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U. S. NUCLEAR REGULATORY COMMISSION

In the Matter of:

QUALITY ASSURANCE WORKSHOP

Room London, Cluster 3
Marriott Marquis Hotel
Atlanta, Georgia
Friday, September 7, 1990

The above-entitled matter convened at 9:00 a.m.

ATTENDEES:

On behalf of the Nuclear Regulatory Commission:

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ANTHONY TSE
DARREL WIEDEMAN
LARRY CAMPER

On behalf of Brookhaven National Laboratory:

EDWARD KAPLAN

On behalf of Pilot Program Participants:

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JERRY MORRIS	ROY LANDERS	SARAH KIRTLAND
LORI HANLEY	TOM CLARK	TONY PULCRANO
THOMAS A. WHITE	SURESH ARGAWAL	DAVID GARRISON
KENNETH FRYMAN		

I N D E X

PROCEEDINGS

MR. TELFORD: Good morning. Welcome to the Friday session of our workshop. Today, we're going to talk about the reporting requirements. I'm going to hear from you on your suggestions of whether you would delete, modify or retain the reporting requirements. Let me call your attention to the fact that we are going break these up. First of all the proposed 35.33 which covers diagnostics and then 35.34 which covers therapy.

Now, while we're covering the diagnostics, I'll put up a view graph that's got the current requirements on it just so you'll realize what's currently in 35.2. The theme here is that overall objective is to have things reported to the NRC which are substantially different from what they were supposed to be. You know, important kind of things. Now, I'll have to admit to you the strategy that we were trying to use when we -- in fact, were using when we wrote the proposed reporting requirements. Don't feel bad about not liking those if you don't like them. But the theme here is to keep in mind that I would like you to help us to determine what's a dose that's substantially different from what was prescribed. Please keep that in mind. And for each of the sections of the reporting requirements, including record keeping, I'll be asking you if you want to delete, modify or retain.

Now, for the NRC licensees, I'm sure you're familiar with 35.2 requirements. For agreement state licensees, as of, I believe, April 1st of this year, agreement states are now, for the first time, required to report misadministrations according to this definition. It basically says that if you make one of these six mistakes, you have a misadministration.

The first one is the wrong source and the second one is wrong patient. The third one is the wrong route. The fourth on is a radiopharmaceutical diagnostic test in which you've got a -- the administered dose is 50 percent different from what was prescribed -- if you will allow me to use that word. The fifth one is, you know, the therapy, radiopharmaceutical therapy in which the administered dose is ten percent different from what was prescribed. And the sixth one currently captures both teletherapy and brachytherapy and says that if the administered dose is ten percent different from the prescribed dose, then you have a misadministration.

In 35.33, we have certain paragraphs. Let me give you a quick overview so you can tell sort of where everything fits. The A type section is things we call events. The B section is for misadministrations. The C is what actions shall be taken by a particular person. D is a notification if certain thresholds are exceeded. This is a

notification as well as a report. E are records retained; requirements for records to be kept. So that's how everything fits together. Now, let me say that the words that I have on the viewgraph necessarily have to be concise and therefore cryptic. So for the exact words you have to look in your handout for what's in the Federal Register notice, otherwise, you may get upset about some of these words, when in fact, they'll -- while the requirement is not stated exactly up here, so you'll have to look through the Federal Register notice to see the exact requirements.

So, let's take the A section first. Now, you will notice, first of all, we've got this new thing here, an event. We currently have misadministration, but now, we have events. Okay, I've got to confess. Here was our approach. We said, what if we could allow the licensee to have a feedback loop for things that happened that weren't necessarily as -- or probably were not as important as misadministrations. So you'll discover that the events only get reported back to the licensee. So, it's an internal loop. The thought was, if the licensee is finding out about a lot of little things, they could make up their own mind that this is a problem that needs a solution or not.

Okay, so what we have here -- this is a use of a material that you don't have in your license and that could occur sometimes. This is a -- we say diagnostic use. When

this was a diagnostic test that neither had a prescription nor a referral.

Three is a diagnostic administration where the amount was not -- the amount of the dosage or dose was not recorded.

Now, your thoughts. What do we do with this? Do we delete, modify or retain?

MR. GARRISON: It seems fair.

MR. TELFORD: It seems vaguely useful if you find out about -- Jean, what do you think?

MS. RHODES: It seems all right.

MR. TELFORD: What if this were a requirement for your hospital?

MS. RHODES: I think it would be fine.

MR. TELFORD: Okay.

What if we kind of looked ahead a little bit and if we have -- I'm sorry, A event, that's the events. What if we said, if you had one of these happen, your RSO has to investigate what happened and make a record of it -- that requires a little work, and that the record is what would go back to the licensee? Of course, here, we said licensee management, but you folks have already told me that you don't like that phrase. So, we could -- in our discussion, we could substitute something like department chairman or QA committee, or all of the above.

MS. RHODES: Okay, now, A is requiring a record or report. Who does that report go to?

MR. TELFORD: The QA committee, licensee -- we said licensee management, but you can interpret that as --

MS. RHODES: Whatever, within your own organization?

MR. TELFORD: That's right.

MS. RHODES: Yes, I think that's okay.

MR. TELFORD: Sarah.

LT. KIRTLAND: Okay, since I'm hearing everybody say how fair it is, I've decided I have to -- I think it -- to me, it gives the NRC an enormous amount of power and it creates a lot of work for the radiation safety officer, and I think unnecessarily.

MR. TELFORD: Okay, good.

MS. RHODES: But how often would this be a factor?

LT. KIRTLAND: Say again?

MS. RHODES: But how often would this be a factor?

LT. KIRTLAND: Supposing you can't find -- supposing any diagnostic use without prescription or referral, the way they -- the NRC usually interprets that, you've got to have something written, otherwise, you don't have any evidence that it happened.

MR. TELFORD: Well, you made -- this group made some very good suggestions yesterday for referrals. Let's

keep those in mind. Let me see if I can remember them. We might have three alternatives for a referral. So that's a written referral. There was one case of using an oral referral with telephone logs and another was an oral referral with the authorized user signing off prior to the administration of -- so the record you might be looking for here would be -- in one case, a written referral. In another case, the sign off by the authorized user and in the third case, the sign off by the technologists saying that they administered what they were supposed to according to both the telephone log and the procedures manual. But you're right, there's some record someplace of what a person is supposed to do. So, are you thinking those might get lost or...

LT. KIRTLAND: Well, I'm wondering if that's the most important thing to keep from the patient's record.

MR. TELFORD: Well see, this one -- number two, is what is supposed to happen and number three is what did happen. Now, I think, if I'm hearing your message, what you're really saying is, okay, that's good stuff to have but is it important enough to cause somebody like the RSO to go investigate and make a record of what the heck went wrong. You're probably anticipating that that may be a fair amount of work if some percentage of your records were either lost or not easily available or apparently lost or something.

LT. KIRTLAND: I mean, our RSO -- we have two permits, therapy and nuclear medicine, while we have one RSO. So he covers both licenses and that really gives him a lot of responsibility. He's a therapy physicist, so his -- although he knows nuclear medicine, it's not where he spends every day. So it's taking time out of what he -- or what his normal duties are to go over to nuclear medicine to make sure things like that are tracked.

MR. TELFORD: David.

MR. GARRISON: I don't see how you can do a patient without meeting all of these requirements. I don't see how you would ever have anything to write down. You have to be licensed to do a particular study. Somebody has to call in and say they want it done. I don't know about anywhere else, but our physician can't interpret the results without the dose.

MR. TELFORD: Okay, somebody else? Stan?

MR. GIPSON: I can see the point he's making there. I'm trying to think of a situation at our institution where we would go through this sequence to have an event reported. You would have the request -- referral, I guess, you would say, or a request generated by say the floor or the out-patient department. It is part of our procedure that the radiologist, when he is interpreting an exam, interpreting the films, he's got the worksheet and

he's got all the data on that particular patient. It sounds good but I just can't think of when we would come up with any of those situations.

MR. TELFORD: Well, if it came up. Let's ask Sarah's question a little bit more pointedly. If it came up, is it worth this to you? This is -- the strategy here was, we want an internal feedback loop, such that you would know when things are happening that should not be happening. A couple of you have already said, we've got to do these things to treat a patient. So assume that something here didn't happen. Is that something you want to know about?

MS. RHODES: Well, I just realized that in our organization, things like this would already be reported in an incident report.

MR. TELFORD: To whom?

MS. RHODES: When you fill out an incident report, they come to me and then I start an investigation. I go back to the department heads and the people involved.

MR. TELFORD: This is an internal incident report then.

MS. RHODES: Yes.

MR. TELFORD: Okay.

MS. RHODES: It's part of our quality assurance.

MR. TELFORD: Okay.

MS. RHODES: Not just for radiologists but for the

entire hospital, anything unusual that happens.

MR. TELFORD: Okay, Roy.

MR. LANDERS: I just wonder why you specifically state the radiation safety officer instead of allowing alternatives.

MR. TELFORD: Oh. Please, give me an alternative.

MR. LANDERS: A designee of the licensee.

MR. TELFORD: Okay.

MR. LANDERS: Also, if -- this is out of my realm, but if a diagnostic test is administered, the dose was measured but not recorded, the test was done. Somebody jumps on the --

MR. TELFORD: What did you put in your dose calibrator, Roy?

MR. LANDERS: Okay, it was done. It just wasn't recorded.

MR. TELFORD: Oh, it wasn't recorded there?

MR. LANDERS: Right. The person remembers it later, is jumped on and writes it down. Is that reportable?

MR. TELFORD: Reportable to whom?

MR. LANDERS: Exactly. Somebody jumped on them, so it was reported.

MR. TELFORD: If you -- your technologist measured the dose in the dose calibrator but forgot to log it in, it was right but they just forgot to log it in; so, whoever

this person is would be responsible for making a record of that and telling our licensee management entity of it. So, that's to whom the report would go.

MR. LANDERS: Right. I -- I don't know how frequently something of that simple a nature occurs but I think that's a little bit onerous to require a report to be written and held for NRC review. Something along those lines. I like your wording up here better than the wording in the text here where you say i.e. investigate and record.

MR. TELFORD: What does it say there?

MR. LANDERS: It's very specific. "For any diagnostic medical use that results in an A or B event. The RSO shall promptly investigate its cause, make a record for NRC review, retain the records as directed in paragraph" so on and so forth. "Notify the licensee management to take appropriate corrective actions."

MR. TELFORD: Okay.

MR. LANDERS: That seems like an awful lot to do for the event I just described.

MR. TELFORD: Okay.

Jean, you said you're already doing this in your hospital?

MS. RHODES: Yeah, because it would be an unusual event.

MR. TELFORD: Okay. Do you do it more simply or

somehow in an easier way than this apparently looks?

MS. RHODES: Well, the policies that we have don't relate specifically to nuclear medicine or radiation therapy. It's a hospital-wide policy that says all unusual events will be reported.

MR. TELFORD: But cover things like A events?

MS. RHODES: Sure. That would be unusual if we did a diagnostic test that we weren't licensed to do or if we did something without a prescription or a referral. I mean, we just sort of did it. That would be unusual.

MR. TELFORD: Okay.

Ashok, do you have anything like this?

MR. DESAI: Yeah, we sure do. But I think it's going to create a tremendous amount of paperwork for the RSO. I have a problem with A(1) because it says any diagnostic use, not authorizing the license. Using an example that is not approved for oral administration. In other words, every time a physician uses oral administration or during a brain scan using FMPO other than stroke that is not approved by FDA, then the RSO is going to make no addition in reporting all of those incidents.

MR. TELFORD: Now this is -- you're saying these use are not in the package insert?

MR. DESAI: No.

MR. TELFORD: Okay.

MR. WIEDEMAN: If I remember, John, that's --

MR. TELFORD: That's under 35.300. It says you must follow the package insert.

MR. DESAI: That's correct.

MR. TELFORD: Okay.

MR. DESAI: It's not in there that you will follow their A(1).

MR. TELFORD: What do you say, Darrel?

MR. WIEDEMAN: If I remember right, number one, the package insert for sulphur colloids, says something to the effect that if taken orally, it will not absorb through the gastrointestinal tract. It says something to that effect.

MR. TELFORD: Right.

MR. WIEDEMAN: To me, that implies that if you wanted to give it orally -- and besides, if I remember right, the new requirements for part 35 that was just recently approved, states that if the physician wants to administer a dose that's not described in the package insert, all he has to do is write out a prescription saying I want to give 20 millicuries of sulphur colloids orally. Then there are no questions asked.

MR. TELFORD: We very recently published what we're called an interim final rule, that is effective immediately, to allow departures for package inserts in the

case of 35.300 where the physician wants to not follow the package insert for the indicated use of the route of administration. The physician would write a prescription to describe the exact departure that's required, why he wants to do that. We're going to keep these -- we're going to collect these records for three years. That's the interim provision. So, we've just solved that problem. I don't mean to diffuse your concern just because of that. Could we put our finger on where most of the work is? I mean, if you're saying, gee, this seems like a lot of work to do, although worthy, although we might need to know it, could we do it with a little bit less work somehow? Is it the investigations step by this person who takes the time? The records are really there already, aren't they? We already have -- we already have these guys setting there. We already have these guys there. Is it the investigation step or is the report back to the licensee? Darrel?

MR. WIEDEMAN: John, I just want to say that in my experiences, that A(1) and (2) in a hospital setting would be extremely rare. Three, maybe. However, once again, as Roy explained, you know, you have your dose calibration ticket, you didn't enter it in the log; well, at the end of the day, you enter it in the log and there will be no questions. I don't see that that would be a big problem.

MR. CLARK: That's probably an unusual thing to

happen. You take your dose out, before you write it down the phone rings, you answer that and sometimes you just forget to do it right then.

MR. WIEDEMAN: I do remember a case that we had where the technologist had performed a bone scan or something on her sister, her girlfriend or something, at a VA hospital and it was never prescribed or ordered by a physician. It was the authorized user that caught it because when he looked at the scan and saw a female at a VA hospital, he questioned where did she come from and found out that it was the technologist's sister. Now that would be a diagnostic test done without a prescription or referral. But that's the only case I can remember in quite a few years.

MR. GOMEZ: How many patients a year do --

MR. WIEDEMAN: In Region III, I would say probably two or three.

MR. GOMEZ: Two or three?

MR. WIEDEMAN: We usually get around 20 to 30 misadministration reports a month.

MR. TELFORD: Let me correct what I just said about 35.300. 35.300 applies to therapy. There are no restrictions on use or route in 35.200 which is diagnostics. So, if you're talking diagnostics, part 35 doesn't restrict. The only thing I could think of that was related was 35.300,

which is, of course, therapy.

MR. WIEDEMAN: We've eased up on our enforcement of route of administration. To give you an example, we used to cite a lot of hospitals for doing cystograms because the route of administration into the urinary bladder was never described in the package insert. We got a lot of complaints about that. You know, if you compare that with the diagnostic X-ray study and fluoroscopy, radiation levels are so much higher. So, we had a requirement under the old part 35 that said as long as you followed the chemical physical form routed administration and so on. So we have really eased up a lot on that. I haven't seen any citations.

Another one that they are using is chopped up chicken livers. That's not described in the package insert but a lot of hospitals are doing them. Scrambled eggs and technetium -- I've never read that in a package insert.

MR. TELFORD: These are diagnostic tests?

MR. WIEDEMAN: Diagnostic tests.

MR. CLARK: Yes, you routinely scramble egg whites.

MR. TELFORD: Well, does anybody have a suggested modification on part A on these events? Sarah, I don't want to put you on the spot but, you know, you can have a --LT. KIRTLAND: Uh-huh, I've heard that story, too.

(Laughter.)

MR. TELFORD: I mean, you know, can anybody give me a suggested modification of what we're either calling these things, these events, or what we do if they occur?

LT. KIRTLAND: I guess I would include more people in C. Allow the radiation safety officer or his designee, or say that -- or his designee and then brought -- maybe brought -- put in a quarterly report to the radiation safety committee.

MR. TELFORD: Okay, so this report ought to go to the RSC?

LT. KIRTLAND: Uh-huh.

MS. RHODES: Well, why not just make it real broad and say any occurrence of A and B above shall require recording, investigation and appropriate action and let every organization decide for themselves how they are going to do this?

MR. TELFORD: Okay.

MR. CLARK: Through the radiation and safety committee is how we would handle it. The RSO would take care of it. We would write it up, show it to him, he would sign it and we would present it at a radiation safety committee meeting.

MR. TELFORD: All right. I think we're cooking now. Do you want to try a harder one now? We'll move on to the misadministrations.

Okay, now remember the theme here. What I want your help with is defining those events that are important, that are substantially different. In one, we have the wrong patient, the wrong rate of pharmaceutical and the wrong route. That's very much like current requirements. So, let's just pick these off one at a time. Again, I want to remind you, these are very cryptic descriptors here, so you should refer to the Federal Register notice for the exact words.

What would you like to do with B(1)? Is this something you want to delete, modify or retain?

(No response.)

MR. TELFORD: What would you like to do with it?

MR. HAIDER: Keep it.

MR. TELFORD: Keep it?

MR. HAIDER: Yes.

MR. TELFORD: Okay, anybody else over here? Tom, what would you like to do with it?

MR. WHITE: (No response.)

MR. TELFORD: No comment?

MR. WHITE: No comment.

MR. TELFORD: Stanley?

MR. GIPSON: I have no problem with that.

MR. TELFORD: No problem with it, okay.

All right, let's look at number two. This is a

diagnostic administration where the prescribed -- I mean where the administered dose is 50 percent different from the prescribed dose. Now, you will recognize that as a current requirement, but is that a level, a threshold that you would say is substantially different and important enough to be reported to the NRC? Now B gets reported internally, however we described this previously. Also, you have to notify the NRC if this dose exceeds these thresholds (indicating). If you have a fivefold error or you have an organ dose greater than two rem or a whole body dose greater than half rem. So, maybe we could look at these together. On number two, what do you say about it? Is that something substantially different enough to be reported?

(No response.)

MR. TELFORD: Do you think so, Tom?

MR. WHITE: Yeah.

MR. TELFORD: You do, okay.

What about you, Tawfig?

MR. HAIDER: (Nodding head affirmatively.)

MR. TELFORD: Okay.

Do you think so, Tom?

MR. CLARK: I see no problem with that.

MR. TELFORD: No problem with that.

Let's link this one with D because we're almost up to that. This says you have to notify NRC and then provide

a report in 15 days if you have a five-fold error in the dosage. How about this requirement, threshold? If this administration resulted in an organ dose of two rem or a whole body dose of half rem, is that something that you would call substantially different? Is that an important misadministration? Roy?

MR. LANDERS: I'm surprised -- I don't know about the two rem organ dose but I'm surprised at the half-rem whole body dose. I definitely would think that would be classified as a significant diagnostic --

MR. TELFORD: Half-rem, whole body is significant?

MR. LANDERS: In my mind it would be.

MR. TELFORD: Okay.

Darrel.

MR. WIEDEMAN: The two rem and the 500 millirem whole body, if you look at the PDR for nuclear medicine, almost every single diagnostic nuclear medicine study using typical doses would fall in that category, except for maybe a couple of millicuries of sulphur colloid.

MR. TELFORD: You're saying it would either meet or exceed this threshold of two-rem, any organ?

MR. WIEDEMAN: Even a ten microcurie, I-131 uptake capsule would fall in that category.

MR. LANDERS: Which of the two categories though, both?

MR. WIEDEMAN: Either one -- either the two rem or the .5 whole body.

MR. TELFORD: Now, let's pick an example here. Let's say that we've got -- we talked yesterday about I-131 and if you're going to do a whole-body scan, you said you could use 5 millicuries. What if you just used one millicurie? If you're 50 percent different, then you gave one and a half millicuries, plus a little bit, just to exceed the 50 percent. Now, what dose did the thyroid get? Or can we assume the patient still had a thyroid if we're giving him one millicurie?

MR. CLARK: Sometimes they have single --

MR. ARGAWAL: It will be the --

MR. TELFORD: Pardon me?

MR. ARGAWAL: It will be --

MR. TELFORD: Wait a minute. Tom had a point about the thyroid.

MR. CLARK: Sometimes they've got one lobe still there.

MR. TELFORD: Okay, so they have one lobe. So the dose to the thyroid is about a thousand rems per millicurie as a rule of thumb. So you're easily going to exceed two rem to the thyroid. In fact, doesn't two rem look -- I mean, as compared to 1,500 rads to the thyroid out of this one and a half millicurie dose that was given, you've got

1,500. In fact, what dose -- you could barely give -- you would have to be given a very small amount excess of I-131 not to exceed that. Roy?

MR. LANDERS: I'm not sure I understand what you're asking here. Something in A or B has already triggered D.

MR. TELFORD: Yeah. We're in the B category which is misadministrations. We've got -- 50 percent has been exceeded and now if we exceed either one of these, then you have to promptly notify and report to NRC.

MR. LANDERS: So you're trying to limit the number of reports that actually have to go to the referred position in the NRC?

MR. TELFORD: My question was --

MR. LANDERS: And that doesn't properly limit it apparently?

MR. TELFORD: My question is, is this something that you would call substantially different? See, we used those words in the Federal Register notice in the front. We said to the public, we're after things that should be considered substantially different. You guys are the experts, so I'm asking you, what would you -- how would you modify this, if you would modify it?

MR. WHITE: The only thing that comes to my mind is how about changing the dose by more than two rem or

changing the whole-body dose by more than half a rem?

MR. TELFORD: Changing the body dose?

MR. WHITE: Yeah.

MR. TELFORD: Do you mean the incremental dose?

MR. WHITE: The incremental dose.

MR. TELFORD: Now, the 50 percent difference, the 50 percent extra --

MR. WHITE: I'm referring to the organ dose greater than two rem, the increment.

MR. LANDERS: I was just going to say that one microcurie of iodine would do that, almost -- two microcuries.

MR. TELFORD: Two microcuries would get you two rem to the thyroid.

MR. LANDERS: I just have a feeling that that's not ever going to be reasonable. That instead of --

MR. TELFORD: Which is not going to be reasonable?

MR. LANDERS: Number three.

MR. TELFORD: Under D?

MR. LANDERS: Yes.

MR. TELFORD: This set of -- this threshold here, the two rem organ.

MR. LANDERS: I'm not sure you're ever going to come up with a reasonable set of numbers there. If you want to do something like that, perhaps the 50 percent may be a

good place to work.

MR. TELFORD: Well, both are open to you. I'm asking for suggested modifications on both. We said in the Federal Register that we would like suggestions on reporting requirements. We said tell us what you would consider to be substantially different.

MR. LANDERS: Double the dose of the intended diagnostic --

MR. TELFORD: You had a good example there, Roy. What if it were two microcuries of I-131? So somehow the 50 percent here is not on the same level as this two rem because -- if I use your example, you've got -- the prescribed dose is 100 millicuries. If you give 102, this is not triggered, but that is (indicating). Okay, 103. Now we exceed -- we've got three rem to that organ and we didn't expect to have it there.

MR. LANDERS: Yeah, but that doesn't -- that doesn't get triggered by A or B, so you never get to D.

MR. TELFORD: Okay, you're not -- you haven't triggered that.

MR. LANDERS: Right.

MR. TELFORD: Okay, let's trigger this one then. Let's use the same example. You have 100 microcuries, I-131 is prescribed, you give 155. So now, we've triggered this. And what does the thyroid get, 15 1/2 rem total or 5 1/2 rem

delta?

MR. LANDERS: Fifty.

MR. TELFORD: Fifty?

MR. LANDERS: One hundred and fifty.

MR. TELFORD: One hundred and fifty. Excuse me. I'm off by a factor of ten. One hundred and fifty rem. Okay, what is your feeling or analytical feeling or analytical reaction to 150 rems to the thyroid?

MR. LANDERS: Again, I don't -- D never comes into play unless A or B triggers it.

MR. WHITE: Do you want D to come into play when A and B are not triggering it?

MR. LANDERS: No, absolutely not. That's the point here. I don't think it's up to us to say what a physician can and cannot prescribe and what's reportable and not. But if A or B occurs, then D could kick in. If you want something down there in that third position, I would say something more along the lines of producing a dose to an organ or the whole body more than twice that what was prescribed or that which would have occurred had the prescribed dose been given.

MR. TELFORD: So that if this were one millicurie -- excuse me, one millicurie is prescribed, one and a half was given, 1.55 was given, what was prescribed was essentially 1,000 rads to the thyroid; so you would say

unless it exceeded 2,000 rads to the thyroid, or you would report when it exceeded 2,000 rads to the thyroid by following your suggestion.

Yes.

MR. GOMEZ: Would you consider misadministration by more than 50 percent diagnostic and ten percent therapy or less than 50 percent could also be misadministrated?

MR. TELFORD: Could a dose of less than 50 percent --

MR. GOMEZ: Less than 50 percent or less than ten percent for therapy be considered a misadministration, too?

MR. TELFORD: Could we stick with diagnostic for now and take the question again for therapy. The question is, if the administered dose is say 45 percent greater than what was prescribed, could it be a misadministration. Well, not by this criteria. But if it's the wrong patient, or the wrong rate of pharmaceutical or the wrong route, then by criterion one, it is.

MR. GOMEZ: I understood that you can consider a misadministration for diagnostic if you give a dose of less or greater than 50 percent of prescribed dosage.

MR. TELFORD: I think you're saying that your understanding is that you can have a misadministration if the administered dose is -- differs either above or below the prescribed dose by greater than 50 percent.

MR. GOMEZ: Yes.

MR. TELFORD: Yes.

Roy, you started to make a suggestion or you were at least thinking about a suggestion for --

MR. LANDERS: Well, it was kind of silly. Obviously the two numbers would be the same, you know, under my thinking.

MR. TELFORD: For this -- were you thinking about a modification for the 50 percent?

MR. LANDERS: Either that or perhaps delete number three altogether.

MR. TELFORD: This one (indicating)?

MR. LANDERS: Yes.

MR. TELFORD: Yes.

MR. ARGAWAL: This three, I think, is related to one rather than two. If it is a wrong patient or pharmaceutical or route, then notification has to be made only when the dose is greater than 50 percent. In the case of wrong patient, pharmaceutical or route, it is not connected by more than 50 percent of the dose.

MR. TELFORD: Well, notice that we have both A and B, both events and misadministration.

MR. ARGAWAL: Right.

MR. TELFORD: Either one or the other.

MR. ARGAWAL: One or the other. So 50 percent --

once that B(2) is 50 percent, that has nothing to --

MR. TELFORD: Oh, you're saying the real function is, that if you have an event --

MR. ARGAWAL: Right.

MR. TELFORD: But this 50 percent is not triggered.

MR. ARGAWAL: Right.

MR. TELFORD: Then this could be triggered independent of the 50 percent.

MR. LANDERS: Give the wrong patient a dose exceeding that.

MR. ARGAWAL: A dose exceeding two rem, then it will be a misadministration that is reportable.

MR. TELFORD: Well, do you necessarily have to have the wrong patient? I mean, if you have any patient here where maybe you didn't do one of these, but you exceeded this threshold --

MR. ARGAWAL: Yeah.

MR. TELFORD: -- then you have to report...

MR. ARGAWAL: Then it will be a misadministration. What I'm saying is, if we do have more than 50 percent where you have given administered dose, other than the prescribed dose, by more than -- less than suppose 40 percent. By more than 50 percent, RSO has to investigate it. But if you have given 40 percent, it will not trigger that unless it is the

wrong patient. In that case, the two rem will come in question.

MR. TELFORD: Okay.

MR. ARGAWAL: But if it is more than 50 percent, the dose will be -- it has to be reported if there is a five point error in the dosage.

MR. TELFORD: Okay.

MR. ARGAWAL: That's how I see it.

MR. TELFORD: Well, how do you react to this threshold then?

MR. ARGAWAL: If it has nothing to do with this B(2), I think it is okay.

MR. TELFORD: Tom.

MR. WHITE: I believe the delta will still apply.

MR. TELFORD: You want to use the delta. This threshold should apply to the extra dose that the patient got that they weren't supposed to get?

MR. WHITE: (Nodding head affirmatively.)

MR. TELFORD: Okay, that's what I thought.

Jerry, you've been quite this morning.

MR. MORRIS: I really have. I'm in the wrong ball game. I don't know. I thought they were making pretty good sense over there myself.

MR. TELFORD: Okay. I get the sense that we're out of suggested modifications for that. Let's go to the

records. That's part E. Now, a couple of people asked about records yesterday. So, we're saying records that you shall keep is these guys, the prescriptions and the referrals in the form we discussed, the record that goes to dosage, which is here, we're going to keep those for three years after the administration of the byproduct material.

Number two is, as you replace a page in your clinical procedure manual, you keep that old page for three years and if you have an event or misadministration, keep the report of it for ten years. Now, do you want to bring up your questions on -- about the records that you had yesterday? Jean.

MS. RHODES: I think you have to keep your old procedures for longer than three years.

MR. TELFORD: The clinical procedures?

MS. RHODES: Yes.

MR. TELFORD: Okay. The government has some sort of standard periods. It's like three years, five years, ten years.

MS. RHODES: Well, I don't know if you have different statutes for different kinds of suits, but one thing they always want is your procedures that were in place at the time whatever it was occurred.

MR. TELFORD: Okay.

MS. RHODES: And there was a child in North

Carolina -- it can run, I believe, 28 years.

MR. TELFORD: Oh.

MS. RHODES: Wrongful death is two years. Some things, the statue is ten years. So, I think you would want to keep that stuff for longer than three years.

MR. TELFORD: Five years or ten years?

MS. RHODES: I would say ten years.

MR. TELFORD: Ten years, okay. I believe Tom had a question on --

MR. CLARK: What I was worried about was the diagnostic referral sheet.

MR. TELFORD: Yeah, you've got a lot of -- a lot of patients that you have referrals on and doses on. Now, if you have -- that's these guys (indicating). That's the referrals and that's your records.

MR. CLARK: We've got the dosage for every patient we've ever dosed in the hospital. We've still got that.

MR. TELFORD: Oh, you've still have these doses?

MR. CLARK: Yeah, we still maintain those logs. We've got them back to '76.

MR. TELFORD: Okay. How do you know that -- do you keep the referrals?

MR. CLARK: No.

MR. TELFORD: Okay.

MR. CLARK: Not out-patients.

MR. TELFORD: Do you have a record -- excuse me, copy of the record that went back to the referring physician?

MR. CLARK: No.

MR. TELFORD: In other words, how do you -- is there some way that you can demonstrate that the dose given was the correct dose, or do you connect that to your procedures manual?

MR. CLARK: That's connected to the procedures manual for our standard dosage chart. We don't -- other than what's on the typed report, that's the only record we have of who referred the patient. Plus, in the patient log, it's got the patient's name, date, requesting physician and exam.

MR. TELFORD: If that's in your report -- the report says referring physician, something like liver scan, bone scan, so it repeats the information in the referral?

MR. CLARK: Yes.

MR. TELFORD: You've got your procedures manual, so you can demonstrate that the procedures manual and the dose are in accordance. How long do you keep those reports?

MR. CLARK: We've got reports -- again, from the first time we ever did an examination. They maintain the reports, as far as I know, for ever. I don't know.

MR. TELFORD: Well, it seems to me that you have

this then.

Darrel, what do you think?

MR. WIEDEMAN: John, I was just going to say, it sounds like they have it. If I went to your hospital and said you did this scan last year on Susie Smith, you would be able to pull out the envelope and show me the scans and you would pull out a written report that was signed by your authorized user describing his findings. He may even state on there how many millicuries or microcuries were given of what isotope. And they would probably have the referring physician's name on it.

MR. CLARK: Well, the out-patient slip that they bring, there's no -- really no point in maintaining those, if all of that information is on the report.

MR. TELFORD: Okay, so therefore, maybe we should say either the -- we should give you a choice then perhaps, either that referral or the report you sent out on the patient because the report would actually contain a repeat of the information that was contained in the referral. You have a record of this that's independent anyway.

Yes, Darrel.

MR. WIEDEMAN: Well with the prescription, let's say, for instance, this doesn't delineate between diagnostic and therapeutic. Your authorized user physician wrote out a prescription telling you how many millicuries of I-131 he

wanted to use. Then he probably wrote up a report to the referring physician saying Mrs. Jones presented herself today and we gave her some many millicuries of iodine and we recommend this and that. Well, to me, that would be -- that would satisfy the requirement.

MR. CLARK: We maintain the special permission where they give us permission to treat them with iodine and the physical prescription itself is in a separate folder in a separate file from the reports.

MR. WIEDEMAN: Oh, you've got it then.

MR. CLARK: We maintain the therapeutic in a separate place and we've got everyone of those.

MR. WIEDEMAN: And you probably have your dose logs, so if I wanted to go back and check and see what was given, you've got that?

MR. CLARK: Yes, we do.

MR. WIEDEMAN: It sounds like you've got everything.

MR. TELFORD: Well, Tom's covered but how about the rest of you?

MR. DESAI: I think that we need to go down to five years, not ten years. You can go from three years to five because we maintain all the records for five years. Not more than five years.

MR. TELFORD: How about this one (indicating)?

MR. DESAI: That too, right.

MR. TELFORD: You're saying that you keep these records and these for five years?

MR. DESAI: All records in nuclear medicine is maintained for five years, yes.

MR. TELFORD: Okay. But if you had a misadministration -- you're in an agreement state right now --

MR. DESAI: Right.

MR. TELFORD: -- period. But so that you just started having to report misadministrations, but if this rule becomes final -- okay, this would be a perturbation to you to have to keep these for ten years. So your sense is that five years is good enough?

MR. DESAI: Yeah.

MR. TELFORD: Tom, how would this affect you?

MR. WHITE: Five years for everything.

MR. TELFORD: Five years for everything?

MR. WHITE: (Nodding head affirmatively.)

MR. TELFORD: Jean.

MS. RHODES: I would have to check with the hospital attorney and see what the statues are.

MR. TELFORD: Therefore, they may want to think about keeping them longer?

MS. RHODES: Uh-huh.

MR. TELFORD: Okay.

MS. RHODES: Depending on what the statues are.

MR. TELFORD: Stanley.

MR. GIPSON: I agree with her. On most of these things, we've kept them since -- I don't know if we've thrown any out or not.

MR. TELFORD: Since day one.

MR. GIPSON: Since day one. That's right.

MR. TELFORD: Till the patient dies?

MR. GIPSON: Yeah, or longer.

MR. TELFORD: Or longer.

(Laughter.)

MR. GIPSON: We've got them stored away.

MR. TELFORD: Tom.

MR. WHITE: Well, we can maintain them five years.

MR. TELFORD: Okay. How about the rest of you? Do you keep records forever?

LT. KIRTLAND: No.

MR. TELFORD: No. How long do you keep records?

LT. KIRTLAND: It depends on the record, three, five or ten years.

MR. TELFORD: The same. Okay, well how about --

LT. KIRTLAND: Some records we keep for 75 years.

MR. TELFORD: How about -- the only thing that -- well, you keep everything for at least three years?

LT. KIRTLAND: Yes.

MR. TELFORD: All right. So the only thing here that exceeds three is this ten year requirement. How long would you keep these?

LT. KIRTLAND: That I think -- I don't know if we would -- well, at least ten years.

MR. TELFORD: Ten years?

LT. KIRTLAND: Uh-huh.

MR. TELFORD: Tony.

LT. CMDR. PULCRANO: We've probably got them since day one but a lot depends on how much room we have to store them.

LT. KIRTLAND: Yeah. I mean you have to take into account how long we've had the license. So, you know, going back to the beginning of the license is not that long ago actually.

MR. TELFORD: Okay.

Jean.

MS. RHODES: I think we've kind of lost sight of what we're doing here. We want to talk about what the NRC will require, not what we might ought to do to protect ourselves.

MR. TELFORD: That's true, but you made that clear. You said --

MS. RHODES: Oh, okay.

MR. TELFORD: -- consult the hospital attorney, consult the laws of the state.

MS. RHODES: Okay.

MR. MORRIS: When did the ten years come around? Why do you have that?

MR. TELFORD: Well, we have a choice of three years, five years or ten years. But, you know, good question. We chose ten years because some of the licensees get inspected each year, especially the larger ones. Some licensees get inspected every three years. If an inspector goes out and finds something wrong that needs correction, but yet, you know, it's not a real terrible event; then we say all right, what are you going to do to fix it. They have a proposal, we accept it and they start trying it. Well now, if this were something different, you see, it may present a problem of the record still being around because this event could have occurred in year one. Our inspector got there in year three. We say try it, try your solution. We come back in year six. Okay, we've exceed five years and it could be that we say well, close but no cigar. We don't think it's working quite as well as you think it is. Give us a better suggestion. So they crank it up a little bit, we come back in year nine, now everything is all right. Okay, so that's more or less why we came up with ten years because five years for our purposes may not quite get it.

Any other questions? Sarah?

LT. KIRTLAND: I have two questions but they are kind of general questions about this part.

MR. TELFORD: Good.

LT. KIRTLAND: One is -- I remember reading somewhere -- I can't find it right now, that you have to notify the patient if there's a difference greater than ten percent. Is that still so, because we have problems with -- if there's no adverse effect to the patient but it really causes an emotional burden to the patient.

MR. TELFORD: Okay. Now, this is actually a current requirement. What you read in the Federal Register is essentially a copy of the current requirement. I believe it's in 35.33 currently. But the way it works is, if you have a misadministration, then, I believe, it says that you are to notify the patient unless the referring physician says in essence it'll do more harm than good.

MR. CLARK: That's on page 1448, down under Item D.

MR. TELFORD: It's in your copy of the notice there, page 1448.

MR. CLARK: It's in the left lower hand corner. It says that he agrees to -- if he believes that it would be harmful to one or the other. If there's no medical problem, then it's not required. It's all in there, the bottom left

hand corner of 1448. Right at the bottom of that left column. The last 30 or 40 lines.

LT. CMDR. PULCRANO: But that only refers to iodine.

MR. CLARK: Yeah, that refers to iodine.

LT. KIRTLAND: So, you know, this is only -- do you know what I'm talking about? I mean...

MR. TELFORD: Well, I think you're thinking of cases in which it would do more emotional harm to tell the patient that something like that had happened to them than it really means clinically. So this --

LT. KIRTLAND: because the patient doesn't really know. He can't really judge.

MR. TELFORD: Okay, some patients just don't know what it means when they are told that.

LT. KIRTLAND: So they get very upset.

MR. TELFORD: Yeah.

Well, is this mechanism sufficient? The built-in mechanism here. Essentially, you go through the referring physician. So the referring physician can say, no, don't tell the patient. Is that a sufficient safeguard?

LT. KIRTLAND: I guess -- at least, at our hospital, the physicians -- they would want kind of a medical reason not to tell the patient. So that in most cases, they would want -- if there was no medical reason,

then they would not feel that they had any justification to say don't tell the patient.

MR. CLARK: In this example, it says one microcurie was prescribed but one millicurie was administered. I don't think that's going to be a significant medical indication, but a mistake from like 30 microcuries to 30 millicuries may very well be. It's up to the physicians judgement with respect to the patient. He would most likely consult with the radiologist or physicist or whomever in that event.

MR. TELFORD: I'm not trying to talk you out of this, I'm just opening it up and saying is this a sufficient kind of a safety hatch.

Yes, Roy.

MR. LANDERS: I see a little problem with the concept of trying to use the referring physician as an outlet here for not having to report anything to the patient.

MR. TELFORD: Okay.

MR. LANDERS: It's certainly more appropriate in therapy later on. If the referring physician, rather than break a physician relationship, tends to go along with the licensee and says okay, this is really an insignificant event and we would probably do far more emotional harm than good by alerting the patient; that referring physician can

potentially be placing him or herself in a joint liability situation in the future. That could possibly stop that referring physician from not requiring notification to the patient.

MR. TELFORD: Okay.

MR. LANDERS: So, I'm a little bit concerned that this may turn into a case of someone, in fact, being required to incriminate themselves.

LT. KIRTLAND: In essence, you're using the physician as a safety net to fill in what if it were designed a little bit better would be --

MR. TELFORD: Yeah, that's the way I read the requirement. It's a safety net.

LT. KIRTLAND: It would be nice to have something in there that said if there's no adverse clinical effect, that the patient does not have to be notified.

MR. TELFORD: Okay.

MS. RHODES: It says that. It says it has the potential to cause serious harm.

LT. KIRTLAND: Say that again.

MS. RHODES: You know, it's not the little stuff, this is big stuff.

LT. KIRTLAND: Well, that's not the way our doctors are interpreting it. Maybe that's what the confusion is.

MR. TELFORD: Okay. Do those words convince you that there's a little bit better safety net?

LT. KIRTLAND: The way this is -- the way this is worded is fine.

MR. TELFORD: Okay. You said you had two questions.

LT. KIRTLAND: Yes. The second one is, is there anyplace where there is a summary of the years that you have to keep all the records?

MR. TELFORD: Yes, it should be in part E of 35.33 and there's a separate section, 35.34.

LT. KIRTLAND: Okay.

MR. TELFORD: Currently it's divided in the proposal.

LT. KIRTLAND: Okay.

MR. TELFORD: Let's see if we can summarize 35.33. Anybody have any final remarks or final suggestions for 35.33?

(No response.)

MR. TELFORD: Does anybody object to taking a break? let's go for about 10 or 15 minutes and come back at ten o'clock.

(A short recess was taken.)

MR. TELFORD: Okay, welcome back to our session after the break. Now let's go to the requirements on --

proposed requirements on reporting on therapy on 35.34. We'll keep the same theme of trying to make suggestions for those things that should be reported that are substantially different. Part 35.34 has the same organizational structure as 33. In part A, we have events. Now these are the -- these will be handled in the same manner as they were for diagnostics. So, let's look at these four for events.

We have therapeutic use without a prescription and a prior review of the case. We have a therapeutic use without recording the dose or dosage. This is a single fraction, teletherapy fraction. What was administered was 20 percent -- don't read this greater than. It was 20 percent different from what was administered and therapeutic use not authorized. Surely this will bring about some manifold suggestions here. Who wants to go first? Roy?

MR. LANDERS: Well, I'll start it. I think there's potential for increased workload on our part and your part significantly here. I cannot say what dose differences are significant in therapy and which are not. I would defer to the physicians on that basis. But I know that it is -- although rare, it is not uncommon to leave a wedge out for one fraction and there's a reportable event.

MR. TELFORD: Okay.

MR. LANDERS: All the way by telephone. I wouldn't get into the reporting. I guess the thing that

bothers me here is that it's [illegible]rly routine for deviations in the planned treatment in [illegible]apy to be made up for over the course of the remaining treatment in one way or another.

MR. TELFORD: Okay.

MR. LANDERS: For example, using TDF calculations and things of this sort. And it's not clear to me that a simple single 20 percent deviation in a single fraction treatment should necessarily be of this magnitude.

MR. TELFORD: Therefore, would you delete this or would you modify number three?

MR. HAIDER: Leave it the same as it is now, ten percent of total dose.

MR. TELFORD: Well, that's over here.

MR. HAIDER: Yeah.

MR. TELFORD: But this is for a single fraction, not total.

MR. HAIDER: Can we take out the fraction and make it ten percent?

MR. TELFORD: Well, let me put this into perspective for you. Over here, these are misadministrations, so if you have fractions over here, that's where the fraction is a factor of two different from what was prescribed. Then we have another one on -- ten percent on the total and then a ten percent on a running total. But this is still an event. It's a single fraction.

Would you like to see that deleted because it's too much work and it's not worth it or would you like to see this 20 percent increased to some other number? Jerry, is this your bailiwick?

MR. MORRIS: Well, I'm thinking. It doesn't seem that significant. If it's early in the treatment, of course, you're going to catch a good ten percent in total dose.

MR. TELFORD: Well, if it doesn't seem that significant, then why do it?

MR. MORRIS: That's right.

MR. TELFORD: Is that what you're suggesting?

MR. MORRIS: I guess so.

MR. TELFORD: So you're really suggesting that we delete that one?

MR. MORRIS: yeah.

MR. TELFORD: Okay.

MR. LANDERS: I agree with the concept of deleting it. I'm not aware of any instances when any of our patients received a quote, significant, unquote, deviation from the planned treatment that myself, the dosimetrist or the physicians were not made aware of in short order. We're already aware of these things and take care of them. So, I would suggest deleting number three.

MR. TELFORD: Okay.

MR. ARGAWAL: The 20 percent error, this is an even which is to be investigated by the physicist and then it must be cleared -- it has to come. Suppose a technologist makes an error of not putting the tray or not putting the wedge or something which makes it more than 20 percent. The physicist has to take that into account, investigate it and correct it the next day.

MR. TELFORD: Yes.

MR. ARGAWAL: The thing has been notified, investigated and that does not make a misadministration. This just makes it an event. Then it is okay. We are doing it at the moment, any deviation, any quality assurance kind of thing to be reported. If it is not to be reported to the NRC, I think if there is a 20 percent error, somebody has to check that and correct it for the next day, even if it is to be corrected.

MR. TELFORD You have to make it before the next fraction.

MR. ARGAWAL: Make it up for the next fraction, because otherwise, nobody knows anything is wrong. So I think it is an event, which must be recorded as an event. So far as it is not to be reported as a misadministration, it's okay.

MR. TELFORD: How about number one?

MR. ARGAWAL: This is without a prescription in

therapeutic use, you have already checked beforehand, you know, at least in any emergency situation, the treatment can be done without a prescription. Now if it is -- suppose that emergency situation -- does it still make it therapeutic.

MR. TELFORD: Oh, if it's emergency, no.

MR. ARGAWAL: But it is not here. Any therapeutic use without a prescription --

MR. TELFORD: These are very concise cryptic words. For the exact words, you have to look at the Federal Register notice. So we have emphasized the cases that have an emergent nature in several places.

Well number two, how about recording the dose that you give. Do you have a chart that you fill in either the dose or its equivalent, like the time?

MR. LANDERS: Naturally.

MR. TELFORD: Okay.

MR. LANDERS: I have an example here. If several ports are treated, one of the ports is not recorded as having been treated. During the chart check the next day that is found, the tech is contacted, specifically remembers treating all ports on that patient, records it as having been done. I have a problem with that being a requirement of a report to management, for a situation of that sort.

MR. TELFORD: Okay, we --

MR. LANDERS: It's not a major occurrence, but if you add up a lot of minor things, they can become major.

MR. TELFORD: Well we had some suggested words for what to do for the diagnostic events that we would have someone investigate -- Jean, these were your words, we were going to investigate it and notify the radiation safety committee or the QA committee?

MS. RHODES: Yeah. I think I said that it would be -- what did I say -- yeah, they would make out an incident report, it would be investigated and reported to whoever was in our organization that it was supposed to be -- not necessarily the radiation safety officer. I think this therapeutic use without daily recording of the administered dose -- I can only relate this to when nurses record medication, I think it's sort of the same thing. You know, they don't make out an incident report or have anything bad happen to them if they forget to record something. You know, a record is not complete until it's complete.

MR. TELFORD: So does the nurse go back the next day and write in we gave demerol so many --

MS. RHODES: Yeah, when it's noticed that it's missing, they contact the nurse involved and she goes back and records it, it's no big deal.

MR. TELFORD: Ashok, no problem -- or are you

shaking your head because you don't like this so much?

Jerry?

MR. MORRIS: The thing that I'm thinking about, if a tech made a practice of doing this, he might need to note it.

MR. TELFORD: Might need a little more training, little closer supervision, some sort of corrective action -- you might want to know about it.

MR. MORRIS: But you would do that.

MR. LANDERS: But you would do that.

MR. CLARK: That would be a routine disciplinary problem, I would think.

MR. TELFORD: Pardon me?

MR. CLARK: I think that would be a routine disciplinary problem between yourself and the individual. Occasionally everybody is going to do it, but repetition by the same person would require correction, not necessarily an incident report.

MR. TELFORD: Okay. Any other comments on the events?

MR. LANDERS: Wait a minute. I'm not sure we've made any progress.

MR. TELFORD: Well I thought you did, you suggested we get rid of number three.

MR. LANDERS: Oh, we're back to number two now

though.

MR. TELFORD: Oh, you want to go back to two.

MR. ARGAWAL: We take it as an incident when the technologist does not record the administered dose and once it is an incident, it has to come to the physicist or the authorized user.

MR. TELFORD: Okay, so you call these things incidents instead of events. Does almost everybody call them incidents?

MS. RHODES: We call them occurrences.

MR. TELFORD: Occurrences.

LT. KIRTLAND: Yeah, occurrences.

MR. LANDERS: That's fine. I don't have a problem with the terminology, what I have a problem with is doing increased paperwork over what we now do. We do not now write a report about all of these things and this apparently is requiring us to do that.

MR. TELFORD: Would you make a record of these things?

MR. LANDERS: Certainly a deviation in the dose is recorded because it's in the chart. The fact that someone did not sign a chart yesterday and we come back and talk to them and find out that in fact the treatment was done and they go ahead and sign the chart, I've never made a record of that.

MR. TELFORD: Okay. You just keep these mentally and if they add up to too many for one person, you take a little supervisory action against that person?

MR. LANDERS: Yeah. You know, the number we're talking about is relatively small.

MR. TELFORD: Okay.

MR. WHITE: How about modifying number two to add the phrase "leading to questionable amount of dose actually received". You know, if somebody did not record for three or four days and doesn't remember.

MR. TELFORD: Okay, you're saying that if that particular administration, if it led to --

MR. WHITE: A questionable amount of dose actually received. I expect that would not involve much additional paperwork.

MR. TELFORD: Oh, that might arise if you didn't catch it the next day, but if you caught it next week. Then it might become more of a problem to you.

MR. WHITE: It's not likely to happen.

MR. TELFORD: Would that make it more palatable to you, Roy?

MR. LANDERS: Not really.

MR. TELFORD: Not really, okay. Stick to your guns, that's all right. Well okay, if I understand what you're telling me, you wouldn't use this at all, you

wouldn't make a record of this at all and you wouldn't make a report of this because to you, it's not a problem and you don't want to see work created over something that's not a problem.

MR. LANDERS: Now wait -- there are instances when it is not signed and you cannot determine if the port was treated. Now that's significant.

MR. TELFORD: Okay, that's about what Tom is saying.

MR. LANDERS: If you can't determine -- yeah, whether it was done or not, okay, sure.

MR. TELFORD: So you would make a record or maybe a report to your management entity, your department chairman or whatever, if the technologist forgot to write it down and you discovered it a week late, hypothetical case, and you couldn't determine that both ports were treated.

MR. LANDERS: Right. Also I guess I might remove one of my objections about making a report because it doesn't say written.

MR. TELFORD: Okay.

MR. LANDERS: We always orally report these.

MR. TELFORD: Okay, so if you could make a record and orally report back to your management entity, that would be easier for you, you're saying.

LT. KIRTLAND: And not just because of the

recordkeeping, but keeping the oral component -- when things have to be written down, people get uptight, the technicians get uptight. And we have had problems in the past where people have hidden things because they're afraid of the consequences. If you keep it on a verbal level, we've found that they're more likely to come forward and tell you, because if they don't think there are going to be any consequences. It's a bit like they feel free to ask questions.

MR. TELFORD: Okay, well the strategy we're following for these events was that it's an internal feedback loop within the licensee organization, so you're saying we could further that cause if we allowed oral reports to go back. Maybe a record is not so bad, but nobody wants to have a report that says they made a mistake.

LT. KIRTLAND: That's right.

MR. TELFORD: Okay. That's a good comment. Anybody else.

LT. KIRTLAND: Nobody wants a reputation as a troublemaker.

MR. TELFORD: Okay. Any other comments on (a)? Roy, are you -- have you made all your comments?

MR. LANDERS: I think so.

MR. TELFORD: You think so. Okay, anybody else?

MR. MORRIS: I'm still having trouble with three.

I guess we had it solved but I've missed something there. Suppose it's a 500 percent error.

MR. TELFORD: Oh, okay.

MR. MORRIS: Oh, it's a fraction, okay.

MR. TELFORD: Are we ready to move to (b), misadministrations? Okay, we have again, wrong patient, wrong source, wrong treatment site, wrong route. This would be a radiopharmaceutical therapy where the administered dose is ten percent different from the prescribed dose and all of three is on teletherapy. This is the current requirement on the administered dose, if the total dose is ten percent different from the prescribed. This is a single fraction where it's a factor of two different from what was prescribed for that fraction. Three is a running total where you take ten percent of the total dose. For instance, if you have 5000 rads is the total dose and you're going to give it in 25 fractions of 200 rads each, then this ten percent threshold is ten percent of the 5000 or 500. So you apply this threshold to each -- to the cumulative each day. So after the first day it's very easy, second day, third day, fourth day, you just keep adding up until you determine if you're still within this.

This was designed to allow the corrections, like if you made a mistake on a fraction early on, maybe it was less than a factor of two, but you needed to make some

corrections. Maybe you needed to give less or maybe you needed to give more for the next ten fractions. Well this window here in the example I'm using of 500, would allow you that window because you're giving 200. So if you have to give 250, it's easily within this window.

Now four is on brachytherapy -- oh, this is a lost or leaking source. Five is also on brachytherapy where you have the administered dose is 20 percent different from the prescribed dose. Currently in 10 CFR, this is ten percent here. So this is a recognition that there's a little bit of art involved and it's a little less precise than the teletherapy.

Okay, shall we start with number one? Anybody have any suggestions on wrong patient, wrong source, wrong site, wrong route? Tom shakes his head no. Sarah?

LT. KIRTLAND: Okay, we had one where the treatment site was off by more than 20 percent, it was across the abdomen and they went down, they read the wrong marks and went down. The tech caught the error, but this is a case where the consequences of it being called a misadministration required telling the patient and there was no clinical consequences to this, the doctor determined. This would be a case where why do we have to tell the patient if there's no clinical consequences.

MR. TELFORD: I think you have the same safety

net.

LT. KIRTLAND: Well --

MR. TELFORD: Well let me pursue your example just a little bit. This is teletherapy.

LT. KIRTLAND: Yeah.

MR. TELFORD: It was supposed to be given -- this is a single fraction of how many rads approximately?

LT. KIRTLAND: Oh, we'll say 180.

MR. TELFORD: 180 rads to the abdomen.

LT. KIRTLAND: Uh-huh.

MR. TELFORD: So they looked for marks and they discovered either moles or tattoos lower than --

LT. KIRTLAND: They were using the center as a top mark instead of the middle mark, so they moved the field down.

MR. TELFORD: By half of the distance of the field?

LT. KIRTLAND: Uh-huh.

MR. TELFORD: And --

LT. KIRTLAND: And then caught it.

MR. TELFORD: So it's the wrong site, but it's 180 rads to the wrong site and it's not clinically significant.

LT. KIRTLAND: Yes, the doctor felt it was not clinically significant.

MR. TELFORD: Darrel or Tony, isn't there the same

safety net in the report there? I mean aren't you supposed to confer with the referring physician?

MR. TSE: If it's determined to be misadministration, then you would. But wrong site --

MR. WIEDEMAN: Presently, that would be a reportable event.

LT. KIRTLAND: We did report it.

MR. TELFORD: But do you have to tell the patient?

LT. KIRTLAND: Do you have to tell the patient.

MR. WIEDEMAN: If the referring physician feels that there's some reason you should not tell the patient, then I believe that -- let's see, "within 15 days of initial therapy, the licensee shall report in writing to NRC and to the referring physician and furnish a copy of the report to the patient or the patient's responsible relative."

LT. KIRTLAND: Okay, this is exactly the question I'm talking about. I mean if the referring physician says we shouldn't tell the patient, you're saying that the patient is emotionally unable to handle it or for some other medical reason. But supposing that's not true. Most patients are intelligent people and very concerned about their health, but they're not able to -- they're going to get overly worried but not to a medical point of overly worried when you tell them you made a mistake even though there are not going to be any consequences -- clinical

consequences to it. That's what our physicians have trouble with, why do we have to tell them in that case.

MR. WIEDEMAN: Yeah, there is an out, I just found it here. It says that "The licensee" -- this is presently -- "the licensee shall also notify the referring physician or the affected patient or responsible relative or guardian unless the referring physician agrees to inform the patient or believes, based on medical judgment, that telling the patient or the patient's responsible relative or guardian would be harmful to one or the other, respectively."

LT. KIRTLAND: Okay, no, that isn't it because -- I don't think that answers it because if it's not going to be harmful to him, then we have to tell the patient. But if there aren't going to be any clinical consequences, why do we have to tell the patient?

MR. WIEDEMAN: I've been involved in several cases where the wrong pharmaceutical -- one I can think of, where they gave chroma (ph.) phosphate intravenously and the physician determined not to tell the patient because he felt that the patient was under enough emotional stress, and the family. He did not feel that the extra 900 rads to deliver was that significant, and so therefore they documented why they didn't feel it should be necessary to report to the patient. And we accepted that, that was a medical decision.

LT. KIRTLAND: Well there's a certain amount of

emotionality that's always going to be connected with being told that your doctor has made a mistake.

MR. LANDERS: Especially if it's radiation.

LT. KIRTLAND: Yeah. And this is dealing with radiation.

MR. TELFORD: Okay, what safety net would you like to see?

LT. KIRTLAND: I don't want the doctor to be the safety net because you're also putting an onus on the patient kind of saying that the fact that they're going to have an emotional response is a reason not to tell them. But just to say -- I'd like to see it changed so that if there aren't going to be any clinical consequences -- because my understanding is that some doctors claims that they can see clinical differences with seven percent error. So it wouldn't be changing two or three, because there could be some sort of clinical consequence. But with (a), if you get the wrong treatment site for one treatment, the doctor determines there aren't going to be any clinical consequences, in conjunction with the physicist, that that is not important enough to require a misadministration.

MR. TELFORD: Okay. Roy.

MR. LANDERS: I would like in all of these reporting of misadministrations to the patient, to have the same nice little out that was given diagnostic

misadministrations. It says for diagnostics "if the misadministration has the potential to cause serious harm to the patient, the licensee shall also notify the patient."

MR. TELFORD: Okay.

MR. LANDERS: One of the reasons I think something like that should be left in there is, as I referred to earlier, if the referring physician must be relied upon to supply an out for the radiation oncologist, that places the referring physician in a compromising situation. Either he's going to irritate a physician or potentially place himself in legal jeopardy. And I don't think that's right to do to the referring physician.

MR. TELFORD: Okay, so use the same words for both diagnostic and therapy for when you report to the patient, that you have to go through the referring physician, and for the same causes. Would that be sufficient?

MR. LANDERS: No, not unless they were kind of like the same ones that are in diagnostic now.

MR. TELFORD: That's what I'm trying to say.

MR. LANDERS: Not go back the other way.

MR. TELFORD: Oh, okay -- don't make diagnostic --

MR. LANDERS: Don't make diagnostic worse.

MR. TELFORD: Okay. All right.

MR. ARGAWAL: The treatment site definition, suppose a patient is treated 10 by 12, the prescription was

8 by 10 to the posterior and the patient -- the machine was rotated and posterior was also treated 10 by 12 in one treatment.

MR. TELFORD: From the other side.

MR. ARGAWAL: From the other side, instead of 8 by 12. Will it be a wrong treatment site because the total treatment area is not the same? It exceeded -- it was 8 by 10 and they treated to 10 by 12 because the technologist made that error. And the doctor decides that 10 by 12 instead of 8 by 10 won't do any harm, or clinical consequence is not there. But will the treatment site -- is decided by the central ring, that's what I'm asking, or is decided by the total area?

MR. TELFORD: What's the target?

MR. ARGAWAL: The target -- you know, the target may be abdominal, but the tumor with the margin is covered with 8 by 10. You are overtreating it by two centimeter on each side, so will that overtreatment mean that you have changed the site?

MR. TELFORD: Well aren't you treating the same target, you're just treating it from the other side?

MR. ARGAWAL: You are treating the same target, but the treatment site, that's what I'm asking, does it remain the same in both cases?

MR. MORRIS: So how wrong can you be is the

question.

MR. ARGAWAL: Right.

MR. MORRIS: If you treat a 30 by 30, that's a little much.

MR. ARGAWAL: But the question is then if you decide on the basis of the field, then -- or if you decide on the basis of the central ring. If you decide on the basis of the field, then anything other than the prescribed will be a deviation and will be a reportable event because it is not defined by the treatment site whether defined by the central ring or the field size.

MR. TELFORD: Wasn't one of the things that you considered when you chose the field size, the organs that are adjacent to the tumor that you don't want to over-dose?

MR. ARGAWAL: That's true, but sometimes we do and a single -- like a spinal cord, let me say, the spinal cord gets 500 more than the certain prescribed 4000, is it over-tolerance. But in a daily dose, it is only 50, which you are putting over the spinal cord. Suppose that field, 10 by 12, in one fraction, the error was not in the total, but in one fraction, it will increase 25 or 50 rads and that is under the spinal cord tolerance. That's why I said it is not of clinical significance. Then in that case, is it the same treatment site, although the spinal cord has been treated that day from the posterior. That was the reason --

MR. TELFORD: Are you suggesting that in the example that you've given, that that's essentially the same treatment site?

MR. ARGAWAL: I'm not saying that.

MR. TELFORD: Oh.

MR. ARGAWAL: I'm saying what is your interpretation of the same treatment site -- that's what I want clarification.

MR. TELFORD: Well most of the ones that I've seen that were misadministrations are something like the brain instead of the lung or the right side instead of the left side -- really gross. Darrel.

MR. WIEDEMAN: That is correct. If you look at the new rule, the way I would interpret it, if the prescription called for spinal cord blocks, you know, during the lung treatment, and the technologist left off -- forgot to put the spinal blocks in -- that would be a reportable event. Now is it significant?

MR. ARGAWAL: In a single incident -- that's the question, is it the therapeutic use other than the one in the prescription --

MR. WIEDEMAN: Well it's an irradiation of the wrong treatment site.

MR. ARGAWAL: Yeah, and if it is a single dose, the block has been left out -- there are four blocks and the

block has been left out.

MR. WIEDEMAN: If it was me looking at it, I would say it was probably not that significant, but remember some of these things go to court and a good lawyer would say well was that a prescribed treatment site and the answer would probably be no.

MR. LANDERS: I disagree with that because if it's in the main port, you're not going to eliminate all the radiation to it.

MR. WIEDEMAN: I agree.

MR. LANDERS: So the question is how much dose instead of whether it's in the treatment site or not.

LT. KIRTLAND: So I guess it should be answered if you leave the cord block out, do you record in the record that the spinal cord has received extra dose.

MR. LANDERS: Generally there's a prescription for the cord dose, right?

LT. KIRTLAND: Right, you usually follow that.

MR. LANDERS: Go by the final prescription for the cord dose.

MR. WIEDEMAN: If you had the prescription for the cord dose and it was below that, you wouldn't have a problem. But I don't think everybody puts in a cord dose, do they? Does everyone record a "spinal cord dose"?

MR. LANDERS: I don't ever block the spinal cord

unless I'm told to or told to start it at a certain dose.

MR. WIEDEMAN: I don't remember seeing that many, you know, like say a lung treatment that'll say X number of rads to the cord with spinal blocks.

MR. LANDERS: My physicians always say limit the spinal cord dose to -- by blocks.

MR. WIEDEMAN: Oh, okay, then I think you'd be covered. But I don't think everyone does that.

MR. WHITE: In treatment planning I put down what the cord dose would be without the block or with the block, I write that down and then the physician determines which one he wants.

MR. ARGAWAL: But everybody doesn't do that.

MR. WIEDEMAN: Okay, let's assume that you calculated that with the spinal blocks in you're going to get let's say 100 rads to the spinal cord. The technologist forgot to put the blocks in and now you've exceeded the 100 rads. According to the new requirement, that's an irradiation of a treatment site that was not intended and it would be reportable.

MR. ARGAWAL: Reportable to the patient.

MR. LANDERS: I disagree with that. You're going to be treating under a block -- whether you want to or not, you're going to be.

MR. WIEDEMAN: I don't disagree with that.

MR. ARGAWAL: No, even radiation block does not block the total amount of radiation, it only reduces.

MR. TELFORD: Let's pursue your example. The field size was changed -- let's just keep it real simple -- for one fraction. Now let's assume for a moment that that does constitute a different site. Let's assume the worst. What would you recommend about that, should it be that way or would you modify it?

MR. ARGAWAL: No, I think it should be an event, but not a misadministration. That is a therapy misadministration in which it is to be reported to the patient and the referring physician.

MR. TELFORD: That's when -- now you're not talking about the case where you have a fraction that goes to the brain instead of the lung.

MR. ARGAWAL: No, I'm not.

MR. TELFORD: Or the left versus the right.

MR. ARGAWAL: No.

MR. TELFORD: But it's just an incremental difference of different field size, but it still included the same site, it just got a little bit more.

MR. ARGAWAL: Right.

MR. TELFORD: Okay, you're saying for a single fraction for a case like that, it ought to be an event, but not a misadministration.

MR. ARGAWAL: Not a misadministration.

MR. TELFORD: Okay, so where do you draw the line?

MR. ARGAWAL: You see, that's where I want some language to be in the treatment site, there should be a treatment organ or something, that's where -- instead of site, the organ to be treated, that is there then the site is not a question. The site I think --

MR. TELFORD: The treatment point, the central point?

MR. ARGAWAL: Right.

MR. TELFORD: Okay. Would that solve your problem?

MR. ARGAWAL: Yes.

MR. TELFORD: Okay. Roy?

MR. LANDERS: I like the way it's worded now, provided you do not supply us with a definition of target organ or treatment site. Let the physician decide whether this slight deviation has eliminated the treatment site.

MR. TELFORD: We saw both, don't we, we say organ or site?

MR. LANDERS: Right.

MR. TELFORD: Okay.

MR. MORRIS: I think that the dose is going to vary, whether the field is too large or too small, so let the dose be the thing that determines, if there's a

significant change in dose.

MR. ARGAWAL: The dose would not vary that much with the field size, that only changes if you make it into 10 by 10 to 10 by 12, hardly one percent.

MR. MORRIS: In that case, that's correct.

MR. ARGAWAL: So those will not ever come into that-- MR. MORRIS: But still let it be the guide though.

MR. TELFORD: Jerry says -- if the dose to the target organ, if the field size is changed or some other small mistake is made, and if a change in dose by a certain fraction, then that ought to be reported.

MR. ARGAWAL: Plus or minus ten percent in the dosage, that --

MR. TELFORD: Okay, plus or minus ten percent.

MR. ARGAWAL: Yeah.

MR. TELFORD: But you would like it to apply somehow to the idea of a variation around the treatment site?

MR. ARGAWAL: Right, treatment organ or site.

MR. TELFORD: Okay.

MR. LANDERS: And that's the way it reads now.

MR. TELFORD: Okay. Any other comments on one?

(No response.)

MR. TELFORD: Okay, how about two? This is radiopharmaceutical therapy when the administered dose is

ten percent different from the prescribed. This might be iodine P-32. Roy?

MR. LANDERS: Just a clarification. I noticed today for the first time, for some reason, I never noticed it before, the word "errors" occurring. That changes my thinking here. If a dose --

MR. TELFORD: Would you like to tell us your page and paragraph you're looking at?

MR. LANDERS: I'm looking at proposed 35.34(b)(2).

MR. TELFORD: Okay.

MR. LANDERS: And in general throughout this, the word "errors" occurs.

MR. TELFORD: Okay.

MR. LANDERS: I will assume that that will rule out such things as power failures, things of that sort. We're talking about human mistakes. If a dosage of ten millicuries is prescribed, 11.2 comes in, no error has been made, it's assayed, it's determined that it's not what was ordered, the physician is checked with, he says use it. No error has been made.

MR. TELFORD: He signed off on the 11.42.

MR. LANDERS: There has been no error, there's nothing wrong.

MR. WIEDEMAN: That sounds great.

MR. LANDERS: Okay.

MR. WIEDEMAN: It's only when he prescribes ten, you receive 15 and you went ahead and administered the 15 and then afterwards said oh, we had five more millicuries than we wanted. And now that's an error. As long as the physician says yeah, 15 is fine, that'll achieve the therapeutic benefit that I want to give, and he writes a prescription change, initials it or whatever, you're in good shape.

MR. TELFORD: Okay, any comments here on two?

(No response.)

MR. TELFORD: Okay, let's go to number three. I'm sure you're just waiting for this one, right? We have three separate, the ten percent in total is as current, the one on the fraction is a new one, that's off by a factor of two, and the one on the cumulative is also new.

Roy.

MR. LANDERS: I don't know how to delete, add or change, I just want to give an example of something that I have a problem with. Two different treatment regimens may have the same TDF, they may differ by more than ten percent in total dose and two physicians who are partners may use the different regimens. Why, I don't know. And I'm wondering if one of them -- and I'll just make up an example, I don't think this is correct, but suppose 4020 has the same TDF as 4525, one of those is 200 a day and one is

180 a day. And suppose the 4525 is incorrectly started at 200 a day and not discovered, for some unknown reason until 20 fractions, whereupon the physician says hey, it's got the same TDF as 4020, let's stop there.

MR. TELFORD: Okay, let's --

MR. LANDERS: Whereas the other physician would have said let's do that.

MR. TELFORD: Was the ten percent in total exceeded?

MR. LANDERS: Yes.

MR. TELFORD: Okay.

MR. WHITE: Then that would be a change in prescription.

MR. TELFORD: Kind of after the fact thought.

MR. LANDERS: The question is why the change in the prescription -- does that come in? Can the prescription be changed for a reason like that if the physician determines it is not clinically significant and it not be a misadministration?

MR. TELFORD: Currently under the proposed, no, it's after the fact. But --

MR. ARGAWAL: Here you say greater than ten percent error in total dose.

MR. TELFORD: Yes.

MR. ARGAWAL: If the doctor prescribes -- he

starts with 4500 and then changes his prescription to 4020, which he has given, there is no error in the prescription.

MR. TELFORD: Well in that case, in that example, you've not exceeded --

MR. ARGAWAL: You would not exceed that, that's right.

MR. TELFORD: You haven't exceeded a fraction.

MR. LANDERS: Okay, let's reverse it then. Start out with a prescription of 4020 and go at 180 a day.

MR. TELFORD: Just stop early. A physician can always decide to stop early by amending the prescription.

MR. LANDERS: Yes, but each fraction is ten percent low.

MR. TELFORD: Uh-oh -- well each fraction is ten percent low but that doesn't exceed this.

MR. LANDERS: Yeah, but his total dose then does.

MR. ARGAWAL: He stopped it.

MR. TELFORD: Well if the physician does not amend the prescription, yes. But let's say that if the fraction, the physician can always make the decision to stop now, change the prescription, sign off on it, you stop.

MR. LANDERS: No question about why the prescription was changed, is that right?

MR. TELFORD: The reasons are up to the authorized user.

MR. LANDERS: Okay.

MR. TELFORD: It could be the patient is not tolerating it, it could be the authorized user is convinced that that's sufficient dose. That doesn't look as if you're correcting your mistake after the fact. But if you go the other way, it gives that appearance.

MR. WIEDEMAN: I'll explain the history behind that particular proposed requirement. A hospital in Cleveland, Ohio, they were going to do a therapy regime on a patient and there was a miscalculation. They were going to give a boost dose each week and -- don't hold me to the numbers, but I think it was like the first week 170 centigrade, 180 centigrade for the first week, per fraction, the second week it was going to go to like 210 and the third week to three hundred and something. The third week they caught where the miscalculation took place and then the physicist went to the authorized user and said hey, we made a miscalculation. Your total prescribed dose was 6000 centigrade, we're right now at 5000. Now what do you want us to do? The authorized user said well I think the patient has achieved the therapeutic benefit of all this therapy even though we gave him a little extra each week, so I'm going to rewrite my prescription and I'm going to write it for 5000 centigrade.

Now the RSO disagreed, that this is a

misadministration. They had a lot of arguments between the staff, it went to the isotope committee, they argued about it. The RSO wrote a letter to the Office of General Counsel asking for a definition, is this a therapeutic misadministration. And if I remember right, the Office of General Counsel said that it didn't meet the exact wording of the misadministration rule, but it met the intent because the intent was to detect errors early and correct them. And the reason the physician was changing the prescription, he said that the therapeutic benefit was achieved; however, in reality one could question whether or not it was really changed because of the error being detected. Nobody will ever know.

So that's what brought about this.

MR. ARGAWAL: What was the decision?

MR. WIEDEMAN: Pardon?

MR. ARGAWAL: What was the decision? How was it decided, was it misadministration or not?

MR. WIEDEMAN: Well it meant that -- the word that we got back was that we have to clarify the misadministration rule to include fractionated doses, and that's why that's in there.

MR. TELFORD: See, that's why we're proposing something for a fraction, so you can't give the total dose in one fraction.

MR. WIEDEMAN: Now one could say that some of these increased fractionated doses are insignificant; however, there are several cases where that could be very significant, such as a hemi-body, 400 rads per day for three days. You certainly wouldn't want to give 1200 rads in one day.

MR. LANDERS: Yeah, but reporting to you people would be the least of our worries.

MR. WIEDEMAN: Yeah.

(Laughter.)

MR. WIEDEMAN: We did have a case where a patient was going to have hemi-body for three days, 400 rads per day, total of 1200 rads, and a miscalculation was made and they gave the patient 2000 rads in three days. Then the patient was admitted to the burn center of another hospital within a week or two with the admitting diagnosis of third degree burns caused by over-exposure to radiation, and it became a coroner's case and a legal case and it's a nasty one.

MR. TELFORD: Well, Roy, do you want to make a suggestion on a modification to the (3)(i)?

MR. LANDERS: Basically I like what I think the intent here is. What I don't like is the possibility that two otherwise clinically similar treatment regimes that differ by more than ten percent in total dose could be used,

one changed into the other. This does not allow this kind of possibility.

Another thing --

MR. TELFORD: Unless it's detected early on.

MR. LANDERS: Or unless it's detected after the last treatment.

MR. TELFORD: How about if it's the second treatment.

MR. LANDERS: Yeah, no problem there. But how about if it's detected after the last treatment and instead of 4020, 4525 was given.

MR. TELFORD: Right.

MR. LANDERS: And in those two examples, the TDFs happened to be very close to each other and the physician says oh, okay, I could have prescribed that way instead of this way. That aspect of it bothers me.

MR. TELFORD: Well --

MR. LANDERS: One other thing that bothers me about number one is it's frequently six weeks after the start of treatment when I know what the final total dose is going to be because I'm frequently told to give so many rads in so many weeks and then re-evaluate for boost.

MR. TELFORD: Okay. But there was a first prescription here that told you to give 4000 or something and then re-evaluate for boost.

MR. LANDERS: Right.

MR. TELFORD: So that total was the 4000, the boost would be a revision to that prescription, the original one, is that correct?

MR. LANDERS: Not a revision to it, but an addition. It was being included in the first place, just how much and how long was not known at the time.

MR. TELFORD: Okay. But what you were told to deliver was the 4000 and then you can either say it was a revision to that one or an additional prescription that told you to do an extra boost of 500 or 1000.

MR. LANDERS: Right.

MR. TELFORD: Tawfig.

MR. HAIDER: Yeah. I think in his case it is a misadministration. It just happens to be he got lucky and the TDF happens to be the same. The other thing about TDF, in the summer meeting, there's four different ways to calculate TDF and they all differ by up to 25 percent, and I'm sure something will fall along that line. And so I think in this case, it's somebody getting lucky that the particular TDF the way you calculate it happened to be the same. So I think we should keep it and call it a misadministration.

MR. TELFORD: Retain the ten percent.

MR. LANDERS: Don't get me wrong, I'm not arguing

against the ten percent, I'm arguing it as an absolute with no alternatives.

MR. TELFORD: Yeah. Well see, in the example you gave, the disconcerting part is that the authorized user made a decision to give the 180 fractions per day and what does the technologist want to do, override that? And that person decided to give 200 a day? We have a problem with that.

MR. LANDERS: Sure, I understand.

MR. TELFORD: Or was that a mistake that they repeated for 20 times? That's something we have a problem with.

MR. LANDERS: I understand.

MR. TELFORD: So I could agree with your first sentiment.

MR. LANDERS: But again the thing that concerns me here is that the physician has to go tell the patient, I mistreated do, if you want to contact your lawyer, do it.

MR. TELFORD: Yeah.

MR. LANDERS: And there's no clinical significance.

MR. TELFORD: Okay.

MR. LANDERS: Those are very small examples that I'm thinking of. Ordinarily this ten percent I think would be fine.

MR. TELFORD: Okay, what if we corrected those words in that safety net to say "clinical significance".

MR. LANDERS: That would probably take care of almost any objection I have.

MR. TELFORD: Okay. Well how about (ii) and (iii). Jerry, how do these strike you?

MR. MORRIS: I'm having trouble determining what (iii) means there, what does that mean?

MR. TELFORD: Okay, each fraction, let's say 25 fractions at 200 rads per fraction, total of 5000. So the total dose is 5000, take ten percent of that, that's 500. So that's the threshold for (iii), is the 500. The first day you're giving 200. If you give 250, you're within the threshold. As a matter of fact, if you give 450, you're still within the threshold. But let's say you just give 250. Second day, you give another 250. You have to do that ten times and add up that 50 increment, to exceed that threshold. So that just means you look at the cumulative after each fraction, to compare to this threshold. Now the downside of that is you have to look at that. The upside of that is that if you made a mistake like what if you gave 150 on each of the first five fractions, you didn't exceed this threshold, but now that you know you did that, you want to give more than the 200 for the next several fractions. So this allows a window within which you can vary and not

trigger any thresholds, correct for small deviations.

But now that I've explained it, what would you like to do with it? Would you like to delete it or modify it or retain it?

MR. MORRIS: Sounds pretty good to me.

MR. TELFORD: Okay. Ashok.

MR. DESAI: Sounds good to me.

MR. TELFORD: Tom.

MR. WHITE: Sounds good.

MR. TELFORD: Roy.

MR. LANDERS: With the proviso that we put in this "clinical significance" out in the reporting of misadministration, I don't have a problem with any of it.

MR. ARGAWAL: Does that mean that every day somebody has to sign or somebody has to say that it does not exceed greater than ten percent of the prescribed dose? What I'm saying is that after the first four days it was going on like 50, somebody did not check it.

MR. TELFORD: I think you have to make a record if you exceed it.

MR. ARGAWAL: If you exceed it.

MR. TELFORD: Yeah.

MR. ARGAWAL: But if you don't exceed it, you don't have to?

MR. TELFORD: I don't believe anything's

triggered. Tawfig?

MR. HAIDER: I'll go with Roy, if the "clinical significance" is taken out, it looks pretty good to me.

MR. TELFORD: All right, Sarah.

LT. KIRTLAND: Same.

MR. TELFORD: Any other therapy folks?

MR. LANDERS: If that change is not made, then I've got a problem with (ii) and with (iii).

MR. TELFORD: Fair enough.

MR. WIEDEMAN: So you're saying -- let me ask this -- you feel that (3)(ii) and (iii) should read at the end "greater than ten percent of prescribed dose if this would cause a significant effect to the patient"?

MR. TELFORD: No, I think he's saying in the safety net --

MR. LANDERS: Yeah, the overall safety net.

MR. WIEDEMAN: As determined by the authorized user.

MR. LANDERS: Chickens, hen houses and all that, right. The physicians that I represent objected in the most strenuous terms to this reporting to the patient.

MR. TELFORD: Unless it had clinical significance, or just in total?

MR. LANDERS: Yes. Now most of them do this, not because they're required to, but just because.

MR. TELFORD: Right.

MR. LANDERS: They object to being required to do it.

MR. TELFORD: Okay.

MR. LANDERS: I guess from technical, legal point of view, there's a self-incrimination aspect here. You have to open yourself up to a malpractice suit. Not only that, you have to do something when potentially can damage the physician/patient relationship. You can potentially damage the patient/technologist relationship. There are a lot of aspects of reporting this to the patient that are extremely objectionable to the physicians.

MR. TELFORD: Okay. Therefore, all of those are very good reasons for having the clinical significance test in the safety net?

MR. LANDERS: Yes, as far as we're concerned, that's correct.

MR. TELFORD: All right.

How about number four, brachytherapy source lost, leaking. What would you like to do with that reporting requirement? Do you want to delete that one, modify it, retain it?

MR. HAIDER: Retain it.

MR. TELFORD: Tawfig says retain it. Roy?

MR. LANDERS: Fine, keep it.

MR. TELFORD: Keep it. Okay, how about number five, brachytherapy administration greater than 20 percent different from what was prescribed.

MR. LANDERS: We're on number five?

MR. TELFORD: Uh-huh.

MR. LANDERS: Again, I think the word "errors", which I have been failing to see here -- in the official wording, it says "a brachytherapy administration such that errors..." makes this significantly more palatable, because when the physician places after-loading devices or the source that can be considered an error. Perhaps he didn't put it where he wanted to put it, but where he put it will be acceptable, and that would not be considered an error as such, unless of course he put it in the head instead of the pelvis.

MR. TELFORD: Right. Darrel.

MR. WIEDEMAN: Well let me ask this, you know, in the brachytherapy insertion of I-125 seeds in the prostate, many times, you know, we miss the prostate and get it in the bladder. Now one could ask was that an error or was that intended. Probably not intended, but it's an acceptable practice.

MR. LANDERS: I wouldn't call it an error, it certainly wasn't intended.

MR. WIEDEMAN: So how do you feel we should

clarify that?

MR. TELFORD: I thought Roy was talking about the example of, let's take the prostate implant, the physician in the pre-plan decided to put in 15 seeds, but in surgery, only 12 could be implanted, or alternatively he got there and said oh, I can put 20 and that'll do the job better. So he comes out of surgery, signs off on the final prescription, it says 20 or alternatively 12. Okay, in that case no error.

MR. LANDERS: Sure. But also in this case where he wanted to put in 15, he did and there were only nine left. But that's the same thing you were just describing. They went into the bladder and were retrieved or came out.

MR. WIEDEMAN: But couldn't the physician -- say he wanted to put the 15 seeds in, ten of them were inserted in the prostate, the other five ended up in the bladder. Now he doesn't know that when he's in surgery. When the patient comes out of surgery and they go over to x-ray and he takes the radiographs, he says oh, we've got a couple in the bladder.

Now I would think that the physician would then rewrite the prescription saying now we want ten seeds in the prostate and determine whether or not that's going to achieve the therapeutic benefit, or else determine we're going to have to take the patient back to surgery and insert

more seeds -- I would think.

MR. LANDERS: Well I'm not necessarily sure that on the spot he would go ahead and change the prescription to say let's apply ten seeds instead of the 15 we wanted to, because five of them got gone. But after some amount of time, if we did radiographs and treatment planning to show what we think will end up being done in that implant, at that time the physician may say okay this plan. Now that was a significant time lapse between the time of implant, between the time of his initial prescription.

MR. WIEDEMAN: Well I think there is a way of doing it. One could write a prescription showing a range, say well I want to prescribe 3500 to 4000 centigrade to the prostate. Then that would allow for the seeds that didn't make it into the prostate and still fall within that range.

MR. LANDERS: Yeah, but obviously if it doesn't fall within that range, and we under-dose, we have to come back and make a recompense for that somehow or other, external beam or some -- we do that.

MR. TELFORD: Well are there suggestions for how to modify number five?

MR. WIEDEMAN: See, I wouldn't consider that an error, I'd just say that's part of the practice of brachytherapy.

MR. LANDERS: That's right. I think the word

"errors" provides a significant easement in this to the way I had been thinking of it before. I don't consider it an error if he can't place that seed where he wanted to because there's bone in the way.

MR. TELFORD: Okay, but what did he do after surgery, he revised the prescription?

MR. LANDERS: No, he recorded what was done.

MR. TELFORD: Right, but then he -- he changes his pre-plan.

MR. LANDERS: Not yet, he just records what was done. And later on, after swelling and so on and so forth, floating seeds have gone to the lungs, whatever they're going to do, then we will try to get a dose determination of what will be in 17 months or four years or whatever, to the volume we tried to implant.

MR. TELFORD: Okay. Tony, you had your hand up.

MR. TSE: Yes, I think in Roy's example, essentially what we had intended, because in the Federal Register notice, we say that during the implant operation, the physician may not be able to implant the seed sources at the precise location planned. The way you stated it, it's not really an error.

MR. TELFORD: Sarah?

LT. KIRTLAND: Just a comment. We're doing the surgical implants -- this is what I've been told by the

physicist -- we're doing the surgical implant less and less precisely because there is a discrepancy. The treatment plan can look very accurate and precise and you know exactly what you're doing, but when they go to surgery, it's very hard to make it look like the treatment plan. And it's encouraging the doctors to do that kind of treatment less and less.

MR. TELFORD: Okay. Anyone over here?

(No response.)

MR. TELFORD: Okay. Well how about -- this is rather similar to 35.33. You could make the same suggestions for the change to the radiation safety officer here to take whatever actions we said before for the occurrences or incidents, if we may call these. And in (a) we notify NRC by telephone during the occurrence, and (a)(4) --

MR. LANDERS: I'm with you now on (a)(4).

MR. TELFORD: Okay, (a)(4) is therapeutic use not authorized, for the (b) events which are the misadministrations here, and (e) have a written report within 15 days and (f) we have the records, the prescription and record of dose, three years. The misadministrations for ten years.

Any comments on these? I assume you would make the same comments here as you made on 35.33. These are the

cryptic descriptors of the same things -- the real words that are in the Federal Register notice, so you should look at those words for exact wording.

Roy?

MR. LANDERS: You're talking about in the paragraph (c) here, you're talking about allowing alternatives and more additions instead of the radiation safety officer?

MR. TELFORD: Correct.

MR. LANDERS: Okay.

MR. TELFORD: The same alternatives that we mentioned before I think should apply here as well as there.

MR. LANDERS: Right, okay. Also, for any medical use that results in a therapy event or misadministration, retain the record as directed in paragraph (f) -- well wait a minute, "shall promptly investigate its cause and make a record for NRC review".

MR. TELFORD: Does it say retain it for NRC review or --

MR. LANDERS: It says "shall promptly investigate its cause and make a record for NRC review, retain the record as directed."

MR. TELFORD: Meaning that when the inspector gets there, the inspector may want to look at the record.

MR. LANDERS: Right. Now my question here is do I

have to have sitting over here a record of each and every event, or can I have a listing of those events and allow the chart to be the record? Do I have to have a written --

MR. TELFORD: Seems like your chart is your record.

MR. LANDERS: Okay.

MR. TELFORD: Darrel, what would you say?

MR. WIEDEMAN: Yes.

MR. LANDERS: Good.

MR. ARGAWAL: Record does not mean record of the investigation?

MR. WIEDEMAN: That's more like what we would look for, what they did -- their corrective actions if they implemented any at all.

MR. ARGAWAL: A record of the investigation. Suppose you have to call a technologist and ask why did it happen and you have to make what her answer or his answer was, and you have to write that down and make all those records for review. Or just the event that that happened, which is in the patient record, that 200 -- instead of 200, 240 rads was given, like 30 percent is in a fraction. So the first fraction went from 200 to 250. Now it becomes an event and radiation safety officer has to investigate it. Now in the investigation when he talks to the physician how should it be corrected and all that -- should that be --

MR. TELFORD: Oh, this is like the incident that gets reported to the committee --

MS. RHODES: Right, it'd be in the committee minutes, but it should not -- the investigation should not be put with the patient's record, in the patient's record you document -- well you'd see the physician's order for 250 rads and you'd see documented that the patient got 500. That's all you would put in there. You wouldn't go on and say anything about this was a bad thing, it's just there.

MR. ARGAWAL: That's what we want, if you're correct.

MR. LANDERS: I seem to have gotten two different answers in my mind here. One sounded like it needed a written record for review.

MR. WIEDEMAN: It says under (c) that the radiation safety officer shall promptly investigate its cause and make a record. Now make a record, that means that the RSO has looked into this matter and has some kind of a document that 200 rads per fraction was prescribed and on Monday we gave 280. And the reason we did this was because -- or we retrained the technologist, or did something to correct the action. That's what we'd really be looking at.

MR. LANDERS: Uh-huh.

MR. WIEDEMAN: Not necessarily the patient's chart. However, I wouldn't say we wouldn't ask to look at

the patient's chart because you may want to look at that also.

MR. LANDERS: Well certainly what I would prefer is to keep a list - patient's name such and such, date such and such, event. Go to the chart to find the event. I mean, this would almost be palatable, but to have to --

MR. WIEDEMAN: Would you really want to put that in the patient's chart, when patients' charts are transferred from hospital to different physicians and --

MR. LANDERS: Wait a minute, I'm keeping a list of my events -- a list, not records or reports. And if an inspector comes and says let me see all of your records of events. Here's the list. And if we want to, we can go see the records. But I don't have to produce a written report for each event.

MR. TELFORD: Well if we do this as we were doing with the 35.33, we had a couple of alternatives for this person here, and we were going to allow for that person making a report to the RSC or the quality assurance committee, and it would seem to me the minutes of those meetings would be the report and the determination about that event. But if you don't have one of those --

MR. LANDERS: I would just go to the president of the PC.

MR. TELFORD: Then you would --

MR. WIEDEMAN: Let me ask, in your particular scenario, if I asked for the list, would you be able to show me what appropriate actions you took to correct this event? You have a list that Mrs. Jones was given 250 rads versus 200. Where would I see what appropriate actions were taken to correct this problem?

MR. LANDERS: You probably could not. As far as a clinical correction or makeup, that would be in the patient's chart. As far as having given a tongue-lashing to the tech or the dosimetrist or myself, there probably would be no record of that except in memory.

MR. WIEDEMAN: I would think you wouldn't be complying with the appropriate action there, "take appropriate action, make a record".

MR. LANDERS: That's what I'm saying, we do take appropriate action.

MR. WIEDEMAN: But the record of that appropriate action.

MR. LANDERS: And now we're required to keep a written record of it apparently. This is the objectionable part of it, producing the paperwork.

MR. TELFORD: Tony.

MR. TSE: The required record, what items should be in the record is stated in the proposed regulation, and it says that you need to have the patient's name and the

people involved, patient's social security number and so on, a brief description of the event, what improvement is needed to prevent recurrence and the action taken to prevent recurrence.

MR. LANDERS: Where are you reading from?

MR. TSE: On page 1449.

MR. LANDERS: But that's beyond this, isn't it?

MR. TSE: No, that's an item in the records. It describes what kind of information should be kept in the record.

MR. TELFORD: That's the information that should be contained in your list. So tell us what you don't want to put in your list.

MR. WIEDEMAN: So far you have the name and you're saying that --

MR. LANDERS: I'm just saying I would keep a list and at the top of the list it would say "Events", maybe on the right-hand side it would say "Misadministrations" and then I would go down the page numbering them and I would have a patient's name and date.

MR. WIEDEMAN: Would not have the allied health personnel, the technologist, dosimetrist that were involved, the physicist, the referring physician's name would probably be in the chart, the social security number.

MR. LANDERS: All of that would be available in

the chart, yes.

MR. WIEDEMAN: A brief description of the event -- that's the key, is the brief description and then why the event or misadministration occurred and the effect on the patient. Effect on the patient is probably in the patient's chart. What improvements are needed to prevent recurrence. That is what I think you won't have.

MR. LANDERS: You're right.

MR. WIEDEMAN: So what do you recommend, that we change the rule to something else?

MR. LANDERS: We're skipped ahead down here to (f), huh?

MR. TELFORD: Well (f) is the records, and if you have an (a)(4) event or misadministration, that description is the content.

MR. LANDERS: No, no, this is for events, all events, isn't it?

MR. WIEDEMAN: It's for events or misadministrations.

MR. LANDERS: Right. So it's for unreportable events also, that's the one I'm talking about.

MR. WIEDEMAN: Let me give you an example of how this may be of benefit to you. Recently we had a case where a small child -- this is pharmaceutical therapy -- small child went to the University of Pittsburgh I believe and had

a neuroblastoma, lethal disease of the kidney, they tried certain treatments, didn't work. And they knew it was a terminal disease, they referred them back to a large university hospital in the midwest and the patient's parents presented the patient to the authorized user. They decided that a therapy of I believe it was MIBG I-131 would be appropriate, and they gave the -- they made out a prescription, they followed the standard protocol and the patient died three months later. Okay, now the parents are alleging that they overdosed their child and killed their child. Disregarding that, the child had a terminal disease anyway.

We originally told -- when the allegation came in -- that we do not require physicians to follow any standard dose in therapy as long as they follow the protocol that's been approved by the FDA, that really we have no jurisdiction over that. They weren't accepting that and I believe they sent a letter to their Congressman and then we had a congressional inquiry, and then we looked into it.

Now fortunately when we went to this large university hospital, they were able to pull out the patient's records, they showed us a prescription, it was prescribed, 5-10 millicuries, it also -- they pulled out their protocol that was approved by the human use research committee and it fell right in that category, and we looked

through the medical records. Everything was top notch. So we wrote up a report and sent it back with a copy to the Congressman saying that we looked into the matter and the proper dose was prescribed, the dose was given and they did everything that was acceptable to the medical community. And now it's closed. But if we didn't have all these little records, I don't know what we would tell them, other than they didn't maintain a record of the dose, what was given, what was prescribed, the protocol.

MR. LANDERS: I'm not suggesting that we don't do that, we do that whether y'all ask us to or not. I'm just suggesting that I don't want to be required to write a written report on every event that's not reportable, including names of all people involved, why it happened, how we expect to prevent it from happening again in the future, when one event that I'm talking about may be the failure of the tech to sign the chart.

MR. TELFORD: Okay, so you're saying that for the (a)(1) through (a)(3), don't require all that information.

MR. LANDERS: Right.

MR. TELFORD: But for misadministrations, or (a)(4), it's okay.

MR. LANDERS: Yes.

MR. TELFORD: Santiago, you had your hand up.

MR. GOMEZ: They said the report must not include

the patient's name.

MR. LANDERS: So it couldn't be the chart, you're right.

MR. HAIDER: Yeah.

MR. WIEDEMAN: I think that's to the NRC. We don't want the patient's name because they may end up in the public document room and there are lawyers that go through the public document room.

MR. TELFORD: Can we take 35.34 in total? Are there any comments that you haven't gotten out?

MR. MORRIS: What is an example on (b)(4) of an unrecoverable spilled source, what are we talking about.

MR. TELFORD: Lost.

MR. WIEDEMAN: You know, keep in mind that a -- it's very common for patients to pull their brachytherapy applicator out. To me that is not really a reportable event and sometimes we have resident physicians that happen to be the resident on the night shift when the source is supposed to come out, he's not sure really what a sealed source looks like, he pulls the applicator out of the patient, the source falls down in the bedsheets -- it has happened many times. Recently we had a case where I think it's the Ammon applicator, the long wire with the source on the end -- well he pulled the wire out but he didn't know that there's supposed to be a little round thing on the end, the source

fell down in the bedsheets and when it set off the alarm at the sanitary landfill, the hospital's position was this is just a diagnostic dose, just wait a day or two and it'll go away. A day or two went by and it did not go away, they did an inventory of their sealed sources by counting the wires sticking down in the safe, everything accounted for except when they went through the trash, they found the source.

MR. MORRIS: Okay, now what about on say a prostate implant of I-125 and the source passed into a commode and is gone. Do you want that reported?

MR. WIEDEMAN: Or they urinated the seed out?

MR. MORRIS: Yeah.

MR. WIEDEMAN: My opinion, that's the best place to have it go.

MR. MORRIS: But it requires a report.

MR. TELFORD: Was it lost? Can you say it went down the commode?

MR. MORRIS: Well it's unrecoverable.

MR. WIEDEMAN: The letter of the law -- you know, the regulations under Part 20 allows disposal down the sanitary sewer, but it says that it shall be readily dispersible and soluble in water. Sealed sources really don't fall in that category. In theory, yes, it would be a reportable event -- a significant event, no. Because you know where it went. There's nothing under your control that

you could have done other than put a little screen over the toilet. Not everybody does that -- at least I don't know anybody that does that. Whenever I would get a report like that, we'd just file it away for information only.

MR. TELFORD: Jerry, how could we fix this?

MR. MORRIS: I just don't see the need to report the situation.

MR. TELFORD: Would you say if you can account for the source?

MR. MORRIS: Yeah.

MR. TELFORD: If you know what happened to it, then you don't need to report that, so you're looking for a safety valve there?

MR. WIEDEMAN: How about using -- I think it's Part 20 language, "unrecoverable or lost sealed source that could cause exposure -- significant exposure to people in unrestricted areas." That's Part 20 language. You know that half a millicurie of I-125 down the commode is not going to cause any significant exposure to anybody, even a sanitary sewer worker.

LT. KIRTLAND: What about if it's the sealed source that goes down?

MR. WIEDEMAN: Now 15 or 20 millicuries of cesium, that's different.

MR. LANDERS: That's different, you've got to tear

the plumbing apart to get those.

MR. TELFORD: Well if I'm understanding Jerry's idea here, he's really saying that we ought to put a proviso in number (4) that says if I can account for this unrecoverable source, then I shouldn't have to report it, if I can say for sure what happened to it.

Tony.

MR. TSE: Do you mean only for the prostate implant or do you mean other sources?

MR. MORRIS: I don't know what else might fit the category.

MR. TSE: So maybe he just needs one special exemption for that.

MR. LANDERS: Well don't name the little bitty sealed source because more and more of them are coming in each and every day, but I think in addition to that proviso that if we know what happened to it, we can account for it, and have reason to believe that it will not cause any significant exposure to unknown members of the public.

MR. TELFORD: Well the Part 20 requirements apply here whether we want them to or not.

MR. LANDERS: Yeah.

MR. TELFORD: So I guess it wouldn't hurt to add that language, that would sort of close the door on being able to account for a large sealed source that's missing,

but those truly ought to be reported.

MR. LANDERS: Oh, yeah.

MR. WIEDEMAN: On unrecoverable sealed sources, I remember a case quite a few years ago where a patient expired during the course of a brachytherapy treatment and the patient was released to a mortuary with the sealed sources still in, and the patient was cremated the following day. That was definitely an unrecoverable source and a horrendous release to the environment. Now that should be considered a reportable event.

MR. TELFORD: Jerry, anything else on (4)?

MR. MORRIS: No, I like that language of someone where it doesn't present a hazard.

MR. TELFORD: Okay. Stanley.

MR. GIPSON: Nothing.

MR. TELFORD: Tony.

MR. TSE: John, I have a question to the volunteers. Both in this particular item and the item which we talked about for notification to the patient, if we said "no significant hazard" in this regulation, how do you determine whether there is a significant hazard or no significant hazard -- what criteria do you suggest to use on those determinations? Like the item (4), it's called a leaking source. Now whether the leaking is a significant hazard to the patient or not significant hazard to the

patient, how a person or licensee could determine whether it's significant or not.

Similar to what happened to the reporting to the patient, who is going to determine whether it's serious or not serious? That's a question I had while listening to your discussion.

MR. WIEDEMAN: I'll give you an example. There was a hospital in Ohio that they decided they were going to put what they called the I-125 super-seeds, I think they're 40 millicuries apiece, into a brain tumor, a young lady. And the technologist was not familiar with how to reload these seeds into a ribbon, and they had used it on a patient -- because these are reusable seeds. So he took a razor blade and he split the little nylon ribbon open to get the seeds out. Well in doing so, he also split the sealed sources. But he loaded them into a new nylon ribbon.

Now the seeds were inserted in the patient's brain in surgery, and within a couple of days, they went up to do the standard, routine radiation surveys and they noticed over the thyroid gland a very high radiation exposure, and then they immediately started taking urine samples and they found iodine 125 in the urine. So now one could assume that we have a leaking source. Now the physician had to make the decision shall I remove these leaking sources or shall I leave them in because the brain tumor is certainly more

hazardous to the patient's life, and it was decided to leave the sources in.

Now that was a medical decision and I believe that we accepted that physician's authority to do this. There was a lot of controversy over it, but anyway, they left seeds in to give the brain tumor the full treatment. But one could ask when do we draw the line.

MR. LANDERS: In my opinion, leaking sources should be reported, period. Whether it has anything to do with the patient or not.

MR. TELFORD: Tawfig?

MR. HAIDER: Yes, report them.

MR. TELFORD: Report them.

MR. TELFORD: Tony.

LT. CMDR. PULCRANO: Yes.

MR. TELFORD: Stanley.

MR. GIPSON: Yes.

MR. TELFORD: Report them. Jerry.

MR. MORRIS: If they're leaking, yes.

MR. TELFORD: Okay. Ashok.

MR. DESAI: Yes.

MR. TELFORD: Okay.

MR. GOMEZ: When they're leaking they have to be removed.

MR. TELFORD: So if they're leaking you shouldn't

use them.

MR. GOMEZ: Send them back to the manufacturer.

MR. TELFORD: All right, send them back to the manufacturer. Okay.

Well could we take 35.34 as in total here? Any other last thoughts, suggestions?

(No response.)

MR. TELFORD: No? Okay.

MR. LANDERS: What is the -- paragraph (g) on there, what does that mean?

MR. TELFORD: Oh, that says that all those other responsibilities that you have, you're not relieved of them. That's a legally driven paragraph. Our Office of General Counsel is driving that.

MR. LANDERS: Okay.

MR. TELFORD: Why don't we adjourn for lunch and we can come back at 1:00. At 1:00 -- we've concluded, we've done everything on the agenda, if you have some final remarks you'd like to make, I'll let you do that at that time, 1:00, and then we can just adjourn the meeting.

For those of you that would like to have a review of the recent misadministrations, I'll go through those for you, but I don't think I ought to make it a requirement that you sit through that if you don't want to, so you could be excused after you've given your final remarks you'd like to

give.

But since there was a question, we'll certainly do that.

Any announcements we need to make before lunch, Dr. Kaplan?

MR. KAPLAN: No.

MR. TELFORD: Okay. You have all the forms you need, and you said send me the originals.

MR. KAPLAN: By the 26th.

MR. TELFORD: Oh, the close of the fiscal year, right. Congress may never give us another budget.

Okay, well let's adjourn for lunch then.

MR. ARGAWAL: Do we need to come back at 1:00, if we don't have any remarks?

MR. TELFORD: No, don't feel obligated to come back. If you've given all your remarks and you don't want to go through the survey of the recent misadministrations, then you may be excused. Let's adjourn.

(Whereupon, a luncheon recess was taken at 11:52 a.m., the meeting to resume at 1:00 p.m., the same day.)

AFTERNOON SESSION

MR. TELFORD: Well welcome back to the final session. I thought I would give you an opportunity to make any final remarks that you wanted to make about this whole endeavor, your experience with the 60-day trial or your experience with the pilot program, or any remarks on rules or reporting requirements, anything that you want to finally add to the record.

I guess we can start over here with Ken.

MR. FRYMAN: (Inaudible comment.)

MR. TELFORD: Okay.

MR. GARRISON: I'm just happy to be part of it. I think the ideas are real good, we're real QA oriented at our hospital. The QA committee, hospital-wide, knows I bring back reports to them and talk with them, and they're real excited about it, even though they don't understand really, my department. We've already, our physicians have put some blurbs into the local medical news and things like that, telling -- and we've sent out flyers to tell physicians that our new rules are going to be to have prescriptions or a written referral. So it has kind of taken hold at our place. It's been a good experience.

MR. TELFORD: Okay.

LT. CMDR. PULCRANO: Well the experience has been different for me, being in the military you know, we're

inundated with quality assurance from one end to the other and being hit with a lot of -- well do we really think this is necessary, don't we have enough quality assurance, why are we getting more quality assurance than we really feel we need -- I think it was a good approach and it was nice having a chance to sit down and discuss what should and shouldn't be in the rules and regulations and I at least appreciate the fact that you're giving us a chance to in some instances help regulate ourselves rather than be regulated by foreign entities, so to speak.

It's been good.

MR. TELFORD: Thank you. Sarah.

LT. KIRTLAND: I don't have very many comments other than what I've already said. I have appreciated this forum, I think it has been a good one and I hope it works.

MR. TELFORD: Tawfig.

MR. HAIDER: I think it has been great for all of us and we really appreciate everybody spending so much time suggesting and trying to improve what we have and have a no-nonsense regulation that makes sense.

MR. TELFORD: Santiago.

MR. GOMEZ: I have been happy to participate in this group and get a chance to talk with you and to listen to you. I have learned many things that I did not know, and I hope that this program will make us to have a real human

use of radiation really healthy, that's what I want. Thank you.

MR. TELFORD: Thanks.

MR. LANDERS: Well I certainly appreciate the opportunity for user input into this process and I hope that some of our input ends up being incorporated into the final results. I feel like the whole project has been beneficial both to NRC and us as the regulated community. I hope it ends up being that way.

MR. TELFORD: Okay. Tony.

MR. TSE: Thank you for your participation and the suggestions. We will consider all the comments given to us from all the participants plus public comments, et cetera. But the process does not stop at this room. When you go back, if you find additional comments you want to convey to us, you could still give me a call.

MR. WIEDEMAN: On behalf of the site team members, I want to personally thank you, along with Ed Kline, Josie Picone, Tony and me. We appreciate your comments and especially your participation in the volunteer program, and we do appreciate your comments and your input that you've given us in the last two days. And one point I'd like to make is remember this is a -- if I remember right, this is the first time we've ever had a performance-based rule that affected a large number of materials programs and so it's

important that it be done properly and we want to get your input and incorporate your comments into that rule so it'll be a working rule that will have minimal impact upon you as a licensee.

So once again, thank you very much.

MR. TELFORD: Tom.

MR. WHITE: I can only echo Roy's comment. My gratitude for the opportunity to participate. I would like to say also that when the changes are incorporated, that the participants will have an opportunity to look at the changes.

MR. TELFORD: Okay. Well we want to thank you all once again for participating. I'd like to say that this group has provided some very convincing suggestions, I was very impressed with your contribution.

Thank you. Meeting adjourned.

(Whereupon, at 1:22 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: NRC-348-293

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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.

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