographs to determine the loading and all that, and the delivery, if I read this correctly.

MR. TSE: Well, the idea here is that somehow you need to know where the sources are.

MR. STEFANAKOS: Why?

MR. TSE: In making your computer calculation to calculate the dose you need the location.

MR. STEFANAKOS: Why? There are people who don't use computer calculations. I mean, I don't think that is the NRC's responsibility to come in and tell that physician he has to take radiographs to say where those sources are.

He's taking the responsibility. That's his responsibility, is to what he wants to deliver and how he wants to deliver. And I don't think that anybody else can come in there and tell him, even the physicist, can go in there and tell him that hey, you better take radiographs, if he doesn't want to, he feels he is perfectly capable of doing it without them.

As I say, that's strange, but it's there, and I think it is a point.

MR. WIEDEMAN: I somewhat agree. However, if you look inside the site evaluation form, when they got to that area, we have a listing of about five different other ways of doing it, radiographs, nomograms, CT, imaging modalities.

So whatever the licensee feels. But I don't necessarily think that it is going to remain as just radiographs.

MR. STEFANAKOS: Okay. The only problem, as long as you say that this is going to change and not going to stay as radiographs, then I withdraw my objection.

But if it does, then too many times, a license reviewer will look at this guide and say hey, that's the gospel, and I want to see that in your thing. And he's going to come back and say, well, and he's going to give you, he's going to try to get you to change it. And eventually you're going to have to, because you're not going

to get your license approved if you don't. Okay?

MR. TSE: That is already in our annual evaluation --

MR. STEFANAKOS: On 4.4, this is a point of question. Any change in the prescription, in writing.

This isn't really a change in the prescription. But let's take the situation where a patient removes the sources themselves, be it an implant, or --. Now, obviously, the prescription has been changed, but that is not really a change in prescription, because here you are meaning the doctor decides he wants to change something.

But I have two questions there.

One, is that handled as a misadministration?

MR. TSE: You mean if you want to --

MR. STEFANAKOS: No, no. The patient physically removes the sources themselves. Let's take the easiest case, in the vaginal applicator, where she just reaches down and unscrews the cap and takes the sources out, for whatever reason, and says, hey, I'm done with it.

Is that a misadministration?

MR. TSE: Larry?

MR. CAMPER: Perhaps.

MR. STEFANAKOS: Perhaps.

MR. WIEDEMAN: I have to agree with Larry. Because a lot depends. Now, I've been involved in cases

like this. We had a case, oh, a could years back, where this very same thing happened. But the nurse checked on the patient, I think every 15, 20 minutes during the night. And sometime during this 20-minute period between when she first checked the patient and went back, the patient had removed the applicator. The sources were laying in the bed.

In that case, the sources were immediately removed from the bed and they calculated what the dose was up to that point, and then they continued therapy within a couple of days, revised the prescription and used external means. In that case, it was not considered a misadministration.

There was another case in Chicago a couple of years back where the patient removed the sources during the middle of the night, and the source was laying on the inside of her thigh. And nobody knew exactly how long that source was on her thigh. And in that case, it was reported as a misadministration, because the thigh received dose that was not intended. But they decided at that time, that it wasn't worthwhile to continue treatment on the patient.

So a lot depends on the circumstances.

In the one where the source was on the thigh, the physicist calculated what the maximum dose to the thigh would be, and the approximate dose. And he also evaluated whether or not the staff, nursing staff personnel, had been exposed. And he used very conservative measurements.

MR. KLINE: I think also the question might be geared towards how some people draw the sources, when they say that there's not a question of another part of the body being exposed to the source. It might be dislocated or across the way.

That might fall into something like an unintended deviation where you identified, you cannot find the sources. You evaluate what happened. And then it would be up to the physicist and oncologist to describe what sort of a modified treatment plan at that point would be necessary to deliver the total dose, taking into account the best estimates of time that the sources were taken out, what dose was not administered.

So it is more of a guessing game at that point. But that's all you have to make a decision as to how much dose --

MR. WIEDEMAN: There was another case not too long ago where, I can't remember what, I think it iodine-125, where they taped the source to the patient's face. And sometime during the night, the patient pulled the tape off. And when the nurse came in to do her routine nursing thing, she stepped on the tape and then she carried it around on her foot all over the hospital.

Now, that was considered a real mess.

[Laughter.]

MR. WIEDEMAN: If not a misadministration. Because no one knew when the tape came off. But you know, with I-125, normally they plan on leaving it there for like a week. It just did not work. They were trying this as a, to see if it would work at all, you know, this type of therapy. It's rather different.

MR. WERY: I hope that you can consider, you know, there seems to be some things expressed here, as it's good to have a good nursing overview of what is happening.

Often, at least what I've often done, is try to make sure that I give the nursing information or the nursing staff enough information so that they can try to minimize their time in those rooms, for a normal patient. Of course, if you have a patient where you think you may have problems, you make sure you transmit that information to the persons.

With a normal patient, we hope that the nurses aren't coming in every 15 minutes just to see how the patient is doing during their treatment.

And certainly it is not beyond what I can imagine happening, that a patient would remove the source or the source becoming removed accidentally, or whatever, and a long period of time going by before anyone notices that. It would be very rare, but I can see it possibly happening.

MR. WIEDEMAN: But you know, in each one of these cases, they went back and revised the prescription, to

either continue the therapy or discontinue the therapy, one of the two. And you would expect that.

MR. STEFANAKOS: What do you do in the case of sealed sources, like a prosthetic implant or something like that, where the patient, it is a permanent implant, but they are discharged from the hospital, they go home, and the seeds are sloughed off, passed through the ureter, and now you don't have the prescription you originally had. What do you propose for something like that?

Do they have to come back every so often and take radiographs and mount sources again or something? What do you do?

MR. CAMPER: I think the point that is being lost in 4.4, Thomas is, any change in the prescription, the prescription is generated by the physician. All we're really saying is if the doctor decides to change the prescription, as he or she has defined it, it will be recorded in writing.

MR. STEFANAKOS: Okay.

MR. CAMPER: You are starting now to get into all types of ifs, ans, buts, and circumstances that it is not of what we are looking at 4.4.

MR. STEFANAKOS: Okay. Well, this is what I want to hear. I mean, this is what we are here for, to find out just what you are looking for and saying. And because the

prescriptions are changed, now, they are not changed, as you just pointed out, at the will of the physician, but at the grace of God, for lack of a better word.

MR. CAMPER: Well, if circumstances were to occur of that nature, and the physician recognizes this, and then looks at it and says we must change the prescription, because such and such has occurred, all we are saying is, you should document it.

MR. STEFANAKOS: Okay.

MR. WIEDEMAN: There was another case down in Cincinnati, where a patient was treated for carcinoma of the prostate. They implanted iodine-125 seeds. The patient had them for two months, then had a restricted urethra. And so they therefore decided to do a total prostatectomy.

The question came up, well, if we remove the prostate with all the seeds, is that a misadministration? Well, of course not. It's a medical decision to remove the prostate.

And so the patient was taken into surgery, and they removed it. And they entered it in there that treatment is terminated because. And that's fully acceptable.

MR. STEFANAKOS: Okay.

MR. TSE: Okay. Any other comments?

MR. STEFANAKOS: 4.8 -- there are situations that

I don't know how you are going to get somebody else coming in there, because you've got institutions, and ours is one, that there is no other person who's qualified to do that.

MR. TSE: Yes, that point was raised the last time also. Do you suggest that one person should do another check or recheck?

MR. STEFANAKOS: Well, I certainly don't know that you don't need another check, as you know we all make mistakes, but --

MR. TSE: So perhaps the person could do another check himself?

MR. STEFANAKOS: Well, you know, what another method are you going to use, if you're using a computer calculation? And hand calculations are very tedious and can be even more misleading than the computer calculation.

MR. TSE: Or double check themselves.

MR. STEFANAKOS: Maybe that's the way to do it, is to come back there and do a double check to make sure he used the right -- right numbers in that. But that independent, by somebody who didn't do it, that's very difficult to do, in many instances.

I think if, usually the physicians, and I don't know, I think usually the physicians are sharp enough when they are at this stage that, like our physicians, what they do is when we give them the time, they'll immediately go

back and calculate milligram hours and they'll say, oh yes, okay -- 38 hours, yes that's 78 milligram hours. Yes, that good.

I think, you know, I don't know how you're going to put that in writing. I don't know how you're going to say, but to me, that would be an adequate check. That's kind of what our check is, what my check is. If the physician says oh yes, that's -- that's what I expected, because it comes out to x-number of milligram hours, and that's what I would --

MR. TSE: It's essentially like a -- letter --

MR. STEFANAKOS: Right, yes. But it's not a formal sit down, do calculation method. And I don't know if they would be -- if -- well, if you are going to use it as that, I guess we could just put that in a signature some place in the computer plan saying -- or on a computer plan saying that physician calculated x-number of milligram hours and it's within 5 percent of what the computer-generated dose or time was. I don't know how to re-word that though.

MR. TSE: But would you think that the one person check referrals and so on, would that be useful?

MR. STEFANAKOS: You mean if the same person came --

MR. TSE: Same person.

MR. STEFANAKOS: -- back and re-did?

MR. TSE: Right. If you have no other person?

MR. STEFANAKOS: Yes.

MR. TSE: Better than not doing it?

MR. STEFANAKOS: Yes. Maybe you could say, "whenever possible" again, in this one and -- other than the, excuse me, other than the original calculator, you can put in there "whenever possible."

MR. TSE: If another person has a problem with this item.

MR. RICCI: Yes. I would like to object to the -- what I consider a misconception that when we do something we always make the same mistake. I found my own errors very many times.

MR. TSE: That's true, that's true. On the other hand, in general, people could just overlook the same error; but that's also true, yours.

Any other questions, comments? If not, we'll go to the teletherapy.

MR. STEFANAKOS: 5.6 would be the same as 4.8.

MR. TSE: Right.

MR. STEFANAKOS: 5.71 would also be as 4.8. Although that one you could -- well.

MR. TSE: Well, that one, it's a little bit different, because there's an alternative in the TLD.

MR. STEFANAKOS: That's true.

MR. TSE: It's a slightly different --

MR. WERY: What -- what kind of evaluation do you expect from the -- if I do a -- let's say we go through the TLD -- I make a measurement with an ion chamber -- calibrated ion chamber, I get a value and then, at the same time expose TLD, send it away to be calibrated. I get the TLD back and there's a two percent difference between the two. The uncertainty from the TLD calibration source, is usually on the order of 3 percent, at least that's what I'm aware of. What -- what number will we -- can I -- I would normally have more trust in my ion chamber number at that point, than would be used in the TLD as a check to make sure that I'm not -- you know, I'm not --

MR. TSE: Not 10 percent off?

MR. WERY: Right.

MR. TSE: Yes.

MR. WERY: That -- that's what you have in mind?

MR. TSE: That you still use the old numbers for ion chamber -- but just want to make sure that nobody --

Any other? Anything?

MR. STEFANAKOS: Yes. I've got a couple big problems here, on 5.8, 5.9 and 5.10.

Okay. I don't understand why you have to keep checking the blocks that you use. Now, I can understand wedges or trays, because those things can change; the screws

could get a little loose and the wedge could shift a little bit. And that way, your transmission factor, your correction factor could -- I can understand that. But standard blocks, I mean, what's going to change in the standard block after you've first checked that there are no voids in it? To do this thing annually is, I think, an unnecessary redundant situation that -- that has no use for.

MR. TSE: So how would you suggest?

MR. STEFANAKOS: I would eliminate blocks.

MR. TSE: Eliminates blocks?

MR. STEFANAKOS: For example, it says trays, wedges, stock material. Well, yes, stock material, blocks, the bolus, I would, you know, I wouldn't change that either, because a bolus is a bolus. If you're using the same bolus all the time, what is going to change next?

The only exception I could see with that is if somehow it got flattened out or something; but even so, you check that. But, I think the only thing that should be in there are trays, wedges --

MR. RICCI: Y trays?

MR. STEFANAKOS: What?

MR. RICCI: Y trays?

MR. STEFANAKOS: Just -- just in case you have a tray with slots in it and it's not sitting in their right and then you have more slot exposed to the thing. I'm

throwing that in as -- as a nice thing.

MR. RICCI: You can easily eliminate the two because, even if you use a slotted tray, you don't want to take the slot value, that transmittal for the tray, nor the full value of the average of the two. And that doesn't change -- or either one doesn't change. The positioning is going to change, essentially, not --

MR. STEFANAKOS: I don't disagree with you. I just thought that in --

MR. RICCI: Okay.

MR. STEFANAKOS: -- as giving them --

MR. RICCI: Yes.

MR. STEFANAKOS: -- one more that they can put in --

MR. RICCI: But that's unessential to --

MR. STEFANAKOS: there.

MR. RICCI: -- it's superfluous. So, wedges --

MR. TSE: So you're suggestion is that trays should not be measured?

MR. RICCI: Yes, there is no reason to.

MR. WERY: Although, maybe what I would suggest is -- is -- maybe it may not be necessary to do it every year. I guess I always feel more comfortable if I've done, at least twice, separated by a fairly long period of time. So, I --

MR. RICCI: You mean you want to check your values?

MR. WERY: Check my values. Yes.

MR. WIEDEMAN: Isn't a tray factor considered on an annual calibration?

MR. WERY: Yes. I'm talking all the -- the other things that are not --

MR. STEFANAKOS: It is, but I don't think it should be and I don't think the block should be either. We do it, but we do it each year. I don't think it's a necessary thing.

MR. WERY: All these things are not in the annual calibrations, as I recall.

MR. WIEDEMAN: Right, yes. But I thought -- you

MR. TSE: But these are not occurring in the regulations.

MR. STEFANAKOS: Tray factor, I believe, is in an annual calibration that you are supposed to do that, wedge factors, tray factors and so forth. But, I don't think it's -- I don't think it's a necessary thing. I agree.

MR. RICCI: It's there out of inertia. Yes.

MR. WERY: I particularly don't find any problem with doing it in a full annual calibration, because you're really doing several other things at least, and doing it is no big problem. But I would agree that the number of errors

that are found because of it is going to be extremely small. So there's, you know, marginal.

MR. RICCI: Sorry, one could conceive that a tray, with the same geometrical dimensions, might be replaced with another similar one. And, in that case, not the same material, assumed to be the same attenuation it is -- yes sure.

MR. STEFANAKOS: If trays are replaced, they should be --

MR. RICCI: Replaced, but --

MR. STEFANAKOS: -- be done regardless, but it's not --

MR. RICCI: -- not -- replaced --

MR. STEFANAKOS: -- the ones --

MR. RICCI: -- but not -- replaced and assumed to be the same. So essentially, this yearly check, essentially, one ensure that the tray is the same one that it was before. I don't know. That's far-fetched but it's the only possibility for keeping -- measuring the tray.

MR. TSE: But, Tom you said that you were measuring -- annually?

MR. STEFANAKOS: I am now, because that's what the regs say you've got to do.

MR. TSE: Which?

MR. STEFANAKOS: I think --

MR. WIEDEMAN: I think we referred it -- what -- TG --

MR. KLINE: Well, TG21 gives recommended things along with -- and other protocols, but there's no requirement for --

MR. STEFANAKOS: Okay. I thought it was in one of the regs.

MR. WERY: But a tray -- when you give a definition of the annual calibration, I think it loses a certain measure, but on the tray factor -- in the definition of what the annual calibration --

MR. WERY: Well, it's used --

MR. TSE: I don't think so, but let's check.

MR. KLINE: The -- the protocol itself is good for calculating what your output is in there. Now, measuring the other compensating and device and whether the trays, this and that.

MR. TSE: I think it's in the guide.

MR. STEFANAKOS: He's got it there. He'll -- he'll --

MR. WERY: I think it's in 35.

MR. KLINE: No, it's not down there. TG21, which is referenced on part 35, does talk about using that -- that protocol for calculating output on the machine; not so much everything TG 21 recommends is a tremendous amount in the

calibration process you can do. Now part 35 -- I think you all agree on that.

MR. TSE: Well, let's continue where that was leading.

MR. WIEDEMAN: No, it doesn't. It just refers you to Scientific Committee of Radiation and Dosimetry, American Association of Physicists and Medicine described in certain task group 21 and I believe it's in that document is where they recommend tray factor.

MR. TSE: Okay --

MR. STEFANAKOS: Okay, we're saying the --

MR. TSE: -- let's say --

MR. STEFANAKOS: -- only thing you should really check or really should be required to check is those wedges?

MR. TSE: This is the recommendation.

MR. STEFANAKOS: That's what we're saying.

MR. TSE: Okay. How about stock material that's used for compensators -- should that be checked, or that's not necessary?

MR. STEFANAKOS: When you talk -- you're talking about like serabin?

MR. RICCI: Wax, whatever, for making compensators?

MR. STEFANAKOS: Yes --

MR. RICCI: You can use all sorts of materials.

MR. STEFANAKOS: Rice bags.

MR. RICCI: And if the energy at the beam and the energy distribution of it doesn't change, which is proven by the penetration of the -- which checked annually, I don't see why anything else should change. It's superfluous, in my opinion.

MR. TSE: Then blocks, as Tom already said -- bolus -- you said the bolus?

MR. RICCI: Same story. The attenuation isn't going to change -- the physical data don't change.

MR. WERY: The same bolus material -- if you get new bolus material in --

MR. RICCI: Definitely, yes.

MR. WERY: -- it should be --

MR. STEFANAKOS: That's what we say with any of it. I mean, if you get something new in, you should change it -- or check it.

MR. TSE: Okay. If one uses the same element of bolus, in time it might shrink or narrow in thickness. Of course, then the attenuation changes. But that's the only thing, again.

MR. RICCI: And then similar is the recassable block?

MR. TSE: Oh yes. Okay. Any other comments?

MR. STEFANAKOS: Yes. 5.9. I have a real problem with that, and I can give you a very good example of where this could be a real problem. And I think what you're doing there is you're asking us to reinvent the wheel. I mean, inverse square has been proven time and time again to -- to be valid. And we do a lot of hemibodies at our hospital and we're delivering 400 to 500 rads a side in a single dose to a whole hemibody.

These people can get sick very very fast. And if I have to go in there in between treatments -- now the first half of the treatment would not be a problem; we'd set them up, pull them out of the room, go in, do the rate measurements, set them up, take the treatment. Then the second half of the treatment we have to do that, you're going to have a sick man -- or person on your hands.

MR. RICCI: For inverse -- I don't think there is a problem, because when you do the annual calibration on the acceptance calibration on the machine, you check what the inverse square behavior of the output is. So that is a measurement.

MR. STEFANAKOS: Yes. But this says that if you do it at a treatment field size or distance other than what you have calibrated --

MR. RICCI: Field size?

MR. TSE: Outside -- outside the range.

MR. STEFANAKOS: Okay. What is the range? I mean --

MR. TSE: Well, let's say you checked up to 80 centimeters, you do a full calibration. Now you want to use 100 centimeters. And you -- your calibration did not go that far, so it's an --

MR. STEFANAKOS: Well, that's what I'm saying. You don't know what your range is going to be with some of these hemibodies. If you get a small person, you can get it into a hundred. If you get a big person, you can get it -- the only thing you can say is, measure it at the wall and then something in between; but then you don't get a real measurement either, because if you measured at the wall, you get back-scatter from the wall that's coming off of that and it's giving you an erroneous reading.

I just think this -- this is unnecessary, in the sense that you're re-inventing the wheel.

MR. TELFORD: Tom, how do you calibrate, if you have a variety of sizes of people.

MR. STEFANAKOS: Well, fortunately in my situation I don't have to, because we've got a linear accelerator and I treat it all by hemibodies on the linear accelerator. But I know institutions that only have cobalt units and I'm trying to play the devil's advocate for them.

MR. TELFORD: Yes, okay. What if you had a cobalt

unit? How would you calibrate it?

MR. STEFANAKOS: Well, we do obviously have a cobalt unit. How would I calibrate it? I'd calibrate it at the distances that I normally use. I use it primarily at 80 and at 90. I'll take readings and see what it -- what the response of the beam is, or what the output of the beam is in those. But what I'm saying is you can't -- the way this is written, it's so all-inclusive that there's no real way you can cover every situation.

Even if you look at this and -- and if you do it by the letter of the law. We -- I do all my calibrations at -- at increment squares: 5 by 5, 6 by 6, 7 by 7, all the way up. And it says that if the field sizes are treatment distances -- now if you're saying in the range, that if he uses like a 15 and a half, then that's in the range because I did a 14 and a 15, then that's fine. But when you say outside the range as far as SSD goes, I find a real problem with that for somebody who does not know the distances that he's going to treat a hemibody at.

I mean, it can vary, it depends on the size of the individual. You have to cover like from umbilicus to knee caps or umbilicus to the chin. And if it's a big person, you're going to have to keep them further away. If it's a small person, you have them c'oser.

MR. WIEDEMAN: Tom, the one or the two that I've

looked at that we're doing hemibodies, they had no other choice. They would bring the teletherapy head as high as it would go. And the patient would lay on the floor, because that was the best distance they could get. I think they used the field size of about 48 by 48. Doesn't that sound about right?

MR. STEFANAKOS: Well, it's probably bigger than that if it's that, because at --

MR. WIEDEMAN: That was a maximum.

MR. STEFANAKOS: -- 35 by 35, yes -- 35 by 35 is -- or you're talking about dial setting, or you're talking about -- okay. I don't know, our's is 35 by 35 on an AECL unit, I think.

MR. WIEDEMAN: And what they would do is annually, during their calibration of doing the 6 by 6, 7, 8, 10 by 10's, they would include the maximum distance, source skin distance that they would use for hemibodies and include a 48 by 48 field size and take a measurement.

MR. STEFANAKOS: [Nods yes.]

MR. TSE: Okay. In that case it would be fine.

MR. WIEDEMAN: That's all we're really asking.

MR. TSE: But the question is though, if such a case occurred and you do not have a measurement -- accurate measurement, would you depend on inverse square log?

MR. STEFANAKOS: Yes.

MR. TSE: With putting them on the ground?

MR. STEFANAKOS: Well, like I say, we wouldn't put them on the ground.

MR. TSE: Well, still --

MR. STEFANAKOS: We don't have a beamstopper.

MR. TSE: -- you're close to the ground or something. Now, then the next question is, if you really trust that -- the question is, why do you measure at 80 and at 90? Why not just use -- to calculate it?

MR. RICCI: To make sure that the source is where it is supposed to be.

MR. TSE: Okay. That's a -- but otherwise you can use --

MR. RICCI: At that point, you know where it's at and the inverse square log par attenuation -- which is a small correction.

MR. TSE: How about the field size?

MR. RICCI: You have tables for TAR factors, to use in dosimetry, that are essentially standard, since the energy of cobalt is fixed. And they are available -- as the British Journal of Radiology reports. They are published and that's what's used for larger field size and one uses for standard calibration. And you wouldn't find anything different.

MR. TSE: Do you think it's necessary to re-

measure at the time, if you use a larger size, or in the distance, would you feel more comfortable to measure it again; or in your case, you would say, no, I used my calculation?

MR. RICCI: I trust the laws of nature and if I -- and my confidence with them on the case, unless I see any reason for undue attenuation, and there isn't any undue amount of scatter, and there isn't any, I would just follow the laws and I'm pretty well on. Better than probably what you get by measuring.

MR. STEFANAKOS: I agree. The only things that aren't in the books that you might be alluding to is the field size factor but you take that anyways when you do your annual calibration.

You get your field size factor for the largest field that you do. You go all the way from 5 by 5 up, so that is the only thing, but Alessandro is right.

It's, you know, I have been doing them for years now and the greatest change that I have ever seen in any of the numbers that I get is less than one percent, and that is well within statistical error.

MR. RICCI: That's a lot smaller than the absolute error in dosimetry anyway.

MR. STEFANAKOS: Absolutely. No question, yes, and I just think that is an unnecessary requirement.

MR. WERY: I don't think Tom is saying he's never doing any measurements because obviously he is because you have a pretty good idea of how far you're off. He's just saying for a particular patient --

MR. STEFANAKOS: Right, and that's what this --

MR. WERY: -- that particular patient because it's at 151 centimeters and he happened to have done his yearly calibration maximum distance at 150 centimeters.

MR. RICCI: Essentially the extrapolation law is well founded.

MR. STEFANAKOS: Sure, I mean people have been doing that for years and it's reinventing the wheel.

MR. TSE: That's true, but what happens in a case if you measure somebody -- not you, somebody only measure at 80 centimeters, 10 by 10, and now they have to use a 30 and 40 by 40 and --

MR. STEFANAKOS: It still doesn't make any difference. The laws that we're talking about still hold. Just because he didn't verify the laws --

MR. RICCI: Knowing that 80 centimeters is actually 80 centimeters distance from the source is essential so it is inconceivable that one would only measure the output that one would have to measure at 80 or 20 or 60 -- in order to determine the validity of the inverse square law.

Once that is established it can be used safely unless there are interposed materials and things like that.

MR. TSE: Or the background scatter -- if a person sits, like the other case, he said I'll lay on the floor, I'm sure that the dose would be different compared to --

MR. RICCI: It's a negligible amount.

MR. TSE: Okay, any other comments on this point?

[No response.]

MR. TSE: So therefore your suggestion is that this element may not be necessary.

MR. STEFANAKOS: Absolutely.

MR. RICCI: Rather the back scatter would affect your measurement with the IM chamber if you weren't using a phantom, that will not affect the dose to the patient.

MR. WERY: The number that you'd want to use would be the number without the back scatter --

MR. RICCI: Right.

MR. WERY: -- anyway.

MR. STEFANAKOS: That's right, absolutely.

MR. WERY: -- so if you get a measurement you'd have to somehow correct for that.

MR. STEFANAKOS: In other words what he is saying is if you did it the way you say to do it, you'd be adding error rather than reducing error.

MR. RICCI: If you were improperly taking the

count, yes.

MR. STEFANAKOS: That's a very good point.

MR. KLINE: I think in fact what the book, the reason for this is you find that the few instances where you fall outside of your calibration standards that you've established you're changing the ADS that you wish to use in your treatment distance, at which point you calibrate to 90 or 100 for human body, whatever your reason for treating or a larger field size.

The question here if you don't have any output in that distance and you're dealing with large doses.

The majority of people who measured confirm those things based on what we see in the field but we are not looking at small differences and the in-between, let's say, 80 and 100 if you took a 100 SSD measurement.

The laws of physics are going to stand and it's not going to be a significant variation if you are using your square law properly.

Mainly we're looking at unique situations where you might not know the scatter or --

MR. RICCI: But you are giving general prescriptions for unique situations and that unwarranted. You are forcing everybody to do a measurement when it isn't really required unless there is such a shortcoming somewhere.

MR. KLINE: What you are saying, that if you're doing a procedure that you have not calibrated beyond the calibration standards or your special case.

I think what the intent is, if you have measurements, if you have the patient you are treating inside of what you have measured, the tendency to make measurements so you could confirm the dose the patient is receiving --

MR. RICCI: It is confirming that the speed of light is whatever it is. It is superfluous.

The inverse square law, once you know that the source is there, is well established.

MR. KLINE: Well, I think what drives part of this indirectly is that people might feel that there are other factors, whether it be the geometry --

MR. RICCI: It's no matter of feelings --

MR. KLINE: Other factors that contribute towards that --

MR. RICCI: Such as?

MR. KLINE: We don't want to just focus on --

MR. RICCI: Such as?

MR. KLINE: The scatter off of any medium outside of the patient, the surrounding walls or the floor. Some people might feel that's a necessary measurement.

MR. WIEDEMAN: Let me offer this comment. Going

back to the hemi-body, now with that particular situation, you know, we are talking about lethal doses -- you know, 400, 500 rads in a single treatment.

To me personally, I would not feel comfortable doing the calculation by hand and using that only as a basis for the treatment. I would feel better if I did the calculation and then I did a physical measurement just to verify that my calculation was within 1 or 2 percent.

MR. STEFANAKOS: Well, the point with that, though, is it's almost impossible to do that with a patient. You've got a patient that you just delivered 400 rads to. Now you've got to turn around, turn the other side to 400 rads. What time are you going to find? This patient is going to be throwing up all over the room.

MR. WIEDEMAN: What I would do is I would include, assuming that I am going to use, say, 100 or 120 sonometer distance, I would take a physical measurement using the typical field sizes I would normally use and then I would say, okay, now I know what the dose would be at that Source Scan Distance, at that field size.

You have ballpark figure.

MR. STEFANAKOS: Well, that's the point that I'm making. There are no real typical situations. I have done I don't know how many and I'll verify what you're saying. I am nervous every day I do it. I go home early those days

because I am very nervous, especially being out of the submarine force knowing that what we call "allowable limits," okay?

I get very, very nervous but the point is that I can go through all those ones that I have done, and we do anywhere from 6 to 10 a year, and I could tell you that I'll bet you there aren't two of them that are within 5 sonometers of each other or 10 sonometers of each other.

What you are saying is really nice but there is no typical thing. There is no way you can say, okay, this will suffice for everything we do unless you do one that you do.

You can take a look around this room now and visualize somebody's umbilicus to chin and how long or how close, how far or how close you are going to have to be to that source to get that field in there.

MR. RICCI: In most critical situations it is most important not to follow gut feelings and consider coolly the situation and if you do your measurement with the IM chamber at the proper distance then the number is going to be significantly different from the number at the standard distance.

Who is going to assure you that the calibration system is working properly? Are you going to have an outside physicist check that the number is right or are you just checking with the inverse square law?

Of course if you had two measurements you would do inverse square law and then check with the experimental measurements. That would be all right if the inverse square law were such an easy operation to do and of course that would require that the original calculator and the physician, whoever else is there checks the calculation before giving the dose but I would consider that very safe.

On the other hand, your measuring it too wouldn't hurt.

MR. TSE: Okay, I think he suggests -- well, according to my watch there is supposed to be a break time. Let's take a break first and then we'll come back to this point and see any other comments.

[Recess.]

MR. TSE: Just before the break we were discussing Section 5.9.

Anybody have any other comments, suggestions to say about that section?

MR. WERY: 5.9 or 5.0?

MR. TSE: 5.0 to 5.9, sorry.

[No response.]

MR. TSE: Okay, then we go to other elements.

MR. RICCI: Could I step back to 5.71?

MR. TSE: Of course.

MR. RICCI: I have already entered my promise that

comment that one should enter after, whenever spot check measurements and I would enter "confirmed" by including full calibration, indicate that the output differs by more than 5 percent, et cetera, because if one makes a wrong spot check and then does a full calibration, checks that the output is all right, I don't think that there should be any further actions.

MR. TSE: Here what he says is that after full calibration measurements and the regulation, full calibration measurements or certain things that you need to make the full calibration --

MR. RICCI: I am not talking about that. I am talking about your part of that sentence -- "or whenever spot check measurements indicate" et cetera, so that's not at the time of full calibration. At the time of spot check measurement it indicates that the output is off by 5 percent or more, and then I immediately at that point, I myself if I did that spot check measurement or my dosimetrist did part of the check with the standard system and the full calibration to see if the fractional reading is wrong.

If the spot check is confirmed, then I would take whatever action is required here and ask for the confirmation of the new value. Otherwise, well, that spot check --

MR. TSE: If your full calibration checks --

MR. RICCI: Check's fine.

MR. TSE: Check's fine.

MR. RICCI: Yes.

MR. TSE: Okay, so you have written --

MR. RICCI: Yes.

MR. STEFANAKOS: When you say whenever a spot check measurement is off by 5 percent, you don't mean the very first reading you get? If you go in there and find out, oh, man, I blew it, I put it the wrong distance or the probe shifted or something like that, you mean if everything verified correct and it's still off by 5 percent, don't you?

MR. TSE: Yes. The regulation, current regulation stated that you needed full calibration if your spot check, you needn't be the person that does the spot check.

MR. STEFANAKOS: No. Well, actually we also said that if you have two systems you can do both as long as you are using the second system, or use one system for one and the second system for the other. That's like an independent check, which it should be.

MR. TSE: That's the next, 5.7.2 (a).

MR. STEFANAKOS: Right.

MR. WERY: If I could talk about 5.2.

MR. TSE: 5.2, sure.

MR. WERY: Actually, 5.1 or 2 MB, emergency conditions. The emergency condition that that it's written

under, under the original things has a written prescription within 24 hours.

We are a small isolated institution, have one authorized user for teletherapy. It's not unusual -- it's not impossible for us to have a situation where he may be out of town for a weekend.

The situation I am envisioning is one where he may be out of town. The patient may show up let's say on Friday afternoon after he leaves town and is seen by a medical oncologist with something like brain seizures, metastatic disease.

The medical oncologist may have a radiology report that documents metastatic diseases. The medical oncologist has seen the patient and believes that it is a metastatic disease and probably have started the patient on some kind of medication for seizures.

The medical oncologist would then in our situation, what I am envisioning at least, may call the radiation oncologist that often is contacted by telephone, describe the situation to the radiation oncologist and the radiation oncologist from the information provided him by the medical oncologist may say, yes, we should start treating this patient whole brain radiation treatments.

Whole brain radiation treatments at least at our institution are set up anatomically, meaning that the

physician does not have to indicate the area that is being treated.

It's done by anatomical points. Even on our normal patients the technical physician reviews it, how it's set up but the patients are set up anatomically.

I guess in such a case according to the rules as they are written we have to get a written prescription within 24 hours.

I guess I would like, I could envision where 24 hours wouldn't be enough for us to get that written prescription there except probably maybe with the faxes these days if things are legal --

MR. TSE: But your suggestion is that the emergency portion of that should be more than --

MR. WERY: More than 24 hours.

MR. TSE: Like what is yours?

MR. WERY: Maybe 72 hours or 48 hours, something more than 24 hours.

MR. STEFANAKOS: You say as soon as practicable and no more than 5 working days after treatment.

MR. WIEDEMAN: Well, the problem is that we have got it in the reg.

MR. TSE: But that's what you're talking about, to change --

MR. WIEDEMAN: But let me say, put it in our

procedures but then our procedures would be contrary to --

MR. STEFANAKOS: I'm sure that would go by a reviewer, wouldn't it?

[Laughter.]

MR. TSE: So your suggestion?

MR. STEFANAKOS: I was going to say, Ray, were you suggesting that we put that in the Regulatory Guide, or change the regulation?

MR. WERY: I don't know how it needs -- I guess if that is part of the regulation then it would have to be changed in the Reg Guide --

MR. WERY: Because a regulation would always supercede a Regulatory Guide. A Regulatory Guide just basically will give you guidance on how to comply with the rules.

MR. STEFANAKOS: You should change the regulation.

MR. TSE: That's what our task is, whether we should go back to that regulation.

His suggestion is to change it from 24 hours to 48 or 72.

MR. CAMPER: Well, the only problem that you get into when you start doing things like "immediately," "promptly," "as soon as practical," things like that.

We often get asked a questionable "What do you mean by that?"

MR. STEFANAKOS: Well, then you follow up with no more than 5 working days -- as soon as practicable or nor later than -- if you want 72 hours, 5 working days or whatever. You don't leave it hanging as such.

You're right, you're absolutely right. What it is, is as soon as practicable.

"As soon as practicable" could turn out the guy goes on vacation. He doesn't come back for two weeks. But if you say "within 5 working days," then it better be in there within 5 working days, vacation or not.

MR. TSE: Well, with that in mind, what do you suggest?

MR. STEFANAKOS: Are we back to 5 again?

MR. TSE: Right.

MR. STEFANAKOS: 5.10 -- oh, I'm sorry.

MR. TSE: After we make this suggestion, if the reg is changed according to your suggestions, what --

MR. WERY: I guess you don't have to change the Regulatory Guides --

MR. TSE: Everything's okay.

MR. WERY: Yes.

MR. STEFANAKOS: First of all, let me ask the question where did this come from?

MR. TSE: 5.10.

MR. STEFANAKOS: Yes, "Depth dose calculations

will be made with each computer program that would be used for teletherapy dose calculations for the following exposure conditions: An open field and air at eight angles to the isocenter, zero and 7 other angles with 45-degree increments and in a field with and without a wedge" -- where did anybody come up with such a requirement?

MR. TSE: John?

MR. TELFORD: That came from a discussion with ACR.

MR. RICCI: It shows.

[Laughter.]

MR. WERY: Thank you, Alessandro.

May I suggest that maybe that you could do, as we have done several other times, say that an institution will provide a method for their quality assurance under computer programs, and let them specify what they think is going to be reasonable.

MR. RICCI: Yes. My comment was to check proscriptions for the computer program is very simplistic, is unrealistic, to be a good one and not to be program-oriented, which it isn't, and it certain does and cannot ever include all the programs that will ever be made, so either you keep it general or you skip it.

MR. STEFANAKOS: I just -- this blows my mind. I don't know who in the ACR, you know -- that's -- what's

that?

It's got me so befuddled I can't even begin to say how to correct it or other than just what Alessandro said over there.

I have never even seen something like this.

MR. RICCI: You cannot correct it because it has to be prescribed for each machine, depending on how it's written -- 45 degrees, what does it mean? Why should 45 degrees have any special value relative to 32, 31 degrees, where this affair might just have a bug? It's nonsense.

MR. TSE: Okay, let's talk about the purpose of the section or this element's purpose.

The idea is that you have at least the calculations -- you have a pretty good staff team and at least some confidence that the calculation matches -- that's the start of it.

MR. RICCI: You made it a lot more than basic when you required you check every --

MR. TSE: Okay, let's squelch all these conditions.

MR. RICCI: Oh, fine, sure. I agree then.

MR. TSE: For the discussion, let's look at that.

Anybody else have questions?

[No comment.]

MR. TSE: Suppose we said we take away the

suggestion from ACR of this -- we show that it matches. Do you have further comments?

MR. STEFANAKOS: No. No problem with that.

MR. TSE: How about --

MR. STEFANAKOS: And that's only with your using a computer program to do the dose calculation. If you are getting TARs, SARs, or BSS off of that, then that isn't included in this.

MR. TSE: Could you repeat, please?

MR. STEFANAKOS: They are saying "dose calculation," okay? To me that means the computer is actually giving you the dose rate or/and time to deliver that dose prescribed to the patient.

That does not include -- like I don't use our computer plan for dose calculations or dose rate calculations with the exception of the irreg field.

I just use it to get TARs off of it or back scatter factors or percent depth doses, so this would not pertain to such a situation?

MR. RICCI: If you use the TAR in your dose calculations, though, you do use the computer, after all.

MR. STEFANAKOS: Yes, but it is not the way it says here. It says dose calculation.

MR. RICCI: It includes it.

MR. STEFANAKOS: To me that means if the computer

is giving you an output or it is giving you a time.

MR. RICCI: -- look it up.

MR. STEFANAKOS: Now, again, it says relative dose calculations. To me -- I'm interpreting that as saying -- does calculation is, in fact, the treatment time or the dose rate for that particular field for that particular patient. To me, that's a dose calculation.

MR. TSE: Relative to circulation means, I think, to talk about dose to a certain point, relative to another calculation point, reference point.

MR. WERY: I think it's totally reasonable to expect some kind of quality assurance be done to demonstrate that isodose distribution that the computer plan is generating, matches measured data. I'd say you have to do more than that.

MR. STEFANAKOS: I'm not questioning that. You should obviously check your computer. There's no question. I think the way you should do it is to just leave it up to the individual to write it the way he wants to.

MR. TSE: Any other comments or suggestions on the whole section?

MR. RICCI: On No. 11, I'd like to enter a suggestion. As soon as possible, or within two working days, so as to remove the bureaucratic -- and add the additional constraint that they should make a good effort to

do it as soon as possible.

MR. TSE: So just add the words, "as soon as possible."

MR. RICCI: Yes.

ME. WERY: That's referring back to that thing again, isn't it, the prescription and all?

MR. WIEDEMAN: One is the determination. Before, we were talking about the prescription from the physician.

MR. TSE: Well, 11 just is for checking calculations.

MR. WERY: Eleven seems to be saying that calculation checks. He's just making a notation that this is an emergency and we're going to do this without --

MR. TSE: Any other questions, additions or comments? Thank you for your attention.

MR. TELFORD: Thank you very much Dr. Tse. Moving right along, let's go to the discussion of the diagnostic --

Everyone should have a copy of the handout material. Page 1442 of the Federal Register. What we will do here is go through a little refresher. What I mean by them is; the kinds of things reported to the NRC are doses are that are substantially different from prescribed.

The recommendations on how to modify this -- feel free to say whatever your opinions are on what should be reported and try to capture those things. We will go

through each part of the requirement.

The first one says you have the wrong route. The fourth one is the diagnostic -- the fifth one is the radiopharmaceutical therapy differing by -- percent from what was prescribed. The sixth is teletherapy and brachytherapy and captures those that are ten percent from what was prescribed.

We used these to prepare what we have proposed. We'll put this one over there. Each of the 35.33 is true for the 35.34 which is the therapy and has an A and B Part, and D and D and E, so we'll go through each of these a step at a time.

In the A Part are the events. First of all, I have to caution you that the words you see on the screen are cryptic descriptions of the actual words. The actual words are on page 1447 for 35.33. Basically A Part says these things are -- these things have to be investigated by the RSO and you'll see in the other section.

They are intended to be something that allows feedback to the licensee so that they can fix the problems. Number One is; you're using some material that's not authorized in your license.

Number two, the diagnostic use -- C is the diagnostic use without daily recording. Use without a prescription or referral -- now it doesn't say written

there. I'll go back to the oral referral. It is important that this discussion consider that the referral is -- let's say it's not written.

Let's say it's whatever we come up with at --

VOICE: They don't always have to be recorded -- at some point.

MR. TELFORD: But here, where you have some use without a referral or a prescription

MR. RICCI: I understand, but then the referral -- it may be oral, but even then, whoever receives it has to write it down.

MR. CLOUSE: We never do anything unless something is written down someplace telling me to do it.

MR. WIEDEMAN: We had a case over in one of the VA hospitals where a technologist brought her sister or girlfriend in and did a scan on her. It was never approved or ordered by a physician.

The funny thing is that she even sent it in to be read by the radiologist. He thought it was kind of odd that he had a female patient in a VA hospital and that's why he questioned it.

MR. CLOUSE: Then on the daily recording of the administered dose, now, this is anyway that it's recorded. This is, say, if my radiologist forgets to dictate on the report, but it's written on my dose book upstairs -- I mean,

this doesn't get very specific here.

Is that saying that you have a patient that received a dose and no place did it say what that patient received?

MR. RICCI: Doesn't it refer to the reporting of the dose by the techs or whoever it administers it, and not the prescription report?

MR. TELFORD: Number 3 is just the record of the does.

MR. RICCI: By whoever administers it.

MR. TELFORD: Right. Okay, Part A; should it be modified or retained?

MS. KING: On 3; if the technologist assays the dose -- is that an event?

MR. TELFORD: Unless recorded -- make sure that -- I ought to mention C; that if you have an event in A, in the RSO -- going to take appropriate action to investigate and correct.

If we have these things, somebody has to check them out. That somebody is the RSO.

MR. RICCI: About 4, what's the purpose of the notifying the referring physician if then it turns out that the dose was the required one.

MR. TELFORD: Number 3?

MR. RICCI: Yes, what would the NRC do with the

report.

MR. WIEDEMAN: That isn't reported to the NRC. John, correct me if I am wrong. This is not a recordable event to the NRC. The RSO does an investigation and writes up his report and it's kept in their file.

MR. STEFANAKOS: Everything under A goes to the licensee.

MR. RICCI: Oh, all right.

MR. WIEDEMAN: It's just saying that you tell the referring physician if it's more than a fivefold error in dosage.

MR. TELFORD: Keep in mind that you're going to have the RSO or somebody like that to investigate and make a record of the A events.

MS. KING: Is there any time limit on when this record has to be made for an event?

MR. TSE: That's in another section.

MR. TELFORD: E is the record --

MS. KING: When do you have to make this record?

MR. TELFORD: Maybe it's under C.

MS. KING: How long do you have to go through daily records to identify it? Is this weekly? Quarterly?

MR. TELFORD: You don't have to --

MS. KING: Annually? All right.

MR. CLOUSE: I have another question. I see under

E there -- E says that each written diagnostic clinical procedure for three years after it's last use, but each occurrence for ten years. Now, the occurrences, therefore, have to be kept separately from all the rest of my files because we only keep files for 7 years in our hospital.

What happens in the event that the patient expires? Do I still keep -- I'm not going to keep the patient's film after the patient expires, or their reports for more than three years. So, do I have to keep this written report on that patient that expired for ten years after they expire?

It's not stated and I'm just wondering what this is. Do I need to make a separate file?

MR. TELFORD: This would say, yes, you do. Now, you have -- also the possibility of B events which are -- Why don't you hold onto your question for a little bit and let us work our way up to E.

Do we have questions about A or B?

MR. WERY: The requirement is for Radiation Safety Officers to investigate the cause and make an NRC review and notify the licensee management.

Only yesterday we had a discussion about licensee management. Whatever we come up with relevant to 33.35, we could also use here. I would like to suggest -- why not do it through the mechanism of the Radiation Safety Committee

for those people who have Radiation Safety Committees.

That would seem to be --

MR. TELFORD: Okay, good suggestion.

MR. LEE: More on 3; I guess I'm unclear on where we're looking at daily reporting or daily dose log, we also report our doses on our film. I mean, are we looking at either or?

MR. WIEDEMAN: I would say that if you have it in one place, that would be acceptable. You wouldn't have to have it in both. One of the things that we do -- let's say, for instance, that we receive some allegations -- which does happen, and I've give you an example.

We had a case where a lady alleged that her son was treated at a very large university hospital and they overdosed her son and killed her son. It was for therapy.

We went back to look into the matter and they showed us a record of what was prescribed, and they also had a record of what was administered. It met the typical protocol of the dosage range and all that, so we were able to write up our report.

If you didn't have what was finally administered, it would be very difficult to try and reenact that. But you say you have it on your films? That would be acceptable.

MR. RICCI: How about standing procedures whereby a certain procedure requires a certain dose, period? Could

there be a default value?

MR. WIEDEMAN: Well, you have to remember that many of the dose calibrator systems have a little ticket system that records the dose that you drew up that day. Many hospitals maintain that dose ticket. That's another way of tracking back to what you gave the patient.

That seems to be the standard.

MR. TSE: The question was; can there be a default value, not expressly written; written in the procedures manual as, essentially, for the kind of examination, we have 3 millicuries, so there it is.

MR. WIEDEMAN: We need to have the document so we could identify what that specific patient received.

MR. TSE: Along with that question is related to the difference between administered dose or dosage. Is that what you -- there are two terms used in the proposal. One is without daily recording of as administered radiation dose, or radiopharmaceutical dosage in that record.

Okay, so those are dosages. Does that address what your point is? You're talking about dosage.

MS. KING: Is there something in 35 about not having to record the dosages if they are less than 10 microcuries; that you have to verify them but not record them?

MR. WIEDEMAN: There's something about that. Yes,

it relates back to dose count. If 10 CFR says you don't have to do it --

MS. KING: Then you don't have to record it. This would be in accordance with --

MR. WIEDEMAN: This would appear in 35.

MR. WERY: Any other suggested alterations for this Part A. If we're talking just about diagnostic events, what does the term dose correspond to.

MR. CAMPER: Activity. I think you're making a very good point. This came up last week, too. We have some concerns and we'll go back and look at this idea of dose, dosage, administered dosage and make sure that we try to make it as clear as possible.

MR. TELFORD: Okay, let's go to the B Part. Now it's called Misadministrations. It backs up the current --

Diagnostic use other than the one stated, need to write prescription, the procedures manual. For instance, you get the wrong patient or the wrong radiopharmaceutical, the wrong route. Those things are captured the same as the current requirements.

Diagnostic use or the administered dose is 50 percent different from what was prescribed, events, is the same as the current one. However, I still want to hear if you would like to modify this or retain it.

MR. CLOUSE: Retain.

MR. TELFORD: Everyone says retain?

Tracy?

MS. KING: This is one hypothetical case: If a technologist gives a referral saying something that doesn't make sense, like a liver screen scan -- she calls the referring position and says don't you really want a gall bladder function or a -- scan? He agrees, and she proceeds without ever speaking with an authorized user and getting a prescription.

MR. TELFORD: What does the clinical procedures manual say?

MS. KING: So, then clinical procedures overrides what the document says?

MR. TELFORD: Well, I'm assuming that that's what the referring physician will want, so that the technologist follows -- is really following the instructions set out by the authorized user.

MR. CLOUSE: You now have a diagnostic referral with that referring physician, because you spoke to him on the phone.

MR. TELFORD: Okay. Now, we can look at C in both parts, either for an event or for a misadministration.

Does anybody have a suggested modification there?

[No response.]

MR. TELFORD: Okay. Now we have -- what triggers

C is to tell the licensee when they'll notify the NRC. We have three criteria. One is unauthorized material; second, a fivefold error in the dosage; thirdly, an organ dose greater than 2 REM or a whole-body dose greater than half a REM.

MR. WERY: The last specification, I think, could be very difficult for many places to evaluate whether the dose -- an organ dose is greater than 2 REM or a whole-body dose is greater than 25 REM, especially when you're not talking -- the organ dose is that they be given product literature are making a set of assumptions that may or may not be true for the particular patient that you're talking about. Now you're talking about a particular patient. And I would think that, actually, very few places would have a means to evaluate that.

MR. CAMPER: Do you really believe that? Authorized users there, you really believe that they could not make an evaluation of organ dose?

MR. STEFANAKOS: Absolutely.

MR. WERY: Not close.

MR. TELFORD: What should it be changed to?

MR. WERY: I don't think that you can do an organ calculation or a whole-body calculation accurately. So, I guess I don't know how to change it and still keep the flavor there.

MR. STEFANAKOS: Let me ask: Is anybody in here, other than maybe the three physicists or even the techs or whatever, done an organ calculation? Have you read the MERD manual? I know you have.

MR. CAMPER: I've done them.

MR. STEFANAKOS: Have you read MERD manuals?

MR. CAMPER: I've done them. Sure.

MR. STEFANAKOS: You've done them? And they're that easy?

MR. CAMPER: Well, not easy. I didn't say that. But I'm just saying that --

MR. STEFANAKOS: And you can do it accurately, without any question. You can say you're within this percentage?

MR. CAMPER: The question is whether -- we're hearing now that package inserts are not an easy way to determine this dose criteria. I'd like to know more about why that's not the case.

MR. WERY: It's very simple: You don't know if the package insert is assuming some kind of normal uptake for an organ. You don't know that the particular patient -- you're talking about a particular patient here -- has that particular uptake.

The package insert is usually assuming a homogeneous distribution within an organ. That is almost

always not the -- or it's not the case for a particular patient.

You're talking about an organ dose. It's assuming, I guess -- I would look at that as an integral dose throughout an organ, but if you have a non-homogeneous distribution, it's very hard to look at, and the whole-body dose is the same -- goes the same way.

You're assuming a whole-body -- a distribution, in that case, that is to each -- from several different organs, now, each have a particular uptake.

MR. CAMPER: Would you buy the concept that if a misadministration occurs, by some of the other criteria, that in almost all nuclear medicine procedures, the does criteria is met?

MR. WERY: I've not done the calculation.

MR. CAMPER: Conceptually, would you buy that in almost all nuclear medicine procedures, there will be a 2 REM dose to an organ?

MR. WERY: If I sat down with a calculator and the books and the product distributions, I probably could answer that. But right now, I couldn't say that.

MR. TELFORD: Richard, did you want to say something?

MR. CLOUSE: You can only be so specific. Obviously, we can't do that for every patient; that's

ridiculous. But I think this is like a catch-all. But you have to say there comes a point where you need to report that this patient received a dose that was significant. Now, what does significant mean? I don't know. But somehow, you have to have a catch-all.

Offhand, I can't think of many exams where a patient is going to get a target organ greater than 2 REM from a diagnostic procedure. I'd have to sit down and look at that. But that's a pretty significant dose.

MR. TELFORD: Richard, you said "target organ."

MR. CLOUSE: I'm sorry.

MR. TELFORD: This is any organ.

MR. CLOUSE: Any organ, right. Well, but you're going to have a target organ with any given radiopharmaceutical, basically. And if I do a whole-body bone scan with 40 milicuries, I'm not going to approach --

MR. TELFORD: What I'm really asking is if I said to you -- remember, this captures misadministrations.

MR. CLOUSE: Right.

MR. TELFORD: So, if I said to you what's the level at which you think something should be reported to the NRC, is this an appropriate criteria?

MR. CAMPER: Or even more generically, is a delivered dose a reasonable criteria, not just this dose?

MR. CLOUSE: Okay. Let's take a specific example.

Let's say that a doctor said that he wanted a compatibility area scan, but the tech injected the patient with a 20-millicurie dose of MDP to do a bone scan. The bladder just probably received more than -- could easily receive more than 2 REMs.

MR. CAMPER: Certainly. That's right.

MR. CLOUSE: So, there is a misadministration by that criteria.

MS. KING: This isn't defining misadministrations. It's just defining whether you report it to the NRC.

MR. CLOUSE: At that point, that would be a reportable incident.

MS. KING: That's right.

When this first came out, that 2 REM and 0.5 REM, that was new within Part 35, and wasn't its attempt to eliminate some of the reports that went to your office, and it doesn't really eliminate very many at all. I don't see that it's served a purpose. Almost every misadministration I see gets reported based on this.

MR. TELFORD: That's a good point.

MR. STEFANAKOS: I believe the mystery there is that there were some commentors that felt that misadministrations should be linked to some dose delivered, not just some percentage of error, as it used to be.

MR. RICCI: Is it easy to get -- it is easy to get

an estimate of what the patient might got at any organ. It's very difficult and, in some cases, possibly most, almost impossible to determine the dose. So, if you are asking to set a threshold on something that's hardly measurable, I don't know how effective it's going to be.

An activity -- well, that can be measured everywhere. What that activity is going to go each patient, well, we can measure it very well if we have the equipment or if we want to spend the time, etcetera. But in practice, it's unfeasible.

MR. CLOUSE: I have to agree with Dr. Ricci. I think that it's fine to set a threshold, but we need to figure out what that means, and you can't calculate that for any given patient.

MR. WERY: You might be able to relate that -- if you wanted to relate it specifically to the product insert, to say, okay, assume that you're getting the distribution in a product insert and then use that --

MR. RICCI: You cannot do that, because that's not what the patient got.

MR. TSE: That's what exactly it said in our regulations last year.

MR. TELFORD: You may use it.

MR. TSE: So, you can use that if you want to. If you have a better way, you can do it another way.

MR. RICCI: But you are asking for something that won't be able to -- can't be used, essentially. So, why ask for it? Why give an option that isn't an option, in most cases? How does it help?

MR. TSE: But this way is stated that if you want to you could use the package insert to determine your dose. It's permissible.

MR. WERY: Let's give a situation where I used the product insert, and from the product insert information, the dose is less than 2 rads to a particular organ. I look at my scan, and I don't believe that the distribution that normally is followed by the package inserts is probably the distribution I got in that patient.

Now, I've got a situation where, well, I guess I could -- you know, theoretically, I don't have to -- assuming that it's not --

MR. CAMPER: Have the other criteria been met?

MR. WERY: Well, you have to assume that the other criteria are not met. Otherwise, I would still suggest that you just eliminate that.

MR. CAMPER: I mean you don't even start thinking misadministration in a triggering dose limitation, threshold, if you will, unless the other criteria have been met to consider it being a misadministration to begin with.

MR. WERY: I just would like to say it's very

difficult to do that measurement, and I don't see a particular purpose.

MR. TELFORD: What would you do with that third criteria?

MR. WERY: I guess my recommendation would be to eliminate it.

MR. TELFORD: Have no level at all. Then you would fall back on 50 percent.

Okay. Richard?

MR. CLOUSE: I say we maybe modify it or replace it with something, rather than just totally eliminate it. I mean I can understand the need for a catch-all here on the end. But I am not sure that that is something that's concrete enough for us to make a catch-all, because how are you going to calculate that? That's impossible.

MR. WERY: That's only used after you have a misadministration or whatever. Has it ever been reported, that the organ dose greater than 2 REM or a whole-body dose greater than .5 REM was the only criteria that made it a misadministration?

MR. WIEDEMAN: Yes. I look at them all that come into Region III. I see it all the time.

MR. WERY: How do they do the dose calculations?

MR. WIEDEMAN: Use the package insert.

MS. KING: It doesn't matter if it's accurate,

because you're not using it to measure an effect. You're just using it as a threshold, a limit to report. Who cares if it's that accurate?

So, just use the package insert as an estimate to determine if you report it or not. You're not using it to determine if a patient is going to suffer an effect. We all agree, for a diagnostic, that they don't.

MR. WIEDEMAN: As a matter of fact, if you look at all the various different diagnostic procedures, the typical doses, almost every one of them fall into that category, except for maybe 1 or 2 milicuries of sulphur or colloid or MAA, even 10 microcuries of I-131.

MR. WERY: I understand Tracy's point, and that may be good, too.

MR. STEFANAKOS: You know, you say what value or good or whatever. What would a lawyer do with this if he finds out it was reportable to NRC and he feels there is malpractice involved, and when, in fact, it wasn't, he says, well, look, you violated NRC regulation. You had a misadministration in this case.

MR. CAMPER: A violation of an NRC regulation is not, in and of itself, basis for malpractice.

MR. STEFANAKOS: I'm not saying it is, but it can help strengthen somebody's case when, in this case, it's not warranted.

MR. TELFORD: Let's take that one step further.

The theme that I want to play here is for the volunteers to give suggestions on how to modify this such that we capture -- we, the NRC, would have misadministrations reported to us that are things that are reportable. There are substantially different -- this is substantially different.

MR. STEFANAKOS: I agree.

MR. TELFORD: Richard is saying and, perhaps, Tracy was implying that it's not all done -- now, we're talking about a thing that's a misadministration. Number 2, B2, is probably exceed, 50 percent different.

Now, you come down to D, and it says all you have to exceed is 2 REM to an organ. Now, you've got to report. Is that 2 REM to an organ something you would call substantial?

MR. CLOUSE: But we're saying, on a normal dosage, you didn't exceed by 50 percent. You didn't exceed at all what the normal dosage would be, but you still exceed it.

MR. TELFORD: That's even worse, isn't it?

MR. WERY: You're saying that, according to the way this is written, that maybe we should have a requirement on the basis of every patient we treat.

MR. TELFORD: I'm asking for suggestions for how to change this if you want to change it.

If what you stated is your fear, that ought to be a motive for making a suggestion here. But what I'm asking for is a suggestion for what to change.

MR. CLOUSE: How is 2 REM and .5 REM total body? How was that arrived at and what is the intent?

MR. TELFORD: I don't know. I can tell you the intent is to capture reported events.

MR. STEFANAKOS: I think it is awfully close to what the general population limits are. That's what they're just using. I think somebody arbitrarily took 2 REM, because they said that's what you can't go into an area that has greater than 2 REM per hour.

MR. TELFORD: That's an organ.

MR. STEFANAKOS: He's asking where the numbers 2 REM and half a REM came from. Okay? I'm saying that the half-a-REM is the -- okay.

The half-a-REM would come from the whole-body exposure on the general populous. That's where I think that half-a-REM came, and I jumped on that.

Where did it come from?

MR. RICCI: I think I would agree with Tracy King when I say that we should keep it as it is, with the understanding, which is obvious at this point, that the organ dose larger than 2 and whole-body dose larger than .5 REM is only and, perhaps, only useful administrative

criteria for screening away events that aren't important, without attaching too much importance to what it was.

MR. TELFORD: Above that level should be reported to the NRC.

MR. RICCI: It's essential an additional constraint upon reporting, and it cannot hurt. It's unlikely that a patient would get more than the standard dose to an organ. It's very likely that he will get less.

MR. CLOUSE: With the exception of the bladder in a patient that doesn't --

MR. RICCI: Right. But that wouldn't enter the picture because of the -- in dosage that has to be part of the constraint in order for you to report anything. If that doesn't occur, the standard dose, whatever the dose is, isn't reportable.

MR. CLOUSE: Well, it is if it was given to the wrong patient.

MR. RICCI: Sure.

MR. CLOUSE: Anytime you gave a dose to the wrong patient, by this criteria, you're going to have to report it to the NRC.

MR. RICCI: Sure.

MR. CLOUSE: Because it's probably going to exceed that.

MR. RICCI: Yes.

MR. TELFORD: Any other modifications or suggestions? Okay. Let's look at Part E. First, it says you retain your prescriptions or your records of referrals and recorded doses and dosages for three years. Number 2 says you take the pages out the procedures manual and you put a new page in. Number 3 says if you have a misadministration, then you put the record of that for 10 years.

Well, one answer is that there are standard retention periods on 3, 5 and 10 years, and it's set up by OMB. However, there may be a practical reason for 10 years for the smaller licensees if they get inspected on the 3-year cycle. If the misadministration occurred in the first year and the inspector came in the third year, the record is now three years old.

There's a suggested change to be made if the inspector goes back three years and the record is now six years old. It's agreed that what was tried was not sufficient. They look back three years later and the record is not accurate. It's kind of stretching the point. It may be useful. But, all that aside, how would you modify this part?

MR. CLOUSE: I think 10 years is unreasonable.

MR. TELFORD: All right.

MR. RICCI: I would say 3 years.

MR. CLOUSE: We're only keeping the procedures manual for 3 years, yet we're keeping this for 10. In that 10 years, we've changed the procedures manual twice and now this thing of misadministration under the old procedures manual is no longer a misadministration under the new procedures manual, and I think that -- well, you know, it becomes this bureaucracy of how much paperwork can I keep right now; I'm overloaded with patient records as it is. And obviously, there probably aren't going to be very many of these, but it's just the idea of having to keep the papers.

MR. TELFORD: All right. Would you like to make a suggestion for deceased patients?

MR. CLOUSE: I'm not sure what our records are.

MR. STEFANAKOS: What is the statute of limitations by federal law? I mean, how soon after an event can somebody turn around and sue you?

MR. TELFORD: It's a --

MR. STEFANAKOS: Well, that could be a very good statute to follow that criteria for that length of time.

MR. TELFORD: Whatever the legal limits are.

MR. STEFANAKOS: Yes, whatever the judicial system --

MR. CLOUSE: I think it's 7 years.

MR. STEFANAKOS: I mean, I don't what it is,

3 years, 5 years, 7 years, whatever it is. I mean, if they considered that long enough, then by God, it should be good enough for the NRC.

MR. TELFORD: Darrel?

MR. WIEDEMAN: Doesn't most hospitals have some kind of a policy regarding retention of X-rays? I remember years ago this was brought up where if you have an adult patient where the X-rays are so many years old, you can dispose of those, but however, if it's a child, you have to wait for so many years after the, I don't.

MR. STEFANAKOS: I couldn't tell you that.

MR. WIEDEMAN: I vaguely remember some rule.

MR. CLOUSE: It seems to me though, doesn't that differ for deceased patients, though? A deceased child, it's still 21?

MR. WIEDEMAN: I don't know. I don't know what the rules are. I just remember people discussing them.

MR. TELFORD: Did you say the records were you were to keep X-rays for 7 years?

MR. CLOUSE: I think that's a state requirement.

MR. TELFORD: That's a state requirement?

MR. CLOUSE: Yes. Five years in Michigan. And there's probably big variations within a state.

MR. RICCI: The usefulness of an X-ray film is much larger than the reports here, so I don't see how they

are correlated.

MR. CAMPER: They really aren't, as John pointed out.

MR. RICCI: Yes.

MR. CAMPER: Our recordkeeping, there's 3, 5, 10, forever, or until the Commission authorizes their disposition. They really are not related at all to the statute of limitations, state-by-state.

MR. TELFORD: Okay. Let's look at 35.33 overall, now and see if we have any suggestions for modification. Let me suggest that we take a break for lunch and come back at 12:30 to pick up 35.34.

[Whereupon, at 11:25 a.m., the hearing was adjourned.]

AFTERNOON SESSION

[12:35 p.m.]

MR. TELFORD: This afternoon we'll talk about 35.34, the proposed recording and recordkeeping requirements for therapy.

On the left I have the current requirements to enable the -- to go to the B part of 35.34, which is the definition of the misadministrations. Again, we have a part A, which are events, and four of them this time. So we're -- calling each of these four mistakes as an event. And we have therapeutic use without prescription. You'll notice we have and in front of review of the patients' case for the therapeutic use without -- teletherapy administration is a single fraction is 20 percent different than what was described in that fraction, or therapeutic use not authorized.

Would you like to delete, modify or --

MR. WERY: One of these -- the -- a clarification maybe would help.

In item number 2 there, we're talking about recording the daily dose in a therapy -- I'm thinking of a teletherapy kind of situation.

MR. TELFORD: What do you do -- replace teletherapy with --

MR. WERY: Usually, what is recorded is the

treatment -- our cobalt machine -- treatment time that is delivered, the dose -- the dose that was delivered associated with that treatment time, and then accumulative dose associated with that, maybe a sensitive structure daily dose and an accumulative dose for the sense of the structure.

On doing quality control, sometimes we find that the -- the time for a cobalt machine again -- the time is recorded, the date and time is recorded. Often the dose is recorded, but there may be a -- a forgetfulness to record the total dose for that particular day or even week of the dose. For example, the time may be there, but they may not have written that -- that time corresponds to 100 centigrades or whatever.

MR. TELFORD: You record the time and the rate?

MR. WERY: Well, the rate would be there some place in the calculation -- those calculations were -- I guess, I would -- I would say that that probably would still -- my question is would that -- if you just had the time without the dose, would that be -- would that be effective?

MR. WIEDEMAN: I would say, in my opinion, if you can extrapolate that time back to a dose that you gave, that would be acceptable.

MR. WERY: That would be -- that -- it's just an error. It means their meant to put down the dose, but when

something is seen often enough that I wouldn't want to have to report it every time.

MR. TELFORD: How about number three?

MR. WERY: We'd like to task about that one, yes.

MR. TELFORD: Okay guys?

MR. STEFANAKOS: Okay. First of all, I don't think with the variances in teletherapy administration throughout the country, in daily given dose, daily fractions and all that, that it's legitimate to come in here and say, anything that is not excessive of the total dose prescribed is considered a misadministration.

MR. TELFORD: Oh, excuse me. Those are events.

MR. STEFANAKOS: Well, okay, well even event. Okay. I don't care. An event.

MR. TELFORD: Okay.

MR. STEFANAKOS: Fine. I don't -- if it exceeds the total dose that a physician wants to prescribe --

MR. TELFORD: Yes. A single fraction.

MR. STEFANAKOS: -- then it should be an event.

MR. TELFORD: A single fraction?

MR. STEFANAKOS: No, no. Total dose. If he prescribes 5,000 rads --

MR. TELFORD: Yes.

MR. STEFANAKOS: And in -- you have 200 and you end up giving 221 rads in the first two or three fractions,

and that has not obviously exceeded the 5,000 total dose, I don't consider that -- I don't think it should be considered an event and I would not consider it an event, other than because you wrote it there. Okay? Because --

MR. TELFORD: Because the extra 20 rads for t. day doesn't mean anything?

MR. STEFANAKOS: That's correct. The question is are you looking to protect a patient from overexposure or overdosage or are you just looking to protect him from a deviation from what the doctor said? And there's a big difference. Because there are people who deliver 160 rads a fraction, some people deliver 250 rads a fraction, 180 rads, or 200 rads.

MR. TELFORD: Okay. So that's what you meant by the variation that might be prescribed?

MR. STEFANAKOS: That's correct. It depends on the person who's making the prescriptions, as to what they can -- you know, it varies.

MR. TELFORD: Well, this -- this is really just an event. This would be reported to the licensee?

MR. STEFANAKOS: Oh, but later on. It's -- it's more than that -- it's reported to you.

MR. TELFORD: Yes. We're not there yet.

MR. STEFANAKOS: Okay.

MR. TELFORD: Yes, but --

MR. STEFANAKOS: But I want to nip it right here before we get any further.

MR. TELFORD: Well, maybe you want to cut this one off, and that's a good suggestion. I mean, we'll listen to that, but I was just confessing that --

MR. STEFANAKOS: Yes.

MR. TELFORD: What we have here is -- is something that's a daily fraction. It looks like it's outside of some sort of reasonable bounds for what you can do. And the question is would licensing management want to know about it. And your answer is no, because it doesn't matter that -- depending upon who's doing the prescribing, it could have been greater or lesser than that, so that's a second reason for not blocking.

MR. STEFANAKOS: And the -- the other part of this is -- is that greater than 20 percent error also refers to an underdosage.

MR. TELFORD: Yes.

MR. STEFANAKOS: And I don't think, by any means, that's any of NRC's business -- that if a patient's underdosed. Your concern is from -- I can understand from the regs and everything is that it's an overexposure or unnecessary exposure of the general populace and the patients now that we've taken that into thinking. And if you underdose somebody, you certainly are not overexposing

them to anything.

MR. WIEDEMAN: Well, you know there's -- let me respond to that. There's two schools of thought on that. And in our training at M.D. Anderson for NRC inspectors, the one thing that they keep emphasizing that an underdose, many times, is worse than an overdose, because now the patient is getting -- or exposure with no therapeutic benefit.

MR STEFANAKOS: I don't argue that point. I don't argue that point at all. Medically speaking, it's a worse thing to do. But I don't think that's NRC's responsibility to step in there and say, you're underdosing a patient, so you're not giving him the care you're supposed to be giving. You're practicing medicine again.

And God forbid I should disagree with the Mecca, but I think they're wrong. Wrong from the point of view of they're saying, you have the responsibility to do that; right from the point of view that, yes, when you underdose that patient, then you have really lost a great deal, because you have limits to how much you can give that patient. And you lose the effect if you come back at a later time.

Now, during treatment, and again, this is what I'm referring to. After the treatment's over is a whole different story. But during treatment, you can make up or reduce dosage delivered and have no really deleterious

effect on that patient.

MR. WIEDEMAN: Biologically?

MR. STEFANAKOS: Right. Well, what are we worried about? Are we worried biologically, the patient wouldn't even be aware of it -- any other reason -- to say psychologically, because he would not be told that, hey, it's not necessary to tell him, because he still has gotten dose overall that the doctor prescribed.

MR. TELFORD: Tom or Ray, is there a level at which would say report to licensing manager for a single fraction -- 50 percent, 75 percent?

MR. CLOUSE: It's still within the -- it's staying within the 10 percent overall dose.

MR. TELFORD: Yes.

MR. CLOUSE: It's 35 -- now that's one of the conditions in there.

MR. TELFORD: Part B. That would be --

MR. CLOUSE: That's one of the conditions in there.

MR. TELFORD: But we're just on events, I mean. You know, let's say you've got a therapist here -- you could say, don't have that at all; you could say, don't use 20 percent, but use x percent.

MR. STEFANAKOS: I would say, in the opinion of the physician or the -- not the -- the opinion of the --

MR. TELFORD: The authorized user?

MR. STEFANAKOS: -- authorized user, the physician in charge of that patient, there has been no deleterious effect to that patient, then it doesn't need to be reported. And any onus is on him. If anything should come back, there's always a court of law that he could be -- he could be taken to for making that -- which it is anyway. So, I mean, he's -- he's --

MR. TELFORD: Okay. We're talking reporting to licensing management now, not --

MR. STEFANAKOS: Right, okay --

MR. TELFORD: -- NRC.

MR. STEFANAKOS: -- even so -- because the management -- 90 percent of the time, don't now what you're talking about anyway -- in radiation therapy and in most part, in -- well, I'll just stick with radiation therapy. They don't know what you're saying because they're not school in it. Unless they happen to be an adminis rator who is past through radiology or a physicist who has decided to hang up his slide rule and go into administration, okay. They're not going to know what you're talking about anyway. Because the first question they're going to ask you, well what effect is that going to have on the patient? They're going to say none, and he'll say, okay, don't worry about it.

MR. WERY: Okay. I think there's a basic problem with the way it's set up, in that -- the way the wording is in here is a certain percentage -- a fraction that are already given kind of thing, which puts the -- the big problem on the first set of treatments where you're not giving any dose yet. In reality, if you're going to make a mistake, you want to do it in the first couple of treatments, because you have the rest of the treatments to make up for the difference. And the correction per treatment would be smaller for the rest of the treatments, although the biological effect would be smaller.

So I think that the whole theory, how it's set up, is not what you're looking for. I can understand that if you may want to have a single -- some kind of flag going up, reportable to a local authority, for a single event that is outside reasonable kind of correction factors. And I guess I would not feel bad about changing the 20 percent to another number. And that probably would be a much higher number, something like 100 percent.

MR. TELFORD: Okay. Dr. Ricci?

MR. RICCI: Well, I think that the 20 percent error in the fractional dose is inconsequential in most cases, and even in much larger ones. So I think that one should require the reporting within 24 hours working time to the user of any misadministration -- fractional

misadministration exceeding 20 percent, or really any fraction or misadministration. And then only when this fractional misadministration brings about an excess in total dose by 10 percent or more, should the management be notified.

MR. TELFORD: Absolutely. 10 percent of the total prescribed?

MR. RICCI: Total prescribed.

MR. TELFORD: Like if it's 5,000, 10 percent of that?

MR. RICCI: Yes. Anything else would be unsafe ground, because it requires a clinical judgment.

MR. TELFORD: Let me -- let me see if I understand this. We've got a patient who's suppose to get a total of 5,000 rads in daily fractions of 200 rads. You're suggesting that the threshold here by 10 percent of the 5,000, which is 500. So we get a patient who gets 700 rads -- now 699 rads and one fraction -- okay. You would not report that to the local authority?

MR. RICCI: I would certainly report that to the user.

MR. TELFORD: To the user? Okay.

MR. RICCI: And then, they might need --

MR. TELFORD: That's -- you use --

MR. RICCI: -- not the licensee.

MR. TELFORD: -- the word "misadministration," and --

MR. RICCI: Fractional misadministration.

MR. TELFORD: Well, wait. We shouldn't use that word yet. We're not there yet. These are all events. These are all events. We'll get to misadministrations in just a minute. These are the -- these are the similar cases that we had in 35.33.

MR. RICCI: Well, an administration that has an error to me, is a misadministration, whatever you want to say.

MR. TELFORD: Oh, okay. But --

MR. RICCI: Now, if you bureaucratically decided "misadministration" is not to be used, then I will have to use the paraphrase "an administration with an excess of 20 percent," etcetera.

MR. TELFORD: Over here. These are going to be the -- here's the proposed events which are -- yes, events which are misadministrations. What I'm fishing for over here under the A part is for you to tell me what level --

MR. RICCI: Yes.

MR. TELFORD: What's the threshold that you say ought to be exceeded before you would go back to your user or your licensing manager, or whoever the local authority is. And Ray is saying 100 percent, which --

MR. RICCI: It's arbitrary. It might be --

MR. WERY: But I'm saying that to the licensee -- I agree with him --

MR. TELFORD: Yes, yes.

MR. WERY: -- that if I'm off by 10 percent, I'll tell the use -- or 20 percent, I'll tell the authorized user, and a much lower kind of number -- professionally, I will do that.

MR. TELFORD: Okay, but.

MR. WERY: If there's going to be a reporting to the licensee, I would pick a number much greater than that 20 percent.

MR. RICCI: And I'll be referring to the total dose and not to the fractional dose because --

MR. TELFORD: Okay.

MR. RICCI: -- for -- particular sides, even 500 rads can be compensated for by multiplying the course of treatment. Even a 1,000 rads, or in some cases, in the physician's opinion, and in his clinical judgment, can be compensated for.

MR. TELFORD: Okay. So you would still say, 10 percent of total? I just wanted to --

MR. RICCI: Yes.

MR. TELFORD: -- verify that.

MR. RICCI: Yes.

MR. TELFORD: All right. Now, any other comments on --

MR. STEFANAKOS: I'm trying to make a comparison between this and prescribing drugs and I'm having a little difficult time getting an example. But to me, there's no difference. If there -- if a physician or a pharmacy or a physician, let's take, prescribes a drug that's contraindicated or in excess of what is supposed to be said, nobody reports that to the administrator, nobody reports that to the licensee.

MR. TELFORD: Could we use I-131 -- radiopharmaceutical therapy?

MR. STEFANAKOS: Well -- well, I'd rather go back to some drug, you know, that the pharmacy puts out to a patient, not a radiopharmaceutical, I'm talking about strictly, a Darvon, or anything like that.

MR. TELFORD: It's got to be by-product material?

MR. STEFANAKOS: No, no. I'm trying to make a comparison as to why should we be required to admit or to report to administration for something that people in a hospital, other places do the same thing and aren't required to report?

MR. TELFORD: Okay.

MR. CLOUSE: Well, they are required to report at a certain point. I mean, if a nurse gives the wrong patient

a dose of something, then there's an incident report, and those are all reviewed by administration.

MR. RICCI: The tolerances for radiation are less high than tolerances for other drugs.

MR. CLOUSE: Absolutely. And the --

MR. RICCI: So --

MR. CLOUSE: -- and often times the effects are transient, not permanent.

MR. TELFORD: Well Tom, I'm open to suggestion here.

MR. STEFANAKOS: Well, I think --

MR. TELFORD: What are your suggestions for --

MR. STEFANAKOS: -- that should be -- if you're going to keep it, then you should reword 3 to say "at the discretion of the authorized user," and that's that -- or you know, words to that effect, saying that the authorized -- if the authorized user felt that it was detrimental to the patient, then a report should be made to the licensee. But it shouldn't -- you shouldn't have a magnitude there for somebody to arbitrarily set, because it's -- it's different. It's --

MR. TELFORD: Okay.

MR. STEFANAKOS: -- different with patients it's different with sites and the whole bit. One part of the body is a lot more resistance to radiation than other parts

of the body. And that 20 percent could be meaningless if we're treating the brain, and it could be very very important, if we're treating the spleen, or a kidney or larynx. I mean, so to arbitrarily set numbers is, I think, very erroneous.

MR. RICCI: Quite true. And I would correct what they said. Even the criterion used in the total dose, isn't quite an absolute one. Because for instance, in paralytic cases, safe doses are given where, by even in excess of 20 percent of the delivered dose, would still be acceptable to the physician.

So, it's hard to set -- and it should be -- I agree to -- at the discretion of the authorized user.

MR. CLOUSE: So is the problem, who we're reporting this to? What if instead of licensee management, it said authorized user up there? Is that a problem?

MR. RICCI: I would have any variation from the prescribed administration dose be reported as soon as possible, certainly within -- before the next treatment, to the authorized user.

MR. CLOUSE: Okay. So if it said --

MR. RICCI: That, no matter what --

MR. CLOUSE: authorized user, and not licensee --

MR. RICCI: -- but --

MR. CLOUSE: -- management?

MR. RICCI: -- that's a different thing. Now, the licensee has responsibilities to the NRC and he needs to be notified whenever something goes wrong, that can cause problem to it administrationally.

MR. CLOUSE: But that -- would be -- come up -- the authorized --

MR. RICCI: If it's --

MR. CLOUSE: -- user is the one who's going to have to make the determination, if that's significant.

MR. RICCI: There has to be a clinical judgment before you say that that --

MR. TELFORD: Okay. Dr. Ricci has just said authorized user -- I think what you're telling me is you would use something less than 20 percent?

MR. RICCI: Oh, definitely, yes. Anything exceeding 5 percent.

MR. TELFORD: Okay.

MR. RICCI: So that he can choose -- he has got to notify --

MR. STEFANAKOS: I still don't think you should put a value on there. If you're talking about to the authorized user, it should say any deviation from the prescription whatsoever, regardless of magnitude. And that includes whether you treated lateral fields instead of PA fields; that means if you treated with a 20 by 20 field,

instead of a 10 by 10 field. You're just -- you're just narrowing in on one little thing -- a dose. An arbitrary number.

MR. TELFORD: Okay.

MR. STEFANAKOS: And if you really want to protect a patient, don't just sit there and say one little thing -- aspect of it, cover the whole thing, and just say, a teletherapy administration which differs from the prescription which was written by the authorized user or an individual under his supervision, etcetera, etcetera, etcetera.

MR. TELFORD: Okay. Ray, did you have one other comment?

MR. WERY: Well, does to muddy up the waters a little bit more.

MR. TELFORD: You're about to?

MR. WERY: I think I'm about to. And this is not an original idea. Someone brought this up to me and I couldn't answer. How would -- if a patient doesn't show up for treatment -- an early treatment, so they get no treatment that day, the prescription says five treatments per day, or whatever --

MR. STEFANAKOS: Yes. Or the machine is down.

MR. WERY: -- or the machine is down or whatever.

MR. RICCI: What's the problem?

MR. STEFANAKOS: Well, under -- under -- I'm sorry, go ahead -- go ahead, Ray.

MR. WERY: It would seem to me that the administered dose then was greater than, or was -- 20 percent -- yes, it was a greater -- the difference was greater than 20 percent of the prescribed daily fraction. The delivered dose was zero.

MR. RICCI: Don't you think that the physician should be notified when the patient doesn't get treated?

MR. WERY: That's what I wanted -- I don't particularly --

MR. RICCI: So, we should --

MR. STEFANAKOS: That's what he's arguing.

MR. RICCI: Yes, I would be -- it would be included in what Tom has suggested.

MR. WERY: But I'm not so sure that I want the physician to have to sit down, and if the machine is not available that day, to have to write a note in every patient's chart that -- to indicate that the machine was down that --

MR. RICCI: There could be an umbrella type of notification, that physician knows that the machine is down so he can infer to hold the patients for the day in order to receive their dose.

MR. STEFANAKOS: We do something differently.

When a patient doesn't show up, our techs are instructed to write down "patient did not show, was sick, did not have transportation, machine down."

MR. RICCI: I'm talking about machine down.

MR. STEFANAKOS: Anything. I don't care what it is.

MR. RICCI: I don't know, the physician needs to know because he might even request that the patient be treated elsewhere, if it is required. So he must be notified.

MR. STEFANAKOS: Well, he's yes, okay. Yes, it's automatic in our situation --

MR. RICCI: Right.

MR. STEFANAKOS: -- that he's told.

MR. RICCI: Sure, sure.

MR. STEFANAKOS: But for record purposes --

MR. WERY: Do we want to have that in -- as a --

MR. RICCI: Well, I don't know.

MR. WERY: -- formal thing that we have to do. I agree. We do the same thing. We note it, but I don't --

MR. STEFANAKOS: I don't think it's necessary as a formal thing. It's common sense that most people do tell that when a machine is down. I mean, I don't know of too many physicians that are running or working in the department that don't realize that a machine is down. That

likelihood, you know, if that's it, the guy doesn't belong there. That I think, you know --

MR. WIEDEMAN: As for the -- the one comment about the machines down, and therefore, we weren't able to give our dose -- fractioned dose. Most prescriptions that I've looked at, do not say, you know, -- they usually imply, you know, so many rads per day for so many days. Well, it doesn't say so many continuous days, they have fractions per week.

MR. RICCI: There are critical cases where the delivery of the dose is important, in so far as time sequence is concerned.

MR. STEFANAKOS: Absolutely.

MR. RICCI: And they have to be included.

MR. WIEDEMAN: Also, we understand that, you know, an event like this, the machine breaks down or the patient is too sick to come in, or just doesn't even show up. This is something that's beyond your control.

MR. RICCI: Well, if you understand it --

MR. WIEDEMAN: You can't --

MR. RICCI: -- your regulations should understand it --

MR. WIEDEMAN: That's right.

MR. RICCI: -- should be included there.

MR. WIEDEMAN: I just cannot imagine anyone ever

citing the licensee for not treating their patient because --

MR. RICCI: Sure.

MR. WIEDEMAN: -- because they were supposed to come in --

MR. STEFANAKOS: I agree, but then it shouldn't be there.

MR. WERY: Well, what if -- what if you went through a chart -- I mean, years down the road, and you go through a chart and you see that a patient was not -- you know, his treatment was missing, you know -- it was not added on -- may not -- you know, if it's not -- if the -- some kind of documentation is there, the prescription was -- as they are all saying, should say something like five treatments a week. We certainly treat people other than five treatments per week --

MR. STEFANAKOS: Absolutely.

MR. WERY: -- sometimes, so it should say five treatments per week, and the prescription is there -- it's written, and there's -- there may not be documentation --

MR. RICCI: Well, every administration of those has to be initialed and written down. So whatever isn't there hasn't been administered. That's how I would treat it.

MR. WERY: Right, but if -- I'm not so sure that

that wouldn't.

MR. WIEDEMAN: Well, you know, once again, I remember when it was rather interesting. The machine broke loose and slammed down on the patient's head, over in Indiana, killed the patient. The hospital came back and said is this a reportable misadministration? Because the patient didn't receive the entire dose?

MR. STEFANAKOS: Of course not.

MR. WIEDEMAN: That was a request that they made of us.

MR. STEFANAKOS: That's -- oh God.

MR. RICCI: Yes, I'd -- considering that. I think that point three is certainly not --

MR. STEFANAKOS: Here you go Darrel, sign that sucker for all of us, that a boy.

Darrell, you say that you know of no inspector who would cite an institution because a patient didn't show up or because of this or that. Then it shouldn't even be in the record, if that's the case. And that's what this is saying.

You've got to take it to the point that Ray brought out.

MR. WIEDEMAN: Let me give you the history behind that particular one. It happened in Cleveland, Ohio, as a matter of fact.

And this particular facility, they did the calculations for the patient. I believe they included a wedge factor. That was the problem.

And on Week 1, they were supposed to give something like 150 rads per fraction. And they ended up giving like 180 rads.

The second week, it went to 220.

On the third week, it went to 300 and some rads. And the third week, they did their chart check and said oh, my goodness, we made an error in the wedge factor. They went to the authorized user, and said well, doctor, you prescribed a total of 5,000 rads. We're at about 4,400 right now. We made an error in the fractionated doses.

The doctor said, I've made a decision that this patient has had enough radiation therapy. And I'm going to rewrite the prescription.

Well, then the Radiation Safety Officer came back and said no I don't think you can legally do that. But it still has to be reported to the NRC, because this is a misadministration.

Well, then, there was a long discussion, Isotope Committee meeting, of whether or not this consisted of a misadministration. They sent in a request to the NRC, to the Office of General Counsel, to determine whether or not this was a misadministration.

Because, remember, the intent of reporting a misadministration was to look for generic problems in the industry, correcting them, and that type of thing.

And the Office of General Counsel came back and said that this was not a misadministration, because they had not reached the total dose yet.

And, however, the problem was that by rewriting the prescription, if it was truly because the clinical effect was achieved, that would have been acceptable. But that wasn't the reason why they wanted to change the prescription. It was because they had made the error in the fractionated dose.

MR. STEFANAKOS: So what was the total dose this patient received at that point?

MR. WIEDEMAN: Around 4,400 or 800, something like that.

MR. STEFANAKOS: Okay. So they did not exceed the 5,000, so they weren't over the 10 percent.

And you say it kept doubling; instead of giving 150, they gave 200 rads per fraction?

MR. WIEDEMAN: I think they were going to give a little boost dose during the second week and a boost dose during the third week. And that's why they kept climbing it.

MR. STEFANAKOS: Oh, I see. It kept multiplying

because they were changing the fractionation.

MR. WIEDEMAN: Correct.

MR. TELFORD: Ray.

MR. WERY: There are two things I would like to say. One is, there are time dose fractionation calculations that will allow physicians to at least attempt to change total dose given as a function of the dose rate that is given.

So it is possible that, given a situation where they may be able to do a calculation, indeed, the same effect, biological effect, would be administered in a shorter time with a higher dose rate than a larger one. Granted, those calculations are fraught with difficulties. I'm not saying you can do that with any accuracy.

But maybe all you need is to go back and find another way to do this, because the way you have it done, a very simple mistake, for example, a technologist putting in -- and I'm taking these numbers from my head -- but if the time calculation was 1.4, or 2.4 minutes, and on the first or second treatment they put in 1.42 minutes, that might kick them over the 20 percent increase.

Now, if, they do the same mistake on the 20th treatment, that doesn't kick them over the 20 percent per fraction given kind of thing. And clearly there is no difference biologically in the two individual events.

So maybe you just need to rethink of how you want to do this.

If you are going to make a mistake, you want to make it early so you can correct it during the treatments.

MR. RICCI: Can you avoid the clinical judgment call?

MR. WERY: I don't know if --

MR. RICCI: I don't think you can. So one might as well defer, or enter that in the picture, or else eliminate it. I don't know.

But if you cannot eliminate a clinical judgment call, it's there.

MR. STEFANAKOS: Wait a minute. What do you mean eliminate a clinical judgment call? You mean --

MR. RICCI: In what is possibly in excess, not, cannot be compensated, essentially, with a correction in the prescription.

MR. STEFANAKOS: You are saying that you shouldn't go, if the physician -- I'm still confused here on that. What you are saying is that you shouldn't go to the physician and say in your judgment, is this deleterious to the patient?

MR. RICCI: I'm saying that we should.

MR. STEFANAKOS: Okay.

MR. RICCI: A physician should be involved --

MR. STEFANAKOS: Okay.

MR. RICCI: -- in deciding whether the dose, the fractional dose administered incorrectly can be compensated for, and therefore, constitute no harm to the patient, et cetera, et cetera.

MR. STEFANAKOS: Okay. That's what I was driving at. Right.

So you're saying that what I mean to say is if the physician cannot make that determination, --

MR. RICCI: He's got to.

MR. STEFANAKOS: Okay. I think we're saying the same thing.

MR. RICCI: Yes, I think so. If you want to do without the clinical judgment call and set a limit, then you have to set it impossibly high to make it really essentially too high.

MR. TELFORD: Let's call in the misadministrations, in this discussion.

MR. RICCI: Yes.

MR. TELFORD: Which I now have on the viewgraph. Therapy misadministrations.

One are any therapeutic use other than the one in the prescription, you would catch. Wrong patient, wrong source, wrong site, wrong route. That's the same as the curve requirements.

Therapeutic use that is 10 percent different. That's a radiopharmaceutical therapy.

Three is the teletherapy.

Now, I have three subparts here. I'm sure you'll get your teeth into this one.

Ten percent here of total dose, 10 percent different. Single fraction with your all-time factor of 2.

Three, a cumulative total that uses the threshold level of 10 percent for the total dose.

And four, we have brachytherapy source that is leaking or lost.

Five, we have brachytherapy administration that is 20 percent different from what was prescribed.

MR. STEFANAKOS: I think we should go one step at a time rather than jumping all over the place.

MR. TELFORD: Okay. Let's take Number 1.

MR. RICCI: Wrong route, you say. And the patient might be treated OPA instead of OPMPA, and the NRC should be notified when the physician says oh, that's all right, next day we'll treat him the other way and compensate.

Isn't that a bit excessive in saying the wrong route for any individual fraction, when it can be compensated for?

MR. TELFORD: Okay. That's a good point.

MR. WERY: What does route mean for a teletherapy

--

MR. RICCI: Port, probably, direction of entry.

MR. TELFORD: Teletherapy may be the site.

MR. WIEDEMAN: In this particular situation, the first thing that comes to my mind is P-32, sulfur colloid, or chromic phosphate. One is given intravenously and one is --

MR. RICCI: Teletherapy?

MR. STEFANAKOS: No, no. Teletherapy is --

MR. RICCI: -- it's teletherapy as well.

Wrong route, what would it mean in teletherapy?

MR. WIEDEMAN: There would be --

MR. RICCI: Fine. Okay.

MR. STEFANAKOS: Okay. Now, let's go back to what he just said about site.

Does site mean that, and the obvious example is, if they treat a brain instead of a chest.

Also, what about site if they treat the entire, as Alessandro said, PA, instead of split therapy, PA-AP; is that also site?

MR. WIEDEMAN: Was AP and PA prescribed?

MR. STEFANAKOS: Yes.

MR. WIEDEMAN: Okay. You just think you got your APs and your PAs mixed up? To me that's a site. That's the same thing.

MR. STEFANAKOS: No, wait a minute now. Okay. Make sure we understand.

It's not that they treated a PA first and an AP, but they treated the entire treatment through one port instead of both.

MR. RICCI: So the skin dose to one site would be quite a bit higher.

MR. STEFANAKOS: We're talking like 180 rads through the AP port instead of 90 to the AP, 90 to the PA.

MR. CAMPER: That doesn't follow the prescription correctly.

MR. STEFANAKOS: Okay.

MR. CAMPER: That does not follow the prescription.

MR. STEFANAKOS: That does not follow the prescription. However, again, I fall back --

MR. RICCI: If the physician says, we can compensate for that, tomorrow, I will just --

MR. STEFANAKOS: And tomorrow I will just treat the PA, or just the opposite.

MR. RICCI: And that may solve the case. Maybe that's too bad.

MR. CLOUSE: But that would be covered under greater than a factor of 2, because that wouldn't be greater than a factor of 2, would it? You're still treating, the

patient got twice the skin dose, but that's not greater than a factor of 2. Therefore, it would be qualified by the other qualification.

MR. WERY: The question is if that is the wrong site, that it doesn't make any difference what the dose is, if it is considered the wrong site.

MR. STEFANAKOS: Yes, but see, I have to go back to my premise earlier.

Are we trying to find, well, what are we trying to determine? Whether a patient has been overdosed, or whether a patient was mis-dosed? And there is a big difference, as I pointed out earlier.

If the physician decided that he wants 5,000 rads to a tumor volume, in my opinion, if he gets 5,000 rads to that tumor volume, his satisfaction or his requests are satisfied.

Because, and I'll give you another. We have some real tunas in there that we've got to treat entirely AP or entirely PA, with no deleterious effect to that patient. Because we cannot treat them isocentrically by rotating the gantry around, because we have to put them on a special cart that the gantry can't go underneath. Okay?

So now, he wrote the prescription differently. But what is the difference between the two? Are we worried about delivering a patient, a dose to a patient; or are we

worried about hurting the patient?

If we're not hurting the patient --

MR. RICCI: The physician decides about the technique, as well, not only the dose, how it is to be delivered.

MR. STEFANAKOS: I agree 100 percent. But, in producing that dose to the tumor volume --

MR. RICCI: That's not the only concern, right?

MR. STEFANAKOS: That, what? Whatever the concern is. His major concern is that a dose is delivered to a tumor volume.

If, in his opinion, --

MR. RICCI: Right.

MR. STEFANAKOS: If, in his -- that's what I'm referring to all around. Let's make that ground rule straight.

The physician has to make the opinion. It's his opinion. Not the NRC's; not yours; not mine; not the vice president. It's his opinion.

MR. RICCI: Below a certain level having to do with --

MR. STEFANAKOS: Agreed. And that's what we're already saying. We're not talking about excess of total dose; we're talking about fractionations. Okay.

I don't feel it's a misadministration in this

case, and I don't think it should be reported, because that physician has to make the determination if it in fact is detrimental.

If it is, then it's reportable. If he says yes, that's detrimental.

MR. RICCI: Or likewise, only --

MR. TELFORD: Wait, wait.

MR. RICCI: Sorry.

MR. TELFORD: Let's stay with one just for a minute, for a few words of clarification.

One says, you've got a treatment which is, an administration which is different from what was prescribed.

And you ask, what are we after. And I said we're after mis-doses that are substantially different should be reported.

Now, if, as Dr. Ricci says, we want the authorized user to make the prescription, and it turns out that we had a mistake here, and they only treated the patient for one side rather than both sides, how do you distinguish between doing it on purpose, and doing it by accident?

MR. WERY: The authorized user would make the decision.

MR. TELFORD: Well, the authorized user decided to treat both sides.

MR. STEFANAKOS: I don't think it makes any

difference whether it was done right or wrong, if in the authorized user's opinion, it did not cause a deleterious effect to that patient.

I think you're practicing medicine when you're coming in there -- and repeat your statement that you just said.

MR. TELFORD: Substantially different.

MR. STEFANAKOS: From what?

MR. TELFORD: From the prescribed dose.

MR. STEFANAKOS: Okay. The prescribed dose is 5,000 rads.

MR. TELFORD: Okay.

MR. STEFANAKOS: Okay. He wants 5,000 rads delivered to that patient.

Now, in the course, he has to state how he wants it done.

I don't think it is the NRC's requirement or position to say what happens between zero and 50 is right or wrong, in how that is delivered.

I agree with you that at the end point, if it exceeds what he says, even though he might be treating less than what normal, other people -- I shouldn't say normal -- what other people in the field are treating. Some people only treat 4,500 rads to a certain site. Other will treat 5,000 or 5,200. Which that is higher than 10 percent.

Okay?

MR. TELFORD: Let's just stay with number one.

MR. STEFANAKOS: What I'm saying though is, it is all tied in, and the fact that what I'm saying is, when you say a dose, it differs for sites, it differs from physicians, and so forth.

You can't tell that physician whether he is doing right or wrong in the interim. That's his call. He's got to make it.

MR. TELFORD: Okay. This case, this example we're talking about of treating the patient for both sides rather than just for one side, that was with a prescription.

Now, you've presented a difficult case, that may or may not be so clearcut that it is a misadministration.

But, we're talking about a prescription, in teletherapy.

Let's take something rather obvious.

For instance, the patient is supposed to get their right sided, but they got their left side treated. Or your case, where they had their lung treated rather than their brain.

That's a different site.

MR. STEFANAKOS: I don't think anybody is arguing that point. We agree with that one, right off the bat.

MR. TELFORD: Okay.

MR. STEFANAKOS: That the site, absolutely. I mean, if you're treating -- that's like the surgeon going in and removing the left leg when it was supposed to be the right leg. That's a mistake.

MR. WERY: That has happened.

MR. STEFANAKOS: Absolutely. So I have no qualms about treating a different site.

MR. TELFORD: Okay.

MR. STEFANAKOS: I'm saying if you are treating a lung and the prescription is written for the lung, the point is if I can use it, if we are leaving from Chicago to go to Indianapolis, I don't think the NRC should tell us what route we should take, as long as we get there in the time prescribed.

MR. TELFORD: Okay.

MR. STEFANAKOS: And we have not exceeded the limits set for getting there, meaning if it should have taken us five hours, and it took us six hours. And that's a very poor example.

MR. TELFORD: Okay. Darrell.

MR. WIEDEMAN: Then the way I understand what you are saying is if the physician prescribes 5,000 rads, and let's say, and I know it wouldn't happen, that you would make a miscalculation in the calculation, make an error, and your technologist went ahead and set the timer and gave that

patient 5,000 rads on the first day, that that would be acceptable?

MR. STEFANAKOS: Oh, no, no, no, no, no. That doctor better say that's deleterious to that patient.

MR. WIEDEMAN: Well, let's say you run off to the doctor and say Doctor, we just gave the total dose in one day. And he says well, let's just watch the patient for the next two weeks.

MR. STEFANAKOS: I don't think there's a physician, I hope there's not a physician in this country that would say hey, well, you know, that really won't have much effect. Because I guarantee you, I don't think that patient will get on the table. Okay. I know that's an absurd example that you brought in just to prove a point. But no.

MR. WIEDEMAN: What limit do you --

MR. STEFANAKOS: I don't think there's a limit. I think, when I say this, I think you're trying to strap that physician with a number that is artificial. He's got to make the determination. He's got to, that's what he's trained for.

He's gone to medical school; he's gone through specialty; he's trained; he's had internships; he's had everything else. That's his call, not my call, not your call or anybody else's call. You can advise, but you can't

tell him what he's doing, because he's the one that's ultimately responsible.

MR. RICCI: You can still make safe calls in the sense that you can say a single fraction in excess of 1,000 rads or something greater. Or, and he can bring the total fraction above something. Beyond that, there is the clinical judgment.

MR. WERY: So I think you're talking about time-dose fractionation schedules, --

MR. STEFANAKOS: Absolutely.

MR. WERY: -- which at best are a poorly understood portion of radiation oncology.

MR. RICCI: Yes.

MR. WERY: I mean, you can argue that total dose is relatively poorly known in radiation oncology.

MR. STEFANAKOS: Absolutely.

MR. WERY: There's differences in total dose schedules.

MR. RICCI: Knowledge of radiobiology, radiation biology is poor among physicians, too.

MR. WERY: But time-dose fractionations are known much poorer than the total dose, even.

MR. STEFANAKOS: Absolutely.

MR. WERY: So you are trying to get that --

MR. STEFANAKOS: I can give you another example.

MR. TELFORD: Let's focus these suggestions on Number 3.

Tell me how you would modify Number 3.

MR. RICCI: A factor of 2 in any fractional dose is unduly restrictive, possibly unduly restrictive.

MR. TELFORD: Therefore, you would do what with it?

MR. RICCI: I would modify it.

And likewise, 10 percent error in total dose, there are cases in which it is unduly restrictive. Therefore, it couldn't stand in general.

MR. TELFORD: Okay. You would do something with that?

MR. RICCI: Yes.

MR. TELFORD: All right. How about -- it's a cumulative total, you total up the fractions given to date, and your threshold is 10 percent of the total prescribed dose --

MR. STEFANAKOS: So what you're saying --

MR. TELFORD: -- 5,000.

MR. STEFANAKOS: -- is to this date you were supposed to have 2,000 and you have 2,300; is that what you're saying?

MR. TELFORD: You're supposed to give 5,000 total. To this date you've got 2,000, is the exact dose you're

supposed to have. So it's 10 percent of 5,000, or 500. It would be 1,500 to 2,500.

MR. STEFANAKOS: Okay.

MR. TELFORD: To this date. That's the window for that period of time.

MR. STEFANAKOS: Okay. If that's what you're saying, I would think that both 2 and 3 should be eliminated. Ten is fine, because 10 percent is what generally the industry, if I'm not mistaken, is considering the difference between cure and recurrence or underdosage, or I'm sorry, overdosage and underdosage is about 10 percent, is what they're saying.

So I have no qualms with number 1, total dose. Even though, even though, as I pointed out earlier, there are situations that physicians will prescribe as much as 10 percent difference between them.

Some of them are very, very aggressive; and they want to go out there and hit that tumor with everything they can give it.

Others are rather timid, and go in there and give it a much lower dose and play on the safe side or say this is fine.

And an example of that is 4,500 rads, a lot of physicians give as a tumorcidal dose to certain areas. Other will give 5,000 rads. Well, if they give 5,001, that

4,500 is now a misadministration. The 5,000 though, is not, even though that is a tolerable dose.

So where do you draw the line? I say you're fine. If he says 5,000, you go over to 10,000, that's fine, because I think that's wrong. But anything in between I still say is a judgment call on that physician.

MR. TELFORD: Okay. Dr. Ricci, how would you modify this?

MR. RICCI: Well, Number 3 is unduly restrictive.

Number 1 may be unduly restrictive. It's probably all right in most cases, but not always. In tailgating treatments, that would be probably unduly restrictive.

Fraction of 2, factor of 2 in fractional dose, I would change to a factor of 5. If you want to stay in the same ground.

MR. TELFORD: Okay. How would you make Number 1? How would you make that not unduly restrictive? What would you do to the 10 percent?

MR. RICCI: Well, I could keep it 10 percent, if it served any purpose. What does the NRC do with this information? Try to avoid errors for the future. In most cases, they will find out that it is an error that will occur again in the same way. And so it will be just paper in the file.

I don't know. I don't know.

MR. TELFORD: Okay. Ray, how would you change these?

MR. WERY: Well, the people have been living with the 10 percent now for a while. Although I will certainly argue that that may be related to biology; it may not be, certainly isn't related to biology at all, for all tumors. But that seems to be, people can live with that.

Factor of 2 in any fractional dose. I guess that and the next one I tend to agree that that's falling into, well within the realm of changes that most physicians would consider, or could consider as not important, depending on individual cases --

MR. TELFORD: What about a factor of 5?

MR. WERY: Factor of 5 is at least two and a half times better than a factor of 2.

[Laughter.]

MR. TELFORD: I'll give you an A for arithmetic for today.

Do you think it is something that ought to be reported?

MR. WERY: It's an arbitrary number. As an arbitrary number, not trying to be related to anything to do with good biology, factor of 5, I think, is a reasonable kind of number. It sounds reasonable right now, at least.

MR. TELFORD: Number 3.

MR. WERY: There I think I would eliminate it completely because of the time-dose fractionation uncertainty. I am not sure that there's -- from any tumors, that whether you're giving 5,000 rads in 5 weeks or 4,000 rads in 3 1/2 weeks that the biological difference might not be the same. I would eliminate that.

MR. TELFORD: We kind of skipped over number 2 there for radiopharmaceutical therapy. Anybody have any suggestions there for how you would like to see that modified?

MR. RICCI: Twenty percent?

MR. TELFORD: For radiopharmaceutical therapy.

MR. RICCI: Yes.

MR. TELFORD: Okay.

MR. RICCI: Twenty percent.

MR. TELFORD: Why?

MR. CLOUSE: We'd stand by the same thing. I mean it's --

MR. TELFORD: Okay.

MR. CLOUSE: It's a guess. You know, we say, okay, if you have a patient, shows up that -- thyroid cancer, you're going to give them I-131. If I have a patient that weighs 200 pounds, I have one that weighs 250 pounds, I'm still going to give them 175 millicuries. That's a standard dose.

MR. RICCI: The uptake can change by 300, 400, 500 percent, essentially.

MR. CLOUSE: I mean it's a stab in the dark. You don't know how much tissue -- that surgeon says I got it all, you know? I find patients that have a tiny bit of thyroid. I find patients -- I swear there's 40 percent of that thyroid gland on one side. You know, how do you -- but you can't calculate that.

So, that number doesn't necessarily mean anything.

MR. TELFORD: Okay.

MS. KING: Is this the difference in assayed activity given to the patient or the dosage?

MR. RICCI: That's the dosage, the activity delivered to the patient.

MS. KING: The activity?

MR. RICCI: Yes.

MR. CLOUSE: Obviously, sometimes those things have to change. The patient vomited, but it was 2 hours later. Now, what percentage did the patient vomit? I can't imagine calling that a misadministration. I mean that's not -- that's out of my control. The patient didn't quite get it all out of the vial. I have never had that happen, but I suppose it's possible. There are areas where -- 10 percent is pretty restrictive.

I think in most of the cases that we do

radiopharmaceutical therapy, whether it be P-32 to a cavernous -- I mean to an astro-cytoma or whatever, there is an awful lot of fudge factor there. The biological response varies so much from patient to patient that 10 percent --

MR. RICCI: Ten percent is an insignificantly low number then. It is unreasonable.

MR. TELFORD: So, you suggest 20 percent.

MR. RICCI: Well, I was just suggesting 20 percent. But something larger should certainly be acceptable. Twenty or 30 percent, probably, I would suggest.

MS. DUFFY: Well, even a case as small as a hyperthyroid, where you have maybe a prescribed dose of 5 but the availability of the radiopharmaceutical is 6, you know, that's greater than 10 percent.

MR. TELFORD: So, you would give the 6.

MS. DUFFY: You would have to.

MR. CLOUSE: Sometimes, in a case like that, you can have the physician write another prescription, and he'll gladly put 6 instead of 5.

MS. DUFFY: Yes.

MR. CLOUSE: It doesn't mean anything.

MR. STEFANAKOS: It seems like there is a tremendous hang-up on numbers, and that's all it is right now is a numbers game. Okay? You're removing everything

from the physician and throwing away all his training and saying that's immaterial, because we're going to set limits on what's right and what's wrong. And I find it very hard to accept throwing numbers at something that is so intangible as the stuff that's going on in a lo[illegible]se.

MR. TELFORD: This is currently required today, 35.2. So, here we are, asking you what you would do. We're asking you for your suggestion. You say 20 percent?

MR. RICCI: I would say 30 percent.

MR. TELFORD: Now we say 30 percent.

MR. STEFANAKOS: I still say that, even in this case, it should be up to the physician, if he feels there was a problem with an organ or another organ. Ask the physician in the back what she feels.

The point is if you have a physician who can make a determination as to whether you have 100 percent over-dosage, is that deleterious to the patient? Are our major concerns the patient's health and well-being or whether something has been done the way it was written?

MR. TELFORD: It's easy. If we could get some agreement as to what that percentage ought to be and some rationale behind it, then there wouldn't have to be a judgement call.

MR. STEFANAKOS: But why? The whole field of medicine is a judgement call. I mean it's not black-and-

white; it's not numbers. It's a whole judgement call. And I think we are really erring when we try to say you've got to put numbers on something, because that's not what medicine is. It's not pure numbers.

MR. TELFORD: Well, of course, what we're trying to do is ensure that the dose as prescribed is delivered.

MR. STEFANAKOS: Well, I think you hit the note earlier. You said it's easier to put numbers and find out somebody made a mistake, and that's not it. We shouldn't find the easy way out. We should find the best way out, be it numbers or what is right or wrong for that patient. And that's the problem with too many of these regulations, is they're easy way out and easy ways of making a quantitative or qualitative decision, rather than the right decision.

MR. TELFORD: Okay. I did say "easy." I was careful to say it that way because of the example that Darrel brought up, and your response was that, oh, nobody would ever do that. But maybe so, maybe not. It's much more clear to have a reporting requirement that is something like this.

MR. STEFANAKOS: Well, I'll guarantee you, the situation that Darrel said, there is going to be a higher authority that's going to be making a decision on that one, and that's called the court system, and that person is going to be shelling out a couple of shackles out of his pocket

for a decision like that, and that's where I think the equalizing factor comes in.

We have the AMA policing these people. We have the NRC policing these people. We have the court systems policing these people.

MR. TELFORD: You just put us out of business. You just said we're going to leave it up to the physician to determine --

MR. STEFANAKOS: To a point if something is deleterious.

MR. TELFORD: Where's the point?

MR. STEFANAKOS: The point is the total dose -- excuse me. The point is something between zero and the total dose. It's a physician's decision.

MR. TELFORD: Zero and 100 percent?

MR. STEFANAKOS: No, no, no. Zero and -- if the patient received the prescribed dose --

MR. TELFORD: We're on radiopharmaceutical therapy.

MR. STEFANAKOS: Okay. We're back to that.

MR. TELFORD: You pick one.

MR. STEFANAKOS: Okay. Even that one, if, in the opinion of the physician, especially in that one, because I don't think -- well, I shouldn't say that.

MR. TELFORD: The example that Rita brought up --

I mean that's a reasonable example. The physician sort of -- I hate to use the word "arbitrarily," but maybe it's sort of a standard dose that they would use in this case, 5 milicuries. Well, 6 are available. The physician says, okay, 6 is all right, use that. But if they had not revised their prescription prior to administering, by the current definition they have a misadministration, which argue for the fact that the 10 percent ought to be higher than it is.

MR. CLOUSE: Twenty percent, which would be greater 20 percent would have allowed the 6 milicuries.

MR. TELFORD: So, I suppose I'm just asking for a suggestion that -- where is the reasonable line? Where would you say that the threshold exists such that we have that -- gee, it's pretty substantially different from what we had in mind?

MR. STEFANAKOS: Okay. In teletherapy, I'd say 10 percent of the prescribed total dose.

MR. TELFORD: All right.

MR. STEFANAKOS: And the things in between should not be considered, in my opinion, other than the point that it's the physician's call to whether it's deleterious or not.

MR. TELFORD: Okay.

MR. CLOUSE: What about the radiopharmaceutical dose we just discussed? I think if we're talking 100

percent difference, that's real significant. I mean giving a patient 10 instead of 5 or 20 instead of 10.

MR. WERY: There again, you're getting into -- as I say, in that range, if you looked at the total dosage, you have a standard patient that you waltz around to every hospital in the country with the same clinical procedures --

MR. CLOUSE: Absolutely.

MR. WERY: -- you're going to have a range of doses that are prescribed, and that range probably wouldn't be terribly small.

We're not talking about what is technically achievable, because certainly, if we were talking about whether it's just technically achievable, our dose calibrators can, you know, give us within 10 percent of the dose that's prescribed without difficulty, and our calibration techniques for the teletherapy machines can give us within -- well, within 10 percent, probably down to 5 percent of the dose, of at least a standard kind of configuration.

You seem to be going beyond the technical -- what is technically capable of being given into the gray area of what is a reasonable medical kind of -- or a reasonable biological effect, reasonable medical kinds of things that are going in, and it's just very gray, and to put numbers on it -- for the teletherapy part, we agree that 5,000 rads in

one treatment is definitely something that shouldn't be done. On the other hand, if that was given over 5 weeks and you gave 220 rads the first treatment, instead of 200, I think most people would agree that's no problem there.

Unfortunately, you can probably go down to 4,000, and I can go up to maybe 240, but we're still far away where we're going to stop, and we become unsure as to where to get a number there, and as long as you're not just talking about the technical capability, and you seem to be going beyond that, I think it's very difficult to try to put numbers on these things.

MR. TELFORD: Well, you seem to be making some inference as to what we're trying to do here.

We've proposed some numbers, and we're asking you what you would change. For teletherapy, you've told us, and you've given us reasons.

MR. RICCI: For number 2, for instance, I would link up my choice of 30 percent error in dosage with the uncertainty with which the dose to any organ or to total burden, total body burden, is now, which is certainly a lot larger than 10 percent and probably even than 30 percent.

So, 30 percent is well justified because of the uncertainty with which the dose to the patient consequent to a certain particular activity is.

MR. TELFORD: Okay. Now, we're talking about

radiopharmaceutical therapy here.

MR. RICCI: Number 2.

MR. TELFORD: Yes. That's radiopharmaceutical therapy.

MR. RICCI: Right.

MR. TELFORD: Which might be I-131 or P-32.

MR. RICCI: Yes.

MR. TELFORD: Okay. So, tell me that again? You would say --

MR. RICCI: That 30 percent --

MR. TELFORD: -- that 30 percent --

MR. RICCI: Because that number is more in the line comparable with the uncertainty, which is larger than 30 percent, which is the dose to any particular organ or total body dose consequent to a certain radiopharmaceutical dosage. So, we know that does, with a large uncertainty, looking at amounts smaller than that uncertainty does not make a great deal of sense.

MR. TELFORD: Okay. So, your point is that if you give I-131, an effective dose to the thyroid could vary by at least 30 percent.

MR. RICCI: By even 100 percent or 200 percent, in that particular case. There are cases that are more favorable.

MR TELFORD: I'm pulling this out so we get it on

our record.

MR. RICCI: Sure.

MR. TELFORD: Okay.

MR. KLINE: John, let me bring up a question for everybody here; I guess more in line with the physics people in oncology.

On A3, what are your feelings -- on A3-II, what are your feelings on large dose administered over 2 or 3 fractions? What are your feelings on that?

MR. WERY: Obviously, it would be very hard, by the way the wording is, your percentage difference that you could have in any one fraction, if you're only giving 3 fractions, becomes vanishingly small, depending on the dose given, but much smaller. I think that's just another good description or a good reason to look at the overall scheme of what you're trying to do.

MR. RICCI: My feeling is that the size of the error, if we keep the purpose of the NRC that it is to try to avoid in the future, to improve things so that it doesn't occur, is immaterial. The same type of error can give place to 5 percent variance the same as 500 percent, and so, saying that the one that produces 500 percent error is more important insofar as preventing future events is felicitous.

MR. KLINE: But do you feel there is more significance, safety-wise, to the patient?

MR. RICCI: Once it's been delivered, it's been delivered. You can't do anything about it.

MR. TELFORD: Okay. How about number 5 and number 6 here? I'm sorry, 4 and 5, leaking brachytherapy sources and the threshold for brachytherapy administration being 20 percent different from what was prescribed.

Recognize that the proposal -- the current is 10 percent for brachytherapy. The proposal is 20 percent on brachytherapy.

MR. RICCI: That I would consider meaningful. The uncertainty with which the dose to any particular point is known can be fairly large, especially -- but not for the usual standard points, such as the A point for a standard intrauterine application, so that 20 percent can be significant.

Again, the input of the physicians for this kind of thing is very important, I would think, but from my point of view, from what I know, from the physics point of view, it relates well with the uncertainty with which the dose to critical organs is known from brachytherapy planning.

MR. TELFORD: Okay.

What do you say bout 4 and 5, Tom?

MR. STEFANAKOS: Well, 4 there is no question, I think. If you've got a leaky source, it's lost or it's unrecoverable. I mean that definitely should be reported.

There is no question in the world about that. Okay?

Five, I can see a situation where, as I brought out earlier, when split therapies are involved in intercapitary, there are many times that we deliver either 3,000 or 3,500 rads in two therapies. Okay? And it's dependent upon a number of things.

So, if you're in the first therapy and you exceed by 20, who's to say that's bad, when you're going to come back and give another 3,000 rads in 2 weeks' time anyways?

Okay. Now, there obviously is a limit.

MR. TELFORD: Is this a high-dose rate?

MR. STEFANAKOS: No, no. This is not. This is with cesium sources is what we're delivering with. Okay?

MR. TELFORD: Okay.

MR. STEFANAKOS: Now, there is a limit that -- I shouldn't say there is a limit. I can't give you the limit as to what the biological effect is over a period of time to the vaginal mucosa, the uterus, etcetera, and all that, as to what the hazard is. But what I'm saying is to put, again, an arbitrary number into something, when we're going to turn around and deliver another 2,000 or 3,000 rads to that same site with the same applicators, with the same sources --

MR. TELFORD: It would make sense.

MR. STEFANAKOS: Yes, 2 weeks or a week, but

usually it's about 2 weeks later or something like that. How can you say the first one was a misadministration?

MR. TELFORD: Well, okay. But you have a prescription that says deliver the 3,000. So, if you deliver a lot more than 3,000, then you would, at some point, say yes, that's not what was intended, that's substantially different; yes, that's a misadministration.

So, currently, we have 10 percent. We proposed 20 percent. Are you saying we should go higher?

MR. STEFANAKOS: I don't know. I can't give you the numb . because I don't have enough radiobiology information at my grasp to tell you what percentage is right or what percentage is wrong. Okay? I can't answer that.

MR. TELFORD: All right.

MR. RICCI: Well, then we would agree that the variance should be in excess, and one shouldn't consider the variance by defect less than --

MR. TELFORD: Less than?

MR. RICCI: Less than the prescribed dose. It says error of 20 percent in absolute value.

MR. TELFORD: Right.

MR. RICCI: Shouldn't it only be considered if it excess?

MR. TELFORD: Oh. Don't consider the under-doses.

MR. RICCI: Yes.

MR. TELFORD: Tom, what would you say about that? It's consistent with everything else.

MR. WERY: We are talking about the medical effects. We seem to be talking about the medical effects. Certainly, medical effects are their own size.

MR. RICCI: Except that the de facto dose can always be compensated by additional treatment.

MR. WERY: True.

MR. TELFORD: What that would allow, if I could interject something here, is if we have a prescription for brachytherapy and you're supposed to deliver the 3,000, but some error is made in calculation, and 1,500 is delivered, is that all right?

MR. STEFANAKOS: I'd have to say it's probably no problem.

MR. RICCI: To the NRC, it is not a problem so far as I'm concerned. The cure is a problem for the physician, and if he is notified immediately afterwards, as soon as it is known, I don't see what action could the NRC take.

Again, that error is of the same importance as any smaller error insofar as correcting for the future is concerned. So, the number would be arbitrary, no matter what, if you looked at it in that way.

MR. TELFORD: Well, this was a mistake that just so happened to give us an under-dose by that amount. What

if it had been an overdose by that amount? I mean just because the error in calculation --

MR. RICCI: What's the difference between a .1 percent or 3 percent error and a 20 or 35 percent error insofar as the mechanics of it all is concerned, are concerned?

MR. TELFORD: Well, you're focused --

MR. RICCI: On correcting it.

MR. TELFORD: -- on the different emphasis. I mean there's two ways to look at this. There is the magnitude of the difference, and then there's the fact that there's just any difference, that any mistake is made.

In this category of things for misadministrations, we are trying to capture things that are substantially different, and therefore, we're looking at the magnitude of the error.

MR. RICCI: May I ask you why you don't look at small errors and only large ones? The mechanics of their occurrence is the same.

MR. TELFORD: Because we have captured small errors someplace else.

MR. WERY: For brachytherapy, going back to Tom's scenario, where we're going to give a split course brachytherapy, a fairly common kind of thing, if we stop short or go long, in brachytherapy -- now, someone correct

me if I am wrong -- I think the physician can change the prescription. You say that they can change a prescription, and you don't put any timeframe on when you change that prescription. We talked about changing it after we get the isodose plan generated or whatever.

If, after the treatment or the first part of the treatment, it's discovered that the dose was off by more than 20 percent, in brachytherapy, you might -- and the physician agreed, because he would have to change the prescription, I think that that is one case where, after the event, the physician then could change the prescription to match whatever was given, and that may not be -- that may be allowed under what you have, so that --

MR. TELFORD: That sounds fishy to me.

MR. WERY: It sounds fishy in terms of -- you know, you know you can't do it for teletherapy after the fact as to what's given, but in brachytherapy, we're saying explicitly, at least in the reg guide, that you can change the prescription --

MR. WIEDEMAN: While the patient is still undergoing the therapy.

MR. WERY: It doesn't say that.

MR. WIEDEMAN: You can change the prescription after you -- you remove the sources, and the you're, oh, wait a minute, we were supposed to give the patient 3,500

and we gave him 4,500. Well, we'll just change the prescription to match 4,500? Is that what you're saying?

MR. STEFANAKOS: No. He's saying split dose if he's given less than that.

MR. WIEDEMAN: Okay. Well, if you say, okay, well, we -- you want to use a medical situation, where the patient couldn't tolerate the treatment or the patient removed the sources on their own?

MR. WERY: No. I'm just saying that in the case for brachytherapy, at least in the regulatory guide here, you are saying that the prescription can be changed after the therapy has started, at least.

MR. WIEDEMAN: Correct.

MR. WERY: At least when I just looked briefly now, I didn't see anything that says a time limit as to when that prescription can be changed, that that would allow the physician, if he did not think that there was a medical difference, to change the prescription post-hence.

Now, if he thought there was a difference, then he would not change the prescription, and you'd have a misadministration. But if he thought that there was not a medical difference -- we're going to give 6,000; I gave 2,500 this time, instead of 3,000, he says no problem, I'll give 3,500 next time, or vice versa, he could change the prescription at that point. And if you don't mean that,

then that's probably another thing to go back and put it in the reg guide, so that that's not allowed.

But in a split-course radiation therapy, you know, it's very, very common, again, from the medical view -- it's not related to errors or whatever. He may go into the idea that we're going to have give split-course; we're going to give 3,000 in two cases. If I get a very good distribution the first time, a lot of packing, and the bladder and rectum is very far away, historically, what I have found is physicians will say let's give a little bit more than 3,000 this time, because next time, I may not get as good a distribution inside the patient, and so, I'll change it, and he will write the prescription in that form, but I'm saying that that is perfectly consistent with clinical practice, not to -- that 3,000 plus 3,000 does not mean that that means anything; it can be 4,000 and 2,000 or something.

MR. TELFORD: I'd like to propose about 20 percent. What do you say?

MR. STEFANAKOS: I'd like to really digress now and ask you a question. What is the charge of the NRC?

MR. TELFORD: Charge? Oh, adequate safety. Sharon said of adequate public health and safety.

MR. STEFANAKOS: Sharon said of adequate public health and safety, okay.

MR. TELFORD: That's my job.

MR. STEFANAKOS: Where does it say in there that you should determine that safety involves the practice of medicine or the prescription of medicine for something that has not been exceeded, and I'm talking about under dosages, now, not overdosages.

There's no question, in my opinion, that you have every legitimate and legal right to say when somebody is overdosed that they have violated their safety. But to turn around and say that somebody who has received less than what the total dose was prescribed, and that can be made up, that that's an error or a hazard to that person's safety.

MR. KLINE: I guess part of the question is what if it is not --

MR. STEFANAKOS: What is that?

MR. KLINE: What if it's not made up? What if it goes undetected for a long time?

MR. RICCI: Again, it's not an excess.

MR. STEFANAKOS: How long is a long time? We have TFDs that we can calculate and come back and give. We get people that's breaking up their therapy all the time, because they want to go on vacation, they get tired of coming in, and they'll come in a month or two or three months later and say, hey, I'm truly having a lot of pain now, I was really stupid to stop my therapy, I want to start again.

So we have to go back and recalculate the TFD, the time fractional dose, to determine how many additional treatments we have to give that patient to make-up for that break period. That's what I'm saying. And you tell me how long afterwards. I can wait a year and start that up again, and people argue on both sides that it doesn't make any difference.

MR. KLINE: Well, now we're getting back into clinical practice.

MR. STEFANAKOS: Ah, my point exactly. My point exactly.

MR. KLINE: Actually, it's my point now.

MR. STEFANAKOS: You are trying to practice medicine when you're doing that. I have given you the fact that over the prescribed the dose, you're absolutely right, you should do it and there's no question about that. But anything less than a prescribed dose should be a physician's call and only a physician's call.

MR. TELFORD: Well, let me acknowledge, as I think we did when we went through when we were talking about teletherapy, that you made a point on the fractions. You did make a relatively small mistake on the rule of fractions to compensate at a later time.

We have this kind of nagging fear that this kind of an underdose by a large amount because of a mistake in

calculation. Next time it's a mistake but it's an overdose by a large amount just because you've swallowed the change in calculation. So, if we're looking at a large number of licensees, looking at a large number of possible potential mistakes that could occur on both sides of overdoses, not as underdoses.

We have this logical problem, and it seems to us that we should be looking at the underdoses as well as the overdoses, because it was the underdose this time and we were lucky, but next time maybe not so lucky.

MR. STEFANAKOS: But you have that covered by the overdose.

MR. TELFORD: We do?

MR. STEFANAKOS: Sure you do. You have the covered fact that if it exceeds 10 percent --

MR. TELFORD: Oh, you mean the next time?

MR. STEFANAKOS: Yes. I mean, you have something in line.

MR. TELFORD: Oh, okay.

MR. STEFANAKOS: But let me ask you a basic question, too.

MR. TELFORD: That's true.

MR. STEFANAKOS: Do you trust the physicians that are running these programs? Do you trust the physicians that are the users?

MR. TELFORD: The authorized users?

MR. STEFANAKOS: Yes.

MR. TELFORD: We give them the responsibility --

MR. STEFANAKOS: That's not what I asked you. I asked you if you trusted them. It's a very basic point. It's a very basic point.

MR. CAMPER: It's not our place to trust them, it's not our place to encroach their practice of medicine. Our place is to review their training and experience and give them the authority to possess these radioactive materials. That doesn't imply that we trust what they will do.

MR. STEFANAKOS: I don't mean trusting what they would do, I mean trusting in a sense that if they see they made a mistake, they would come up and say I made a mistake.

MR. RICCI: Not necessarily.

MR. CAMPER: I don't think we need a basis for knowing that.

MR. STEFANAKOS: Well, you do when you refuse to say leave it up to the discretion of the physician.

MR. CAMPER: No, we can only expect a physician to say something to us about a statement they might make as it relates to our regulatory criteria. Beyond that, we have no basis for any such expectations.

MR. RICCI: Right.

MR. STEFANAKOS: Okay, but you are still practicing medicine when you're telling the physician if he underdoses somebody that he's wrong and that it should be reported and logged by the NRC. That's practice of medicine, without a question.

MR. WERY: You're not saying necessarily that wrong, you're just saying that's has to be reported.

MR. TELFORD: Yes.

MR. CLOUSE: Thomas, suppose you go to the pharmacy, your doctor gave you a prescription, he wanted to you take a certain antibiotic 3 times a day for 10 days, but the pharmacist writes down he wants you to take 4 a day for 7 days. Now, is that his right? I mean, he wasn't off by that much. I mean, is that going to affect whether you're going to well or not? I mean, does that have an affect on it?

MR. STEFANAKOS: Yes, but it goes back to the physician who made the prescription, and he's going to make that determination and say, hey -- if I saw that, I would go back to my physician and say, hey, look, he gave me 4 for 7, you told me 3 for 10.

MR. CLOUSE: No, no, suppose you don't notice that, you don't notice that until after the fact and you go back to your physician. Now he has the right to say, oh, that's all right, it's not much difference.

MR. STEFANAKOS: Now wait a minute. You're taking it out of the wrong thing again. You're taking total dose, not fractional dose. We have already conceded that total dose, if it is exceeded, than that's definitely a misadministration.

MR. CLOUSE: Oh, no, because this wasn't exceeded, because you took 4 a day for 7 days. So you actually were 2 under.

MR. STEFANAKOS: No, no -- that's right, it's underdosed or undertreated by this prescription, and you go back to the physician and you say, is that all right? And he says, yes, that's not bad, that's okay. And that's exactly what I'm saying.

MR. CLOUSE: Okay, but you're saying that's not right if that pharmacist did that. He made a mistake. But you're saying well, the physician said that's okay so that doesn't matter.

MR. STEFANAKOS: So, what's wrong with that if it didn't affect the patient? What is wrong?

MR. CLOUSE: That's what I'm saying, it didn't. What about next time? What if the pharmacist says 5 a day for 3 days? I mean, what they're trying to do is prevent this from happening.

MR. STEFANAKOS: No, wait a minute. You're missing something very important here. That physician would

go back to that pharmacist and say, hey, look, Jake, you best start putting out what I tell you to put out or I'm sending my patients to another pharmacy. That's a correction and that's exactly what I'm saying here.

If the authorized user finds out that there is a mistake in the fractionation, he's going to go to that technologist and he's going to tell that technologist, look, you made this mistake, let's not make them again because we're going to have to take action. Same thing.

MR. CLOUSE: Well, I get the impression that there's something more than meets the eye. I mean, we have people here that don't agree with what's said, but not nearly as adamantly as you do. I mean, are you lobbying for your physicians or are you --

MR. STEFANAKOS: No, I'm trying to get my point across and I think the people are saying the same thing. I think Ray is saying the same thing. I think Alessandro is saying the same thing. If I'm wrong, tell me. Do you agree with me or not that an underdose is --

MR. RICCI: Well, at this point I don't know what to agree with.

MR. TELFORD: Rita wants to say something.

MS. DUFFY: Well, I would just say I think we're losing the concept that I don't think that we're practicing medicine and the fact that we are technically protecting the

user in this rule in that they have a 10 percent leeway and it's a technical area what they're trying to correct.

MR. CLOUSE: Exactly, a technical area.

MS. DUFFY: I mean, they're not trying to tell the physician or the authorized user because he is the one that is writing the prescription. They're just saying, you have a limit of 10 percent. Now he has the ability to change that prescription.

MR. STEFANAKOS: Well, they just said that you can't do that.

MS. DUFFY: They're giving the technician --

MR. STEFANAKOS: No, no, they said you can't do that after the fact. They said you cannot change that prescription after the dose has been delivered. You cannot change that prescription. That is now a misadministration.

MR. WERY: Teletherapy.

MR. STEFANAKOS: Right, strictly teletheraphy. They've already said that that's a misadministration. Nobody has anything else to say about it. I don't think it's their call.

MR. RICCI: No, no, the physicians can change the prescription over what anybody else says.

MR. STEFANAKOS: That's not what they said. That's not what the regs said.

MR. RICCI: It doesn't matter. They can and they

will, and if they change the prescription and they write, now you give this patient this much and everything will be fine, that will be fine. And at this point, if the NRC intervenes and says, well that previous prescription was out given by 20 percent and so I want to know, they can do it. And they will find studies for what the reasons for the errors may be, but I don't see what that will achieve.

MR. STEFANAKOS: Darrel, do you agree with that, that that is not a misadministration?

MR. TELFORD: Let me give you an example, Tom.

MR. STEFANAKOS: No, let Darrel, because that's --

MR. TELFORD: No, let me give you an example and then we can have the opinion, but I think we need something to focus on because I don't really understand what you're asking.

We have a patient that's supposed to get 5000 rads and 25 fractions. Now, let's use the 10 percent overdose, So we've got 500 rads to play with here. At what point are you talking about changing the prescription? Because if we're at the 20th fraction, the physician says, that's enough, we're going to stop. He revises the prescription and says stop. No problem.

But if the 25th fraction has been given and it turns out that it's 6000 rads, not 5000, then do you think it's right that the physician can go back and say, well,

it's only off by 1000 rads extra, I'll just revise my prescription and everything's all right. Well, of course that's a misadministration.

MR. STEFANAKOS: First of all, I have never said changing the prescription is the way to do it. That was Alessandro.

MR. RICCI: No, it's not me.

MR. STEFANAKOS: I never once said change the prescription. I'm saying if the thing was changed, if the things was short, the physician doesn't change his prescription, he could just state --

MR. TELFORD: Oh, it's under.

MR. STEFANAKOS: It's a comment saying, that's right, I've already given you the 10 percent over. I've conceded that 45 minutes ago. Yet we keep coming back to that. I'm talking about any dosage less than the prescribed total dose.

MR. TELFORD: Okay, let's change the example then. It's 5000 --

MR. RICCI: Well first of all, I would advise Thomas not to put words in my mouth. I can speak for myself.

MR. STEFANAKOS: Well, I'm including what you said, so he took yours in mind. Go ahead, John.

MR. TELFORD: Okay. 5000 rads is the total

prescribed dose, 25 fractions, 200 rads each fraction. But his time, all fractions have been given, but the patient only got 4000 rads.

MR. STEFANAKOS: Okay.

MR. TELFORD: Now, shouldn't the physician be able to go back and after the fact change the prescription and say, I really intended to give 4000, therefore, it's not a misadministration. Is that what you want to allow?

MR. STEFANAKOS: Okay, no, absolutely not. But I think it's a moot point, because he should come back and say, hey, we only gave 4000, let's give another 5 treatments, and then we're at 5000 where we're supposed to be. And he puts a note in the chart saying patient, as we do whenever I find a mistake in calculations on my checks, I make the calculation. And let's say the patient was supposed to get 200 rads per fraction, and it comes out at 100 or 210 rads and they did it for 2 fractions. I say, okay, the patient has now received 20 rads in excess in 2 fractions.

I make the determination along with - or I should say I make the determination, I go to the user and I say, we've got 2 20-rads excess out of 5000 that we're going to treat total. In my opinion, I don't think we should have to worry about making that up. What do you think? He says, right, that's fine. I go back to the chart and I write,

tech used tray factor, delivered 210 rads per RX for 2 RXs or 20 rads in excess of prescribed dose, not significant, don't change chart, and initial it.

Now, I don't see anything wrong with that, or the other way, if it's underdosed, the physician comes back and says, hey, we didn't treat everything we were supposed to treat. I can go in there and we'll give another 5 treatments. That's not a misadministration, that's not an overdose, that's not an underdose. But by your definition, it is.

MR. TELFORD: Well, not yet. You'd have to exceed the 10 percent of total.

MR. STEFANAKOS: Well, I'm talking about 10 percent of total. Okay, let's make it 3999.

MR. TELFORD: Instead of 200 rads for the fraction, make it 150 per day per fraction.

MR. STEFANAKOS: Okay.

MR. TELFORD: And you're saying you would catch that along the way? But what if you didn't?

MR. STEFANAKOS: I'm saying at the end, whatever point you find out that you have underdosed a patient -- we're strictly talking underdosage -- the physician can come back and correct that as he sees fit because he has not done anything detrimental to the patient.

And again, there are so many varied dosages and

delivered prescriptions to the same site throughout this country that make your head spin. There are so many different times in the city of Cleveland that they differ in what -- I've seen dosages of 160 up to 250 to the same site differing. Who's right and who's wrong? Nobody. That's their personal call. And when you come back after the fact and say, somebody who has delivered less than what he prescribed is wrong when he can make it up, is wrong.

MR. TELFORD: You're saying that ought to be allowed?

MR. STEFANAKOS: Absolutely.

MR. TELFORD: Okay.

MR. STEFANAKOS: No question.

MR. TELFORD: We understand that point.

MR. KLINE: Let's assume -- let's go with that underdose scenario. Let me just propose to people here, what would you feel would be a limit or if you were to say how much less than the total prescribed dose? Say if you had a patient who was to get 2000 and say they only got 800. What would be your idea of what limit on how much you can underdose a patient?

MR. RICCI: Are you asking us to play physicians?

MR. STEFANAKOS: Yeah, right.

MR. KLINE: No, I think I'm looking at numbers. I'm just putting it up in the air.

MR. WERY: I think as long as the physician is willing to stop the treatment at that point --

MR. STEFANAKOS: Or continue it.

MR. WERY: Or continue it. I mean, you have to have a physician make that decision. You can't have the tech not show anyone and just file the chart away. But as long as the physician at that point is making the decision, should we continue to give treatments or should we stop here? I don't see that that's any different than his decision at during a weekly review of the patient or weekly examination or he determines should we stop. Basically, every week he's determining should we stop here or should we continue going on?

Now, of course, if you have a physician that is not as ethical as he might be expected, he may take into account the appearance that there was an error made, that the patient will know and ask embarrassing questions or whatever for the additional treatments. But I think we would hope that most physicians would have the ethical responsibility if they really thought there was a difference in outcome for a patient to be able to make the -- go in and say to the patient, we have changed our plan here, we are going to be giving you an additional amount of radiation that will complete your plan of treatment and will get you to the point where we want you to be that we think will get

the maximum effect for this radiation.

MR. TELFORD: Okay. Can somebody make a suggestion on number 5 on brachytheraphy? Now this includes the high dose rate. Is 20 percent something you would consider to be substantially different?

MR. RICCI: Well, my suggestion then is for regular administration for larger than 20 percent excess error.

MR. TELFORD: Rather than 20 percent overdose? Okay. Well, let's see if we can sum up 35.34. Taking this overall, does anybody else want to offer any suggestions?

We have the same remaining parts as we had in 35.33. We have the RSO taking the appropriate action of investigating the record. We have the four -- if we retain that, or the events which were misadministrations and the report going to the NRC, and the follow-up telephone call -- the report gave the same -- periods of three years for prescription of the regular dose and 10 years for -- of the events or the misadministrations.

So I would assume on -- on F that you would -- comment you made before on 35.33 would apply here. Any other suggestions on these parts?

[No response.]

MR. TELFORD: Okay. Let's -- let's try to take all of 35.34 then. Any suggestions on that?

[No response.]

MR. TELFORD: Let's take a break for say 15 minutes and then come back and you can have individual --

[Brief recess.]

MR. TELFORD: Okay, let's go back on the record.

Okay, we've come to the point on the agenda where we're going to allow the volunteers to have their final say. So, let's see. Where did I start first last time? We started first over here last time, so why don't we start first over here with Bill.

MR. ERICKSON: I don't really have any comments, remembering that specifically, I'm working with diagnostic medicine and radioisotope therapy. I'm very satisfied with the conversations that we've had in those areas. I don't think there will be in any problem with our institution adopting the proposed rule, with some minor modifications that we may have spoken about.

And once again, I appreciate the opportunity to give input into this rule.

MR. TELFORD: Okay, Richard?

MR. CLOUSE: As Bill says, I appreciate the opportunity to offer my input.

I -- I believe that perhaps some of the input we had as to the threshold levels, perhaps 20 percent is a more reasonable number -- whatever we consider reasonable, for

some of the thresholds than 10 percent. However, I think we've deviated from the main intent of this whole proposal, and that was to help prevent mistakes, not to tell a physician how to practice medicine.

I believe what we're looking at is not whether the physician in brachytherapy, teletherapy or whatever, is prescribing something, but the fact that the technical person who's administering that is varying from that dose. And I believe that the physician wrote that prescription with something in mind. If he wanted -- if he didn't want that given, then he would have written something else. And I think if we vary significantly from that point, then that becomes an incident. I think we kind of got off the track there, as to what the whole intent was.

MR. TELFORD: Okay, Rita?

MS. DUFFY: I think that the proposed rule and the changes that we have suggested is a very good rule in helping us to practice better medicine and practice better therapy in nuclear medicine as such, and that sometimes in our numbers and our calculations, we forget the human element of what we're doing here. And I think it's a good opportunity for us to hash these things out and get down to the basic realism of what -- where our intent is. And I think it's a good intent.

MR. TELFORD: Okay, Thomas.

MR. STEFANAKOS: I think that the NRC should go one step further than from this meeting and somehow devise some kind of a forum that their inspectors, when they're going out to the field, can kind of make a check on the licenses that there be -- or that are being inspected at the time, to see how many of these things are really being done by the institutions at this time, prior to the enactment of this reg. and go from there and make sure that an equal number of broad-scope licenses, as well as specific licenses are included in that because they're the ones that are going to really be hammered by this thing; with all the various and sundry isotopes and so forth that they're using.

And I think that in conjunction with what is carried on in these discussions, should go a long way in how the regs should be written. Because they should have an input, or at least, you can see what's happening.

I think that this is a very select group that you have, and I hope it's not a misrepresented group in the field.

MR. TELFORD: That's all?

MR. STEFANAKOS: Yes.

MR. TELFORD: Tracy?

MS. KING: I don't really have any additional comments. My perspective is just nuclear medicine -- I don't see where it will be that much more of an imposition

on most facilities, provided that leeway is given to licensee or individual facilities that don't match the general requirements.

MR. WERY: I really don't have any additional comments that I haven't done already, so. I'll just stop.

MR. TELFORD: Okay. Ed, is there anything?

MR. KLINE: I appreciate every input, the candidness and also the participation. On site, I know it is an impact when you're being visited by people and you have to stop your activities and go out of your way to answer questions. It's been very helpful that we have evolved to this point where we openness with a Government agency and the medical community -- and it ought to be a landmark.k And I think the people ought to realize that everybody may be in some way a co-author of any -- whether it be good or bad, as you interpret it -- what comes out of this -- whether you're going to put it on your publications' list is a different story.

But everybodies' input will be looked at, as indicated and viewed accordingly.

MR. TELFORD: Darrell?

MR. WIEDEMAN: I just want to say, on behalf of the site team members, I want to thank every one of you that -- we went out to the site. And we know it was a great imposition and we appreciate your time and effort. And

especially today -- all volunteers. I appreciate your comments and we -- we will definitely review your comments and try to incorporate those in the rule change and the reg. guide.

Once again, thank you.

MR. TELFORD: Tony?

MR. TSE: I appreciate your giving us your views. This is not the end of our conversation. If you have some -- anything later, if you feel you want to talk to us, please give me a call, because you have my number.

Thank you for coming.

MR. TELFORD: Larry?

MR. CAMPER: This is a difficult area for us as a regulatory agency to deal with. We are making a concerted effort to interact with the medical community that we regulate, to seek the greatest amount of input possible from individual institutions, individual practitioners, and professional organizations.

You all have been a very important part of that. And we appreciate that input and we thank you for taking the time to participate in the pilot program, to give us your views. And we certainly appreciate all your efforts. Thank you.

MR. TELFORD: Charles?

MR. LEE: I think that, as part of the medical

community, I have to appreciate the NRC and their thoughts of coming out through the community and asking for our input. As far as our hospital is concerned, we are state licensed, but -- what NRC does falls back to us. During our period of time that we've participated, during these 60 days, we felt like we were doing a good job. I know there are some things that we could do better. And I think that with some modifications in the program it shouldn't be too hard to work on.

MR. TELFORD: Okay, Judy?

MS. BASTIAN: As far as 35.35, I think that -- a term we're familiar with by this time. But, I'm comfortable with that. And we found some real good, you know, points in the objectives. I think 33 and 34 are going -- are complicated and time consuming, compared to what we were dealing with before.

MR. TELFORD: Okay.

MS. BASTIAN: I think that will be -- will take more time and effort, as far as now identifying the lesser significant things, such as the events.

Well, one thing that I -- I just wanted to ask a question about -- how we would monitor whether the physician had actually reviewed the case. Is this something that is expected to be documented? And I'm speaking of radiopharmaceutical therapy, where the user talks to the

attending physician and makes a -- writes a prescription and it's saying that we will call it a misadministration if they do not review the case. How are we going to know?

MR. TELFORD: Is that an event?

MS. BASTIAN: No. That's a misadministration.

MR. TELFORD: Is that under Part A?

MS. BASTIAN: Well, maybe -- it's under Part A.

MR. TELFORD: A?

MS. BASTIAN: That's called an event.

MR. TELFORD: A -- A's are events.

MS. BASTIAN: Okay. But by the same fact, this still would need to be identified.

MR. TELFORD: Okay. Anything else? Robin?

MS. SCHAEFER: I think, as everyone is pretty well agreeable, this isn't going to be a real burden to what most people already had in place. And as always the soapbox person, I think we ought to sit back and remember that they're not doing this to be a burden. The NRC's not doing this to be a burden on medical facilities; they're not doing it to regulate physicians. They're doing it to protect the general public. And we are the general public, although we are a part of the medical community.

I think as long as we all remember that, they're not doing this just to be a burden, there's a regressed baseline here that they're trying to do and protect people -

- that we're taking care of it. I think that's why we all went into this field. Obviously it wasn't for the money. So, I think as long as we sit back and remember why we're doing this, we're all going to make this work just fine.

MR. TELFORD: Okay, Dr. Ricci?

MR. RICCI: I don't have any additional comments to make on specific issues. I am grateful for the opportunity of expressing my opinions and I've become more aware of the issue conflicts that are present in any kind of regulation. That's it.

MR. TELFORD: Robert?

MR. LAWALAN: I can only echo what Bill has said earlier. Coming from a small hospital where we do just diagnostic work, and a lot of this stuff, definitely -- but from what we've discussed, along with the diagnostic issues, there's no problem. And there seems to be pretty much stuff that's -- you have already done and it's not going take that much more effort.

And I do appreciate the opportunity to go ahead and take part in this, and get a good understanding of it as it's happening.

MR. TELFORD: Okay.

Well, I'm going to thank you one last time for your participation. Let's end the record -- to off the record.

[Whereupon, at 2:38 o'clock p.m. the meeting was adjourned.]

REPORTER'S CERTIFICATE

This is to certify that the attached proceedings before the United States Nuclear Regulatory Commission

in the matter of:

NAME OF PROCEEDING: Quality Assurance Workshop

DOCKET NUMBER:

PLACE OF PROCEEDING: Rosemont, Illinois

were held as herein appears, and that this is the original transcript thereof for the file of the United States Nuclear Regulatory Commission taken by me and thereafter reduced to typewriting by me or under the direction of the court reporting company, and that the transcript is a true and accurate record of the foregoing proceedings.

Ronald N. LeGrand

Official Reporter
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