OFFICIAL TRANSCRIPT OF PROCEEDINGS

Agency: U.S. Nuclear Regulatory Commission

Title: Quality Assurance Workshop

Docket No.

LOCATION: Irving, Texas

DATE: Friday, September 14, 1990 PAGES: 228 - 458

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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

QUALITY ASSURANCE WORKSHOP

Regency Ballroom C

Holiday Inn

Irving, Texas

Friday, September 14, 1990

ATTENDEES:

MR. TELFORD

MR. KAPLAN

MR. NELSON

MR. KLINE

MR. TSE

MR. DADARI

PATRICIA WOOD

SURESH BRAHAMAVAR

DAVID WOOD

MR. LA FRANCE

OSCAR HIDALGO-SALVATIERR

TERRY ROY

DOUGLAS BENNETT

SUE GOODWIN

ED MOK

JOHN FELDMEIER

BRANDY WALKER

MARK SHAFFER

NELLIE KELTY

DAVID BELLEZZA

EMERY JANICE

BRUCE HAMMOND

RAY FOSTER

PROCEEDINGS

[8:34 a.m.]

MR. TELFORD: Good morning.

Welcome to the second day of our workshop. I have the agenda on the view-graph.

I would point your attention to the fact that, this morning, we're going to talk about the regulatory guide, and this afternoon, we're going to talk about the recordkeeping and reporting requirements and, also, the definition of events and misadministrations.

This morning, we're going to have Dr. Anthony Tse go through the guide with you. I'd like you to feel free to suggest if you would like to delete, modify, or retain or make additions to each of those sections as we go through.

So, I'll turn it over to you, Dr. Tse.

MR. TSE: This morning, we will be turning our attention to the details. Yesterday was the performance-based objectives. Today, we'll talk about the elements which the NRC staff suggest as a way that the licensee could develop their QA program to meet those objectives. Keep in mind, those are suggestions; they are not requirements.

Yesterday, we discussed the different elements related to the objectives. Those discussions will be also applicable to the guide, because the reg guide eventually will be modified to match whatever the changes and

modifications made in the regulations.

Second, yesterday, there was some problem of suggestions about terminology. The terminology here, in our regulations, draft regulations, proposed regulations, and the draft guides, says one thing, and you may think it's another way, another meaning. So, please, again, make suggestions on the terminologies in the guide for alternative suggestions, so we may be able to consider to use another term which, perhaps, is more appropriate.

The guide is developed into several different parts. The first portion is related to the introduction, the purpose of the guide, and the second portion was related to auditing and the responsibility. Then comes the general elements applicable to all program areas, like nuclear medicine, teletherapy, brachytherapy, and then comes with the radiopharmaceutical therapy, brachytherapy, and finally, teletherapy.

What I intend to do is to go through each section of the guide. I will not go through each element to expand the element, because you're already supposed to read this and already knowledgeable about those elements. So, I would just go to the section and ask you for any suggestions or modifications -- retain, delete, or, very important, what additional items you may want to add.

I think that's important, because if somebody may

use this guide as a regulation, if it is so, then it will have many different alternatives of acceptable ways to meet, to be concluded in that guide, than in essentially give the -- make the alternatives available to the licensees.

If there is no further general questions, we'll go to the Section 1. Unless somebody has questions, we can skip the introduction or the purpose of the guide, etcetera, go to Section 1.

Anybody have questions on the introduction portion?

[No response.]

MR. TSE: If not, then we'll go to Section 1, which is at page 4, on page 4.

This section has two elements, and they are related to the responsibility, authority, and audit. I heard yesterday -- Terry has some suggestions or comments.

Please start.

MS. ROY: Well, first of all, we're going back to this basic QA program; it's listed as QA program. That's already been discussed.

The other part is the auditing. In Section 1.2, it says that the audits will be performed by qualified personnel who are not involved with the activity being audited.

Now, in certain situations, that's going to be

perfectly in fine, in large hospitals or in communities where there's different centers that can trade off someone to audit. But in some of the rural areas, where you've only got one camera, just a few procedures being done, they may have difficulty bringing in someone that's not involved with the activity to audit them. They may not have personnel coming, health physicists coming in quarterly to do an audit or whatever. That may be a problem with some smaller areas. That's what I was concerned about.

MR. JANICE: It could end up being an expense problem, also. The parochial school system has to have evaluations, also, and you might have teams from Corpus Christi going up to San Antonio to evaluate schools or from San Antonio to Dallas, and there's an expense problem there, and let's face it there aren't too many hospitals that are just throwing money up in the air for the hell of it.

MS. ROY: Especially if they're a small situation. They don't have the money to throw around.

MR. TSE: The question, though, is that involved -- not being involved with the activity being audited.

MS. ROY: Right. Couldn't it be an internal audit, where they're doing it themselves and just making record of that?

MR. TSE: Okay.

MS. ROY: If you could change the wording to

"qualified personnel," period.

MR. TSE: Well, this does not really say you cannot use an internal auditor. But the question is this: If I'm doing the work, I design a program, and doing my work, and I thought everything is all right, that's how I designed it.

MS. ROY: Right.

MR. TSE: If I go back to audit myself, if I make some errors, is it likely I will find my own error?

MS. ROY: Well, you're going to have your licensed user, your authorized user, and probably the technologist that's doing the exams themselves.

MR. TSE: They are two separate persons.

MS. ROY: Two separate people, but they're both involved with the activity, and I can see the state coming back and saying, now wait a minute, you're being audited by yourselves and you're both involved in the activity -- bingo.

MR. TSE: I see. So, the words may not be clear.

MS. ROY: Right.

MR. TSE: The intention is that as long as the person is another person to audit --

MS. ROY: If it's going to be an internal audit, let it be two people conferring on it, at least.

MR. TSE: Is there always two people in a small

hospital?

MS. ROY: You have an authorized user and you have a technologist.

MR. TSE: So, how you would suggest to modify, perhaps like involved directly with the program or something? If you don't have any suggestions, that's fine, too, because I understand the point. We'll try and figure it out.

MS. ROY: I would just leave off the last phrase, "who are not involved in the activity."

MR. TSE: You would suggest just to leave it out.

MS. ROY: "By qualified personnel."

MR. TSE: Okay.

Any other suggestions?

MR. FOSTER: A suggestion that I may have is that you could have it stop at "qualified personnel," but have it reviewed by one person not directly involved.

MS. ROY: Yes.

MR. FOSTER: You can do the audit yourself, but then that would be viewed by, let's say, the medical director or the management, have them review it. That way you would be able to cover, you know, have an unbiased opinion or an unbiased person at least reviewing your audit.

MR. TSE: A couple of sentences down, there is a phrase that says audit results will be document-reviewed by

management. So, already, there is one layer.

MR. FOSTER: You already have that covered.

MR. JANICE: By the same token, that does not necessarily mean that -- when you say "management," it might mean management in another department that's reviewing what you're doing, but then management itself would be the director of your department or would be the director of the hospital or an assistant administrator of your area.

MR. JANICE: It still boils down to words that you're playing with.

MR. TSE: ht. But any kind of rule in the guide will have to e transmitted by words. There is no other way of communicating between different persons. But we want to be clear.

The word "management" in element 1.1 says management means licensee's management. So, management -- we view that management, if you truly follow the words, would be the licensee management.

Does anybody have a problem with that? Do you have a problem with that?

MR. JANICE: The licensee management can end up being yourself again.

MR. TSE: No. Management -- it's not so. The licensee management is not you, to do the actual work of designing these procedures. They sit somewhere in the --

MR. JANICE: In the ivory tower. Okay?

MR. FELDMEIER: But management isn't always qualified personnel, because they are dependent on their health-care specialists, technologists, physicists to present the information to them.

Could you solve the problem by saying ideally this audit should be conducted by personnel who are not directly involved, but the NRC recognizes the fact that this might be impractical for a very small clinical operation, something like that?

MS. WALKER: We would have to pay someone to come in and do it. There is no one -- there is no one qualified who is not directly involved, and the radiologists aren't qualified. A radiation oncologist isn't qualified, in my opinion, anymore that I am qualified to audit their operation. And everyone that is involved are the ones that qualify.

MR. JANICE: By the same token, you have the same thing when the JCAH comes around to review your place. not always someone that does nuclear medicine and comes in and evaluates the nuclear medicine section. It's not always an oncologist who goes to oncology; it's someone who is totally disinterested, supposedly disinterested in what's going on.

So, what's the difference in JCAH coming in?

MS. WALKER: So, why do we have to pay yet another person to come in and do the same thing?

MR. JANICE: Well, to be able to stay in business.

MS. WALKER: It seems like we're keeping them in business.

MR. TSE: The first item is not intended here to have somebody else to come in and do your audit. You have the technologist, you have the chief tech. The chief tech can audit the procedures.

MR. TELFORD: What if we drop the words "not involved," as don't audit your own work, don't audit yourself?

MR. JANICE: That's what it boils down to.

MR. TELFORD: Another idea that might be -- I earlier heard Terry say was what if you used a team, and even in a small place you've got two people. So, maybe there's only three people in the whole place -- the authorized user, the physicist, and the technologist. So, if you took the physicist and the technologist and used them as a team, even though they're auditing the work that they did, the other one keeps the other one honest, because -- and also, they see their blind spots. I mean that's what we're after.

MR. TSE: Okay.

MR. HAMMOND: I understand the team concept, but

maybe some of our operations are extreme. If you've got a hospital that does 10 or 15 procedures a year, they've got to have a physicist come out to audit work that's already done. You know, the cost factor gets to be prohibitive for these people to continue.

Obviously, most of the 10 to 15 were the ones that actually needed to be done. They were lung scans or some other kind of emergency procedure. But if you keep loading the cost to these people, between the license fees and inspection costs and then the audit costs, what benefit are you really going to get?

We're talking about some places that do 6,000 procedures a year and there's a lot of opportunities for things to fall through the cracks. This may be of some importance there. But if you're talking about a small place -- and half the hospitals in the United States are 150 beds or less -- you're talking about a minority of hospitals that are going to do thousands of procedures per year.

This guide will nail down the 150 and less hospitals, such as well as it will the 700-bed hospital. And in our operation, we have circuit-riding radiologists, the tech circuit-rides, the physicist circuit-rides, and physicists help write the procedures, the tech does the procedures, and the doctor is responsible for it. So, who are you going to get that's not interested that's qualified?

If you go to some tiny hospital out here, 300 miles from the metropolitan area, you're not going to find anybody for 300 miles that's qualified.

MR. TELFORD: Can't you use a team?

MR. HAMMOND: Who is going to pay for the team? If I set up a team to go to all these hospitals, who is going to pay for it? If I've got two or three people -- or you know, we're going to take our guy that works in east Texas and send him to west Texas and send the guy from west Texas to east Texas. You know, who is going to pay for all that? Are the hospitals going to pay for it? Am I going to have to absorb more cost?

Eventually, the patient is going to end up paying for it, and if you've got, according to your information in here, 7 million procedures done a year and a error rate of 1 in 10,000, what benefit is all this audit and all this other stuff going to be for anybody?

I mean if you're doing 10 procedures a year, you're going to be there 1,000 years before you see a mistake.

MR. TELFORD: Can't you let the guy who is in east Texas, can't you just let him stay there and work with the technologist, working as a team? So, even though that team might be examining work or auditing work that was done by -- some of the work is going to be done by one of those people

because they're working as a team.

MR. HAMMOND: I don't think you understand.

MR. TELFORD: He would see the blind spots and, therefore, minimize cost because he didn't have to go anywhere.

MR. HAMMOND: I don't think you understand.

We've got, for instance, in our operation, we have one technologist in Lubbock, we have one circuit-riding radiologist, we have two circuit-riding radiologists that read all that stuff in west Texas.

MR. TELFORD: That's enough.

Take the technologist that's in Lubbock, take the circuit-riding radiologist, and let them do the audit.

MR. JANICE: Who's going to do the work when they're doing the audit? I suppose that's what Bruce is saying. Who's going to do the work when they're doing the audit?

MR. FELDMEIER: John, are you saying that technologist checks on the doctor, the doctor checks on the technologist, the technologist checks on the physicist?

Let's say you have -- the minimum teaming, probably, that you have is one physician, one technologist, on physicist -- all right? -- in a nuclear-medicine operation. So, you're saying if you have that team, then your audit involves a physicist looking at the doctor's

prescriptions, the doctor looking at the tech's calibration, both of them looking at the physicist's standardization and calibrations.

Then the issue is whether they're really qualified personnel. I'm not sure the technologist is qualified to look at the physicist's work or vice versa.

If you're going to require that there be both qualified personnel and personnel who are not involved in the activity, then it's going to have to increase the expense of the audit, because you will have to bring in -- it seems to me, you know, keeping with the flavor of the way this is written, you would have to invite a team in for the audit who includes, as a minimum, a physician, a physicist, and a technologist, and that would cost significant dollars.

MR. BELLEZZA: What's an audit?

MR. TSE: We discussed it yesterday. An audit is some review of your program, of your charts and checks, to do the quality-assurance. You recall, the basic quality-assurance program is effective.

MR. BELLEZZA: I'm still not clear. You have quality-assurance programs ongoing that, when you see errors, you're going to record them, and when you have so many errors of this type, this month, by the end of the year, you've got these totals.

So, now, a group is going to come in and look at

those numbers and then do what? They're going to also pull charts, sampling the charts, and see if they get comparable statistics. If they're doing that, then where is the -- there seems to be such a concern that things are done wrong in setting up this QA program that this audit is going to detect things should be done a different way.

MR. TSE: Well, the audit is intended to try to self-evaluate a licensee, and they're trying to find our whether your basic quality-assurance program is effective.

So, what -- I believe that Bruce's question, also the comment, and your question and comment, is that perhaps the audit does not really produce any additional benefit. Is that what you're saying? Or maybe you propose to drop it or something.

MR. HAMMOND: The audit may produce some benefit, but the problem is when you get restricted to qualified personnel who are not involved in the activity, by the definitions we've been using for 2 days, most of the state inspectors are not qualified personnel. They're not physicists, they're not a doctor, they're not a technologist. They can't even review it.

I mean if you set your definitions, how can a state come in and even do your audit? Most of these people are not medical professionals of any sort. So, they're not qualified to do it. And if they've got to be not involved -

- I mean you've got to change some of these definitions, or you've got to have a little more latitude in here than just saying it's going to be -- I mean these are assumptions that we're all in a metropolitan area and all in a major medical center, and we've got 10 people in this department. And those three people at that end of the table are going to write it, and those three people at that end are going to audit it, and the two in the middle are going to review it for management, and that isn't happening.

You're going to get a lot of places where there's not all these people available.

MR. TSE: It says in the next sentence the audit personnel qualification will be determined by management.

MR. BENNETT: Yes, but can that be overridden by the inspector? That's my concern. I agree, if the inspectors come in and accept that verbatim, we could probably live with it, but if he comes in and says, well, I don't agree with management's interpretation of their qualifications, then we're down the drain.

MR. TSE: So, your suggestion is that -- is the suggestion that we delete the words "with qualified personnel"? Or are you agreeing with Terry Roy's suggestion just to delete the word "not involved" in the activity involved? Which one?

MS. WALKER: Not involved in the activity being

audited.

MR. TSE: Okay. So, I thought that there is a question here --

MR. HAMMOND: My suggestion would be that the audits will be conducted on a schedule approved the management with personnel whose qualifications will be determined by management.

MR. TSE: If you take that phrase off, that's what you have left.

MR. HAMMOND: Take out everything from "qualified," just that we'll do an audit of the written policies and procedures.

MR. TSE: Your suggestion is taking out, also -- delete the three words "by qualified personnel."

MR. HAMMOND: And substitute "by personnel whose qualifications will be determined by management." So, that gives you some flexibility. If you're in a 600-bed or a 1,000-bed teaching facility, you may have plenty of people. But if you're in a 40-bed hospital, your qualified personnel may be whoever you can get.

MR. TSE: Any other comments?

MS. WOOD: My thoughts would be to use my radiation safety committee, because all of those people are qualified by what's defined as a radiation safety committee.

MS. WALKER: On our radiation safety committee,

there are three people, I know of three people who know anything at all about radiation. The rest are scientists. There's a biologist. There is a nurse; she doesn't know anything about radiation.

MS. WOOD: That's not the definition of a radiation safety committee.

MS. WALKER: It is by our records. It has to have a representative from the nursing service. It has to have a representative from all of the user groups, who don't necessarily know anything about it. You've got research people. The CAT labs have somebody. The use very small amounts, but they're users. They don't know anything about it.

MS. ROY: The other thing is, in a small private-practice, you don't need to have a radiation safety committee.

MS. WOOD: I was thinking more of a hospital.

MR. HAMMOND: In Texas, you don't have to have a radiation safety committee at all, if you're a hospital or whatever, only if you're an NRC licensee in Texas do you have to.

MR. TSE: But Pat, in indicates that --

MS. WOOD: That's what I would anticipate using, because the people on our radiation safety committee are therapy, the physicists are on it, nuclear is on it, x-ray

is on it. Those are the people I would have in mind having audit this.

MR. TSE: Right. So, if it says that the management could determine who should be conducting the audit, then they could determine that the radiation safety committee can conduct it. So, that's essentially permitted under the wording here. The management can decide. The department head or the RSC or public assurance committee or whoever they believe are qualified to conduct an audit.

Oscar?

MR. HIDALGO-SALVATIERR: To me, you should allow the institutions to carry out their QA program their own way. There is no need to tell them how to do it. If an institution wants to have a QA committee, a QA committee that meets every month and reports to everybody, presents a reports, the minutes of the committee should be enough documentation, and it should be available to NRC. And if an institution wants to have an extended audit every 3 years, that's fine. But you have to allow the institution to do it their own way.

MR. TSE: That's the idea we tried to build in here; the management decides who should be conducting the audit.

MR. HIDALGO-SALVATIERR: If there is a QA committee and everybody is reporting to the committee on a

periodic basis, there is no need for another audit. That's the periodic audit.

MR. TSE: I think that -- the wording in the annual audit is that you conduct audit no more than 12 months. You can conduct audit on every quarter.

MR. HIDALGO-SALVATIERR: If the committee is meeting every month and everybody has sent in their report, that report is being evaluated by the whole committee, and the chairman of the committee should report to management on the progress of the QA program.

So, I don't see why, on top of that, to have an audit of it --

MR. TSE: So, your suggestion is that maybe the requirements of audit, the proposed requirements for audit is not necessary.

MR. HIDALGO-SALVATIERR: If an institution is already meeting periodically and reporting, that should be enough.

MR. TSE: Well, let me see. If your institution already has satisfied the audit, already do your audit either continuously or monthly or quarterly, that will automatically satisfy the proposed requirements. Only those institutions who do not do any audit at all within the 12 months will then need to do one before 12 months is over.

MR. HIDALGO-SALVATIERR: But that's not clearly

stated in here, I don't think.

MR. TSE: We do not have a problem with yesterday's proposed regulation, but you have a problem in this wording here.

MR. HIDALGO-SALVATIERR: Right. It is a little bit more restrictive in here.

MR. TSE: How do we modify this do you think?

MR. HIDALGO-SALVATIERR: I think we should have, for instance, like they were saying, in the small institution, all qualified personnel are going to be involved in QA, all of them, because you have to use qualified personnel only. So, who is going to do the audit? You have to ask for an extended review. And to have an extended review every year, I think that's too much.

MR. JANICE: I think the whole rub on the thing is the two words, "qualified personnel." You take the "qualified personnel" out of that sentence, those personnel are going to be determined -- their qualifications are going to be determined by management in the second sentence.

So, it really doesn't make any difference whether it's inhouse, out-of-house or whoever you want to bring in. Management is the one that's going to do it. And if you leave the term "qualified personnel" in that sentence, then inspectors come in, and they're going to the licensee for the qualifications of those people that have been doing the

audit.

So, if you say audits will be conducted following written policies and procedures, by personnel who are not involved with the activity being audited, period, the audit schedules and the audit personnel qualifications will be determined by management, period.

The whole rub there is "qualified."

MR. FELDMEIER: I don't think so. I think the rub for the small places is not involving procedure.

I mean I think if you're going to have any kind of a credible quality-assurance review audit, you have people involved who have the expertise to make the determinations as to whether the procedures were done properly or the paperwork and documentation was done properly.

I think the rub is, with the small places, that they're not going to be able to afford to bring in a group of people who weren't involved in some fashion with the procedure. I think, in a small place, you have to consider if you have a manager of a nuclear-medicine department or radiation/oncology activity, diagnostic, administrative, or an x-ray department, that even that management is involved in the treatment in some fashion.

I mean by their supervision of people under them, they're involved in every treatment or every diagnostic study.

So, I think, that to be fiscally practical and possible, you have to delete "not involved in the procedure."

I can't think of any other medical specialty where they are required, for their quality-assurance program, to have procedures reviewed by people that were not involved in those procedures.

I mean if you have a transplant surgeon at an institution, you're likely only to have one of those. And I don't think there is anyone else who can really review the activities of a transplant surgeon, because it's very highly specialized, than that transplant surgeon.

If you're going to trust the people to do the activity, I think that they should have a role in performing the audit and determining the appropriateness of the activity. In the best of all worlds, you know, you'd like to have people looking over each other's shoulders, I guess. I don't think it's practical, unless we want to double the cost of these modalities to the patient.

MR. TSE: We already have Terry's suggestion on these words. But how do we resolve his problem?

Oscar, you still have some problems.

MR. HIDALGO-SALVATIERR: Well, I agree with John.

MR. TSE: Does that solve your problem?

MR. HIDALGO-SALVATIERR: Yes, because in a small

place, everybody that is qualified is going to be involved in this part.

MR. TSE: So, we have the comments.

Any other comments related to this item or other items on this section?

MR. SHAFFER: I think if we delete the entire second sentence, it would take care of the problem.

MR. TSE: Which one?

MR. SHAFFER: Go from the first to the third sentence.

MR. TSE: Any other comments?

MR. HAMMOND: Tony?

MR. TSE: Yes.

MR. HAMMOND: In the last sentence, what is your intention with regard to "will be distributed to appropriate organizations"?

MR. TSE: That is essentially the components.

MR. HAMMOND: It says "appropriate management and organizations."

MR. TSE: The radiation safety committee or some other committee. "Organization" doesn't really mean like an outside organization.

MR. HAMMOND: That's what I read. That's what I'm afraid that outside organizations are going to read, that without question, by definition, access to all that

information.

MR. JANICE: Even management is going to start wondering who the organization is.

MR. TSE: It's like your radiology department.

MR. HAMMOND: I question why that whole last sentence is in there, because the sentence before says to be followed by management regardless. So, if you deficient conditions that are going to be corrected, they're going to be corrected by the department. Management will be following it. So, why do we need the last sentence in there, except if we mean by invasion by other organizations?

MR. TSE: So, your suggestion is that sentence is not necessary? It's already covered by the earlier sentence?

MR. HAMMOND: Okay. Yes.

MR. TSE: Does anybody agree with Bruce's suggestion?

MS. ROY: I agree. Just delete that last sentence.

MR. TSE: Any response on Section 1?

[No response.]

Then we go to section 2. Section 2 contains several general elements which is applicable to all program areas. Does anybody wants to start? All four elements -- you may make your suggestions on any of the four elements.

Bruce?

MR. HAMMOND: 2.1. Assuming that we're successful with our discussion yesterday, how are we going to maintain records and oral diagnostic referral? We -- it may -- if we're successful in that argument, then their may not be a written diagnostic referral and would be unable to maintain that record.

MR. TSE: But I thought that somebody would still have to write it down.

MR. HAMMOND: Yes, you'll write something down.

MR. TSE: But -- who is the physician, who is the patient, what diagnostic studies have been requested and so on. Any other suggestions? Oh, by the way, excuse me, I forgot. I did not ask you on section 1, any additions? I'm supposed to request any additions you want to add in the other portion -- the section which is the audit portion.

Anybody? I'll just repeat the question, yes?

MR. TELFORD: Think of the additions as alternatives too. They may be more important later.

MR. TSE: If you think of any additions pertaining to section 1, please raise that later, but now let's go back to section 2. Any other comments or modifications or additions to section 2?

MR. TSE: Let's see, Oscar Hidalgo on paragraph 2.3. What is the meaning of therapy event? The third line

diagnostic therapy events are stated in the regulation in --

MR. HIDALGO-SALVATIER: Is that like an error?

MR. TSE: Yes, errors.

MR. HIDALGO-SALVATIER: Not necessarily an accident.

MR. TSE: Not necessarily. It could be just any human error. Accident it not -- not necessarily, it could be an incident. Terry?

MS. ROY: I have a question on 2.2. Request clarification from an authorized user or physician under the supervision of an authorized user. In diagnostic nuclear medicine, sometimes you maybe just clearing up something from a referring physician. Here it's saying that you must request the clarification from the authorized user -- if any element. And right there you're saying the diagnostic referral -- I'm just -- if I'm an authorized user and I have a question on something that's just questioning something about the -- what the referring physician is asking for, I'm going to go to the referring physician first and talk to him before I go to my authorized user. And then if I have a question, I'll go to my authorized user. I'm not going to bother him at that point, when I'm just questioning the, you know --

MR. JANICE: The authorized user is going to come back and say, well what about this, that, that and the other

and everything else. You've still got to go back to the original referral to get the answer.

MS. ROY: Right.

MR. HAMMOND: Doesn't the argument that we had yesterday between 4 and 5 on the objectives still apply to 2.2, 2.3 -- aren't those essentially saying the same thing. You know, if 2.2 more or less correlates to objective number 4, which was that if you have a question, you're going to stop --

MS. ROY: Right.

MR. HAMMOND: We kind of agreed yesterday that we'd like to see -- understanding was that we'd like to see 4 go and have some adaptation done to five, which would tie the 2.3. It's kind of redundant between 2.2 and 2.3. It says, "all workers will stop the medical use, if there's an apparent discrepancy in records, observations or physical measurements." And that would be -- that record would include the diagnostic referral. So that if you have -- you know --

MS. ROY: Just delete 2.2.

MR. TSE: 2.2 says that the --

MS. ROY: Request for clarification.

MR. TSE: That if they're not clear you've got to ask.

MS. ROY: Right. And 2.3 is saying you'll stop

and seek guidance if there's any discrepancy in the records. So you still -- if you're seeking guidance, you're going to clarify it.

MR. HAMMOND: Because you may have to go back to the referring physician.

MR. TSE: Well Terry's first question started off as -- here on this -- on this authorized user and the physician's supervision of an authorized user, but if it's a diagnostic referral case, he might want to seek clarification from the referring physician, an if that's satisfied, you -- then you would go ahead and do it. But if still you're not satisfied, then you need to go to your authorized user. That's the first part.

Then the second part. The second point is why do we need 2.2 if we already have 2.3? I thought that yesterday's discussion, we were sort of thinking -- discussing around combining the two items together in one item in one objective; but the idea -- but I understand -- and follow the description is still maintained.

MR. HAMMOND: The idea is still maintained. Look at 2.4. It ought to come before 2.3 anyway, because it says before medical use; and 2.3 kind of implies that if you've got 2.4, why do you need 2.2? If you've got 2.3, why do you need 2.2. You've got three sections all saying the same thing. If you have any question, don't do anything

until you have the answer. To of them address before you start with the patient and one of them is after you've already started with the patient. If you've got 3 and 4 why do you need 2?

MR. TSE: So your suggestion is to remove --

MR. HAMMOND: Remove 2.2.

MR. TSE: Do you mean to say in 2.3, that if it's not clear --

MR. HAMMOND: 2.4 says that, and I'd move 2.4 ahead of 2.3 because it's before medical use, it's kind of out of order. 2.3 implies you've already begun work and 2.4 is back to before you started again. So, if you're reading this manual trying to find out what to do, you'd already have started before you got to 2.4.

MR. TSE: Does anybody else have a question on this particular suggestion?

[No response.]

MR. TSE: Okay, any others?

[No response.]

MR. TSE: Any additions or alternatives you would like to see in section 2?

[No response.]

MR. TSE: Then we can go to section 3.

Section 3 contains several specific elements relating to radiopharmaceutical therapy and administration

of Iodine 131 or 125, greater than 30 microcuries.

Yesterday we had some discussion with hipuran, so assume hipuran is not included for now for this inspection. Any questions or comments?

MR. WALKER: Maybe it's just me, but when I read 3.2 it says to me -- implies to me that for each patient, the authorized user will make a prescription, date it and sign it, which is what we do. But nevertheless, what you said they didn't have to do. They could have a procedure's manual and a prescription does not apply in a procedures manual. See what I mean?

MR. TSE: The procedures manual -- you'll notice only tied it into the diagnostic procedures. Like remember yesterday the objectives 2 and 3?

MR. WALKER: Okay.

MR. TSE: This is related to therapy and to special case of iodine. So, diagnostic is not included.

MR. WALKER: Would it include the 5 --

MR. TSE: Would you think that's important enough to have a prescription -- write a prescription? Now the idea is this: There are several cases -- have been done in the microcurie, iodine and -- or a technologist may take a scan -- or a physician did not write it clearly and just said scan and they may call it a whole body scan. So the idea here is that as long as you see Iodine 131, more than

30 microcuries, no matter what the referring physician says, don't do it until your physician says do it. That's the idea.

Any other questions or suggestions? Bruce?

MR. HAMMOND: And 3.5. What is -- I guess I need clarification because I don't understand why the person will regard the agreement or lack thereof between the radiopharmaceutical administration and the prescription, if he has already verified that the prescription and the dose that he has are one and the same, or has had the prescription changed.

MR. TSE: I think that this question comes in the pre-trial pre-test workshop. I think -- I believe that we said that if they are -- if the dose is side-by-side, you really do not have to right it out, so we might modify it.

MR. HAMMOND: I don't remember it coming up.

MR. TSE: I have a note here. The one I have is the QA program, Dallas last time. So I have a note here. So, I agree that we will modify some of the words.

Any other comments? Suggestions?

[No response.]

MR. TSE: Any terminology problem? If anybody has a terminology problem, they should say so.

[No response.]

Any additions to this section?

[No response.]

MR. TSE: Then let's go to section 4 which is brachytherapy. I notice there are a lot of questions here, so please start.

MR. FELDMEIER: On 4.5, after radiographs will be obtained and used as the basis for calculated the liver dose. This may not apply to sources used for certain -- I think first of all, there are some cases where you have a very superficial lymph node and you can put some gold seeds and some iodine seeds into it. Where you have a very small iodine volume, you know what kind of activity you want to put into, you've already done a pre-plan or done a plant, I'm not sure you really add anything to the patient's management or to radiation safety by doing orthogonal x-rays and doing a computer plan afterwards.

So I think, first of all, there are some cases where I'm not sure you need to do radiographs demonstrating the exact position of the seeds. Beyond that, I think that we should broaden that to -- if we are going to say that radiographs should be obtained in most cases, I think we should broaden that to allow for ultrasound -- CT scanning. Because, in my mind, radiograph is probably just a plain film or orthogonal pair of plain films. I think we should broaden that.

MR. BENNETT: I don't feel that you should implant

the radioactive sources and then take the radiographs, I think you should use dummy sources. There are certain instances where you do a permanent implant by injection or something of these seeds. But for GYN applications there are non-radioactive simulated sources that should be used to take the radiographs to minimize the exposure, rather than using th radioactive sources like --

MR. FELDMEIER: That's exactly right. After you do the implant you're going to take it with the dummies in place, not with the implant actually located.

MR. TSE: That's correct. That was also discussed at the last meeting. We heard that one last time, about appliances, so -- but this -- so what you say, Dr. Feldmeier, is that in some cases, it may not be needed. While we can already accept the certain cases -- in some cases, even if it's implanted, you may not need to take any other verification.

MR. FELDMEIER: There would be very few cases that there would be permanent implants. I think there are instances where all we do is drive up the cost of a medical care expense to the patient and don't really add anything to the quality of their care or radiation safety, which I think are our two concerns in brachytherapy.

MR. TSE: How do you calculate the dose, if the source is located in -- for some time. For example, we just

used one single cesium in the -- why do you want to calculate the dose? It's already published in the tables. And at that time, there's no point of taking a radiograph to verify the source; you know the old dose is in the patient. So there would be a certain situation that you really don't need to verify it. Although sometimes you don't need to verify it. How do you suggest we modify it -- that those cases will be taken care of.

MR. BENNETT: Can't we change the reading of that -- the radiographs will be obtained at the discretion of the authorized use and used as a basis for calculating and determining dose?

MR. FELDMEIER: Imaging modalities will be obtained and used as a basis for calculating delivery doses. This may not apply in surface applications. Some permanent or temporary implants, as Ed says, they are well published, except in tables for vaginal mucosa dose, using cesium or radium. You really don't need to get x-rays treating an individual cancer after a hysterectomy. You don't need to do x-rays.

MR. TSE: You've heard, I think, in our -- in our program evaluation, we have those CT plan.

MR. FELDMEIER: Let me comment on that. You bring up a very valid point. What has happened is, during the site visits and prior to the program evaluation, we adjusted

the evaluation to consider special situations, where you used dummy sources, where you don't use dummy sources, where you use different modalities and where you don't use any imaging at all. You know, published data from past tables, the benefit from additional exposure to the patient is not worth the risk versus the benefit. It does not justify it.

MR. MOK: You have -- you have to, like gold seeds or iodine seeds, there's an opportunity there, outside the patient. In those situations, you definitely want to get radiographic confirmation. So, in that case, for some situations, like for cesium, I don't see any point to very that, but for interstitial implant, I feel that there's a necessity to take a radiograph.

MR. TSE: So, it's not true that all interstitial you think requires the radiograph, is that true?

MR. MOK: Just about all interstitial properly --

MR. FELDMEIER: Just about all, but I can think of a case where you have a one or two centimeter lymph node, and you put two or three gold seeds in and you can do what it is saying -- make sure that the seeds are in there by seeds are in there by surveying the patient. You don't need to do a radiograph. And I'm not sure that you really add anything to the patient. You're not going to change anything, you're nct going to go back in and retrieve a seed. You probably not going to add a seed, based on your

radiographs.

So I don't think it's necessary. I think that although 90 percent of the time, maybe 99 percent of the time you will get radiographs. I think you need to have some leeway, so that on occasions and special circumstances, when established tables are in a situation where you're not going to change anything based on the information you get, that it's not necessary.

And certainly, as Doug said over there, there's no question that you shouldn't read after implanting the brachytherapy sources, because if it's an after-loading implant, you're certainly going to do it with a devised catheters and needles -- the ovoids in place; but before they've been loaded, one of our aims here is obviously to be consistent with the principles of exposing as few people to low doses of radiation as possible. You don't want to have the patient in an x-ray department who's got an odd implant in place.

MR. KLINE: Keep in mind that brachytherapy does look at the implants. So, unless you use a radium -- the radiographs are taken after the implant, so there would be odd sources. It's difficult to word so that it fits all situations. Once you break down the isotope groups, then it becomes more of a prescriptive and actually gets into medical practice.

MR. FELDMEIER: I think I -- all you'd have to say is after placing either the carrier plants, or after loading device and the actual isotope for permanent implant, a radiograph is taken. I don't think it's too hard to see.

MR. TSE: Any other points on -- on brachytherapy? Yes?

MR. BELLEZZA: On section 4.8, I think to specify 50 percent is arbitrary. If you want something checked, it should be just before the completion of a treatment, if we're going to go that route. But, I think to just arbitrarily set a specific limit doesn't mean anything.

MR. TSE: So you would want to change it to before?

MR. BELLEZZA: Yes, if we're going to do that secondly.

MR. MOK: I have the same problem.

MR. TSE: He has a second point. Let him finish.

MR. BELLEZZA: Just that brachytherapy -- first off, the calculation is going to be very complex an. it may be in a small institution that with one physicist, that physicist is the only one who understands what is going on with the calculation, and it may not be practical to require someone else to come in and check that. That person may not be available -- someone who is qualified to check what the physicist is doing in the calculation.

It may just have to apply to that one person.

MR. TSE: So, your suggestion is, he could make a double check on himself.

MR. BELLEZZA: There just may not be anyone available besides that one person to double check.

MR. TSE: He should double check.

MR. BELLEZZA: Sure.

MR. TSE: So, essentially you're saying that, under those circumstances, the person should be checked to do another calculation, because nobody else could do the check. Is that what your suggestion is?

MR. BELLEZZA: I have trouble with that because you get into -- as you're going through it, you're doing it carefully, and ideally, someone goes back and reviews their own work to make sure of what they have done. But to regulate that someone go back and double check themselves, I have trouble saying -- that's relevant.

MR. TSE: Well, suppose you design your QA program, you only have one person there. What would you tell this person? You do a calculation and don't worry about, or you do a calculation and you check again -- which one?

MR. BELLEZZA: Go back and check to see that your point -- thank you, okay.

MR. MOK: I have the same problem with 50 percent

prescribed dose. The calculation has to be checked before the 50 percent prescribed dose. I think you have to look at different kinds of implants. First of all, if you do permanent implant, somehow we don't do the calculation until the patient comes back, like a couple of weeks after it. We put gold seeds or iodine seeds in the patient, which would be impossible to be over 50 percent of the prescribed dose in those cases. I don't see the rationale for doing the second check before the 50 percent prescribed dose is delivered because the seed is already in the patient. There's not much you can do about it.

And if you find a discrepancy, I mean, you're not going to take the patient back into the OR and retrieve the seeds. So in those cases, there is no sense in doing a second check before the 50 percent prescribed dose is administered and safe for permanent --

MR. MOK: Yes, for permanent implants, and special cases. For most of the cases, usually we have to finish the computer plan. The patient is lying on the table. They give us 15 minutes to finish the initial calculation, that's the only way you can do a second check, before the patient -- patient's treatment is over. For a higher dose rate, I think again, it should be excluded from this 4.8 exception.

MR. TSE: You say that's a computer calculation?

MR. MOK: Yes.

MR. TSE: Is it possible you can check the inputs into the computer?

MR. MOK: Oh, yes. You can make a schedule check, and we do that. When we change the source, we always do a hand calculation of one single source at one single location and compare them. Now we're only checking with the computer program. Accuracy of the calculation, that does not check. The operator inputted the data.

MR. TSE: But the question is, before your implant is completed, probably minutes -- how many minutes is it, generally?

MR. MOK: Probably ten to 20 minutes.

MR. TSE: During that period, you also do a computer calculation. Somebody has to input this information, and then the computer comes up with certain minutes at that point before you complete. Is it possible somebody can complete?

MR. MOK: Well, what you said here, you said the program has to be checked.

MR. TSE: Yes. We check the input.

MR. MOK: Yes, I think that's what it says.

MR. FELDMEIER: Well, we could probably do that at our institution, but if you have a radiation oncology facility where there's only one physicist on site, it would be impossible for that to be done because, I mean, you

can't, you know, arrange to have somebody there or call somebody else in to second-check it when the whole procedure is only going to last, you know, 20 minutes, and do the calculation, and maybe the implant itself is only going to last five to ten minutes.

MR. MOK: It might be input data. The input data is transferred by the computer card by manually typing into the computer. So there's quite a few points of input that you can make error.

MR. TSE: So how can you avoid making these errors? How do you check to see if you make those areas?

MR. MOK: I think you can check it before the end of the treatment. You just have to rely on the operator in those cases, and then you can go back and do a second check after the treatment, and then, of course, when you discover error, there's not much more you can do after that, but you have to give the person who is doing -- he is supposed to be a qualified person. You have to trust him to do the first treatment.

We are a large cancer center. We have several dosimetries and physicists and pathologists, and in some cases, we just have one single machine, and they have physicists and dosimetrists that maybe come to you just to do that case. How do you ask somebody else to check those calculations when he is the only one there?

MR. TSE: I think there's one case, the one like you just described. Somebody input a number, a decay factor, into the computer, and it was the wrong decay factor. So the patient received about double the dose.

MR. MOK: You should hang the physicist.

MR. TSE: The result of that is this institution says we're going to check all the input to avoid a recurrence of that. My impression is, is it because it is, physically, the time is too short? You really do not have time to check the inputs.

MR. MOK: We do most of the check, as much as we can. We check the typing error, how it went in, and the physician checks the time from the treatment. We check those. But you have to understand, in most of those cases, the patient is in very bad condition, and he has a tube in his mouth down to his lung. It's a very bad situation, and we barely have enough time to finish the calculation.

MR. FELDMEIER: Four-point-nine probably gets us down to that.

MR. TSE: The question, though, is that all these high-dose rates after loading device, they are all -- those dose conditions are only, in some cases, emergency conditions.

MR. MOK: I think the majority of those cases used for high doses are for lung and esophagus. Those are the

cases.

MR. FELDMEIER: And most of those patients are critically ill.

MR. TSE: Then you can use 4.9.

MR. MOK: So what you're saying is the worse cases can be considered as emergency.

MR. TSE: So with that, do you still have a problem with that 50 percent, or use, like he said, after -- before completion.

MR. BALLEZZA: I would add that in some of the iridium implants, we have a large number of seeds, and a great deal of time is taken in identifying which seed was which, and inputting it into the computer. You may be lucky to finish the original calculation before it's time to pull the implant.

MR. TSE: Like 48 hours.

MR. BALLEZZA: If it turns out that it was loaded hot, and then the physicist looks at it, by the time of logistics, the patient having come back from recovery, the taking of films, and now it's the next day, you've been working all day putting this into the computer, and you leave it on the physician's desk, and he comes in the next day and takes a look at it, it could take quite a while.

MR. TSE: We realize the computer only checks the input, not the calculation.

MR. BALLEZZA: Well, I mean, that's all part of the same thing. If you're doing the calculation, you're doing the input into the computer, and sometimes you're just barely finishing that on time.

MR. TSE: So would you think that you want to modify your suggestion? Earlier, you suggested before completion.

MR. BALLEZZA: I would say at least that in that you cannot say 50 percent. If you're going to have it done before the end of the implant, sometime before the end of the implant, then you have to have a conclusion. I think there's another issue involved in that some physicians don't offer calculations.

MR. TSE: If there's no calculation there, you don't have to check it. What are you going to check if a physician doesn't give you any calculation?

MR. BALLEZZA: The way I read that, it says that there has to be a calculation.

MR. TSE: We'll check the dose calculations. If you don't have a dose calculation, you wouldn't have to check it.

MR. FELDMEIER: You're saying like for cesium or radium, they give milligram hours, or something like that.

MR. BRAHAMAVAR: Right.

MR. FELDMEIER: They don't ask for calculations.

MR. BRAHAMAVAR: It's a simple implant. They just go by milligram hours. What's your milligram hours? If you tell them that this implant is going to come out around six p.m. on Friday evening, sometime they decide to take it out at 4:30 just before they're going home, and say, Well, I made that judgment because that was enough in the patient, and there's that. So with 50 percent, you really have a problem. Are they going to come in the middle of the night, before 50 percent is over, and check? You don't know when the 50 percent is going to -- the time.

MR. TSE: I thought, in your case, that you don't have to make a calculation.

MR. BRAHAMAVAR: But in other cases, other cases, also. Like iridium implants, when they have to be removed at a certain time, they normally don't come at nice time like four p.m. on Friday; they end up on Saturdays or midnights, or some time. It is just the timing, when to insert and when to take them out.

So this 50 percent -- I just don't think that it is appropriate to mention any percent. Perhaps you can say that before the termination or completion of the treatment, it should be double-checked, and that should be sufficient.

MR. TSE: That's what David's suggestion was. Okay, so if we change that, do you still have a problem?

MR. FELDMEIER: I don't think that still is

adequate for the high dose rate. You might say for a low dose rate standard brachytherapy, a second check should be done before the implant is completed, but for a high dose rate, I think you'd have to allow special checks.

MR. TSE: Your suggestion is that, except high dose rate?

MR. FELDMEIER: Yes.

MR. MOK: I agree with Dr. Feldmeier about the high dose rate.

Also, on some cases in Texas that I can recall, we requested them to do dosimetry. Generally, they send the film to us after they load the source, and quite a few times, before we finish the calculation, they've already finished the treatment. So if we insist us to finish the calculation before they finish the implant, that's fine with me, but I think it would be difficult for them to understand. They have been doing this for so many years; why, all of a sudden, do we have to do the computer inputs before they can treat a patient or finish treating a patient.

MR. TSE: Well, the question is, do you think a double-check should be done before they finish?

MR. MOK: I'm not so sure, because, to tell you the truth, they really don't care whether we do a calculation or not. I mean, I hate to say that. But I

don't understand why, in Texas, they are the authorized user for cesium; in other states, they aren't. But in their case, I don't see the rationale for doing a second check at all before they finish up the treatment.

If you want to insist on doing a second check before finishing treatment, then you would have to worry about those special cases. They might even order a computer. They might just go ahead and say, How many milligram hours, and go ahead and use it. I don't know. We are defeating the whole purpose of the regulation here.

MR. TSE: So, let me understand. They could use milligram hours. That's how they determine when the source should be finished, even without the calculation.

MR. MOK: Yes. I don't know why they'd order the computer for --

MR. BALLEZZA: Just for documentation.

MR. MOK: Probably yes, just for documentation.

MR. KLINE: Dr. Feldmeier, when you were talking about the kind of application, and you then indicated the plant data regarding the high dose rate after loading system, you represent the process by which you transfer the data from the treatment planning system to the planning computer to the high dose rate console. I believe that you indicated that you do the calculation and that you have some time that's necessary to input into the console, and I

believe you said that you would look at that. Did that not constitute a double check?

MR. FELDMEIER: In a way it does.

MR. KLINE: It does. And the double check does not necessarily have to be, at least based on our field observations, the blown out full calculations. If you check the inputs, if you go to the milligrams table -- let's say you have a second configuration, and it's expressed in milligrams, the use of that correct number of hours, though a small calculation, a check could be done on that.

We realize that there are a lot of situations that don't warrant the plan, a replan that is actually generated by a computer system because the geometry is already fixed and well established, and a lot of oncologists, I'm sure, have been doing this for years, and know often better what their plan will generate. So we looked at that in the field and felt that the check could be performed in a number of different ways, and even a simple check we thought would satisfy that requirement. So we don't want to lose perspective.

It does say that you can do a dose calculation, but it does say that you can check the input and the output data and the simple arithmetic.

MR. FELDMEIER: If that kind of activity -- the physician looking at the times and making sure they're

consistent -- constitutes a second check --

MR. MOK: I think that has to be clarified. The check being done is only checking the data transfer from the computer to the treatment console; it doesn't check the input of the actual location of the source. A formula x-rays, so it doesn't check that. So it's not a comprehensive check. You are saying that is considered a separate one.

MR. KLINE: I can understand that.

MR. MOK: I can't if a state inspector comes. It's how do you interpret it.

MR. KLINE: Yes, I can understand that, and that's justified. We realize that there are certain processes that in order to get the total dose, you require quite a bit of checking of numbers, calculations, and by that time, your 50 percent could be exceeded. So we'll try to take that into consideration during the evaluation. I believe our results are based on that interpretation that I've given. So often, you'll see that.

As I mentioned, in my thought, it's a living document, and now with the feedback from this, we're adjusting this document.

MR. TSE: Any other points?

MR. HIDALGO-SALVATIER: Just coming back to these, I don't see any problem removing the word 50 percent.

MR. TSE: That's what they suggest, to. Just to

use like a -- after -- before the completion or treatment is a suggestion.

MR. HIDALGO-SALVATIER: Actually, all calculations should be checked before the treatment is delivered, and most everybody has a double-check. Why to check it again before 50 percent?

MR. TSE: For that, if you have already double checked, you don't have to do it a second time.

MR. HIDALGO-SALVATIER: Right. So this, you say before the treatment is delivered, the calculation should be checked, you should have a double check. It doesn't have anything to do with 50 percent, or nothing. They have to be checked, period.

MR. MOK: Well, Oscar, it has to be checked. I have no problem with a second check. The problem I have is should that be checked before the treatment? We have done some brachytherapy with 300 or 500 seeds. About the time we finished entering the data in the computer, they have finished the treatment.

MR. HIDALGO-SALVATIER: But you do have double checks, right?

MR. MOK: Yes. Well, at that time, it's already past the 50 percent dose.

MR. HIDALGO-SALVATIER: No, but at the beginning, before you implant?

MR. MOK: Not the way it's done in our institution. They don't care when we start the computer plan; they're going to load the source as soon as they finish putting the needle in the patient.

MR. BRAHAMAVAR: Most of the iridium implants of what he's talking about, preplanning is done, and you have the tumor volume, and you're determining how many seeds you're going to put in what configuration. It is done in the OR, and it is done, and the treatment planning comes after you see when you are going to remove it.

MR. HIDALGO-SALVATIER: Yes, but a preplan has to be checked.

MR. BRAHAMAVAR: Yes, the preplan. Preplanning is done even before you order the sources for that.

MR. MOK: Sometimes you even don't do a preplan. What they have in mind is they follow a certain recipe, and they just go ahead and do what they think is appropriate. By that time you start doing the treatment plan, the treatment has already begun, and by the time you finish the treatment plan, the 50 percent dose is already over. It's already delivered.

MR. HIDALGO-SALVATIER: Okay. But the idea of the vague relation is that we should strive to reach our goal. We think it's important to have a double check, and we should do the best we can to do that. If we're not doing

that right now, I think we should try to do it.

MR. MOK: Well, we can do that, but I think a lot of physicians might not like that idea. You might want to ask some others. In some situations, they have an idea how the institution works, and in their opinion, they don't need any preplanning.

MR. FELDMEIER: Ed, I think, is talking about using templates, you know, where it's pretty well established that if you order a radium of a certain milligram, radium equivalent activity, you place it in a many of the templates, that you're going to get a dose rate that's about what you wanted.

So during the formal preplan -- you know, in a sense, it's already been done since the template's been used over and over and over again, but we don't go through the exercise of doing a preplan every time we do a template implant because it's unnecessary. But then Ed, I'm not sure -- Oscar is saying to take the 50 percent. I think we could always add the calculation done before we pull the implant.

MR. MOK: For you, not for some others.

MR. FELDMEIER: I can't speak for others. Are you talking about permanent iodine implants? Like with the ultrasound techniques, are you talking about iridium?

MR. MOK: Ultrasound? Well, first of all, permanent implants -- this is not appropriate.

MR. BRAHAMAVAR: That's done.

MR. FELDMEIER: What's done is done.

MR. JANICE: The seed is already there.

MR. MOK: We can do it. We can force the physician to do it. I think that's fine. I agree with Oscar -- everything should be double checked before the end of the treatment, but, in my opinion, I think it would be difficult to enforce it.

MR. HIDALGO-SALVATIER: What I'm saying is that to me, it looks impossible to do an implant if you don't think about it beforehand, which is a preplan. You have to plan it. No matter if it is temporary implant or permanent implant, you have to have some -- even if you have different preplans, you have to choose one, and that process is, you can say during your calculations, which are already done, why should I suggest the preplan? Somebody has to check it to make sure that you selected the proper plan.

MR. BALLEZZA: But that preplan may be in the physician's mind, so how are you going to check that?

MR. HIDALGO-SALVATIER: What implant will be in the physician's mind?

MR. FELDMEIER: You have fixed geometry, like the templates. You have fixed geometry, and you know if you --

MR. HIDALGO-SALVATIER: Well, you still have to have a certain distribution in your mind -- on a piece of

paper.

MR. BALLEZZA: He's not necessarily going to write down this.

MR. TELFORD: How do you order the seeds?

MR. MOK: They just order X number of seeds. They come in a standard kit, seven ribbons or twelve ribbons and 14 ribbons, and you order a half a kit or a full kit.

MR. MOK: To give you an example, I just did a brain implant a couple of weeks ago. The seed was ordered weeks ago, a couple of weeks ago. What they do is the physician estimates the size and the volume of the tumor, and they just estimate the number of seeds you need, and then you just go ahead and order. When it comes in, the size of the tumor has almost doubled, and naturally you don't have enough seeds.

In that case, again, for this kind of implant, in order for me to prepare for it, it would probably take me a couple of days to do it. So it's very difficult to have a second check before the end of the treatment -- I mean before 50 percent of the treatment.

MR. BALLEZZA: Just one other point on the way it was written. When you say 50 percent of the prescribed dose, you have two prescribed doses, the before-implant prescribed dose and the prescribed dose which can be revised after the implant. So which prescribed dose are you talking

about?

MR. TSE: Well, you have to go back because we do not even know -- at the time when you need to check, you do not really know the other dose.

MR. BALLEZZA: You're acknowledging later on that you're probably going to change that prescribed dose, so you're taking 50 percent of something that was meaningful --

MR. BRAHAMAVAR: Fifty percent goes with the prescribed dose. If you decide to eliminate 50 percent, you can say before the completion of the treatment. The dose doesn't come in.

MR. BALLEZZA: Then you still get back into permanent implant?

MR. TSE: No.

MR. BALLEZZA: So you have to put in something here excluding permanent implant, and then there's the issue of someone who did not make the original calculation.

MR. TSE: That's the suggestion that you make.

I think it's ten o'clock, and according to schedule, we said we would stop for a break. Can we break now and we'll come back and do this item.

[Recess.]

MR. TSE: Is everybody ready? Before the break, we were discussing brachytherapy, Element 4.8, and the suggestion is that before 50 percent completion of the

treatment and another suggestion is that the person may not be necessary -- the person who did not do the original computation and another one is a permanent implant should be excluded from this before computation of the treatment.

Okay, any other discussions on this particular element?

MR. BELLEZZA: Talking to Ed during the break, he made it kind of -- this may actually encourage people not to ask for calculations. If you have to go through all of this requesting documentation, just don't request it.

MR. TSE: I think the physician has to make a judgement whether he wants to use the hours or not. He, as the physician, has the duty and responsibility to make that determination.

MR. BELLEZZA: Especially on the GYN implant where the documentation in the chart and the dosimetry; he wants to know just the documentation. He's not interested in why the implant is underway. What happens if he doesn't request it? He may say that if all this rigmarole has to be done in this short period of time, let's just not do it.

MR. TSE: Let me ask you a question: would that affect any safety if he says, I'm going to determine to use 48 hours and he later does a dosimetry according to safety concerns.

MR. FELDMEIER: I think he could, because if

you're doing two 48 hour cesium or radium implants and he gets an unexpectedly hot dose or something like that with the first application, then he makes adjustments during the second application.

MR. TSE: So that the physician generally would order a calculation.

MR. FELDMEIER: Well, you know, I think that the issue has come up and we were talking about it, is not radiation oncologists doing this, but primarily a GYN physician who has been doing it forever and has been using milligram hours and knows that computer dosimetry is available and does it and puts it in the chart but doesn't adapt or adapt or adjust or modify his treatment based on that computer dosimetry.

I think that for radiation oncologists, they're going to get -- if it's one of two implants, they're going to go ahead and adjust the second implant according to the dosimetry of the orders. I think the problem comes up with people who don't do brachytherapy as a primary part of the practice.

MR. TSE: But the responsibility whether to order a calculation still lies on the physician; is that correct?

MR. FELDMEIER: Yes.

MR. TSE: Don't do it? So what do you suggest?

MR. MOK: Maybe you should suggest this has to be

done for gynecological cases; how about that?

MR. FELDMEIER: You know, this is perhaps a significant problem. My number is small I think that maybe consideration ought to be given to taking critical -- the licensee.

MR. TSE: There is some reason gynecologists can be authorized to use and I have some problem with that.

MR. TELFORD: Would these folks satisfy the NRC's training requirements for authorized users?

MR. SHAFFER: I think these are people who have been doing it for years and years and years. They may have gotten a license prior to the time when criteria weren't as rigid as they are now. I don't see any young gynecologists coming out and being named as a licensee.

Some of the old fellows who have been doing this for 20 years plus, continue to do it, and if you look critically at the way they do it, it's pretty haphazard. If they were doing it -- if they did the dosimetry and if they adjusted their implants according to the dosimetry, it's fine, but they don't do that.

It's sort of -- I think the other physicists in a bad situation where they're doing dosimetry kind of after the fact, it's just something for the gynecologic oncologist to show that he can do it as well as a radiation oncologist, document it and put it on the chart, but in fact, they're

not using the information the way it should be used. They're not using computer dosimetry. They're not -- Some of them do okay. It's a difficult problem trying to sort out which ones can do it and which ones can't. I think that when anybody does something like this, handles isotopes or give brachytherapy as sort of a sideline, it's potentially hazardous.

MR. BENNETT: I think too frequently the system that's in place to handle those situations don't work, and that's why we're here today. There is a peer review process that every institution is supposed to have to evaluate the appropriateness of care and physicians are supposed to monitor that kind of thing.

You know, if there are people that are practicing medicine inappropriately, the question should be asked, and they should be moved out of the practice if it's inappropriate.

MR. MOK: I don't think you understand the situation we have in Texas here. The physicians, the gynecologists who do the implants do not belong to our institution. They don't even come to our center. They just send us the film for us to do the dosimetry, so there's no way we can control this practice.

MR. BENNETT: There's a mechanism to control the production of the isotope's plans.

MR. MOK: We can inform them. We only do the computer dosimetry. I wish I could say that we don't do the computer plan for those people, but if I would do that, I would probably be fired tomorrow.

So, it's a very bad situation and I don't think we are unique.

MR. TSE: Oscar?

MR. HIDALGO-SALVATIER: Yes, the point is that even if the gynecologist is prescribing in milligram hours, because that's what he do, still somebody has to sit down and calculate the time of the implant. That's a calculation.

Somebody checks the division. The regulation doesn't apply only to complicated dosimetry calculations. It applies to any simple calculation.

MR. MOK: We do that, Oscar, exactly what you do. The point David and I tried to bring up is, if we require them to do all those things before the treatment is over, the gynecologists say, oh, to heck with it. I'm not going to order any computer plan at all. I'll just use what I have.

MR. BENNETT: It sounds like a good way out of it.

MR. MOK: You go and tell him that, and the next time you send me the film so that I can finish the calculation before the treatment is over. They say, well,

forget it, I don't want to do.

If a GYN physician prescribes 48 milligram hours after they determine if they have delivered 48 milligram hours -- they put in however many milligrams or how many hours to get the product, to get the 48 milligrams. It's simple arithmetic. The number of milligrams of radioactive materials times the number of hours of the implant.

MR. TELFORD: So, the location is immaterial. There's a case in Indiana where the referring licensee was just closed down for such a practice, because the delivered doses were as prescribed. This guy was doing them by rule of thumb. It sounds precariously close to the situation you're describing here.

MR. BENNETT: Who is an authorized user? Our post radiation, our guide assumes authorized users are folks that satisfy our requirements. These folks are going to have a problem and they may no longer be authorized users. It sounds like they're in trouble.

It also occurs to me that some of the cases that I know about, they can't prove any better than that they're delivering the prescribed dose, I don't know how they're going to remain to be authorized users. We have certain cases where we've shut down these operations.

MR. MOK: Maybe you should put those things you said in the guide here so that it is clear to us that a

milligram hours is not acceptable.

MR. TELFORD: You may be a t nat, but I don't think we can say you can't use hours. But even if you use it, you somehow have that the administered dose is the right dose.

MR. MOK: What's a prescribed dose? Do you prescribe 48 milligram hours and how are you going to prove it?

MR. TELFORD: It even becomes a bigger issue because probably in Texas, Radium 226 is controlled by the state, but in non-agreement states, you can have physicians out there doing whatever they want with Radium 226. Most, or at least the non-agreement states that I've had to deal with know very little about this any way.

The NRC does not regulate Radium 226. The states don't have anybody that know anything about what to do with this, and so the GYN oncologist can be out there doing all that he wants. He can say, okay, in a non-agreement state, I'll use Radium 226 and forget all of this mess.

MR. FELDMEIER: The NRC does not regulate Radium 226?

MR. TELFORD: No. It's naturally occurring.

MS. WALKER: Maybe that's something else. If the government wants to regulate the use of radiation, maybe they ought to do it right. Make it all or nothing. It's

not written in stone.

MR. KLINE: It's about as close as you can get.

MR. MOK: Maybe you need a good definition for the user who is a qualified expert who is an authorized user. Maybe you need a better definition than what you have now.

MR. TELFORD: I think in Part 35 is there is a fairly tight definition of authorized user. It's just that most of Part 35 is not required for agreement states. However, this regulation would affect those folks in a brand new way.

It's going to be a big surprise to some of them.

MR. BELLEZZA: I just heard two conflicting statements from John and earlier from Ed. I would relate that to 4.2. You said John was talking about someone who just got shut down because they were going by the rule of thumb in prescribing a dose.

Ed was talking earlier about how they acknowledged there were different types of fixed applicators and a physician with a lot of experience would have a good idea from the dose what the distribution would be before he ever saw a computer plan and wouldn't need it. Those two seem to be in conflict.

MR. KLINE: I'd like to make a comment on that. The nature of that case -- the reference that I was talking about is using a standard geometry and fixed where you don't

have various configuration used. In this case, this oncologist allegedly was using various configurations, various appliances, various applications of different loading sequences but did not know that those distributions and the time to take the doses out except when he felt it was reasonable.

There were no dose tables used. There was nothing and there's no reference. He practiced a long time in the field and there have been a number of patients which he had treated, but he could not tell you what doses they had received at any points and to any reference points. It was a little more involved. There was a question also on behalf of the State as to some other practices of this individual.

In regards to what I was talking about, it is that if you would need to demonstrate, but your demonstration does not mean that you have to have a computer program to prove that you have -- inserted into the tissue. If you can demonstrate that that geometry was standard all the time, that that dose, in your mind, that that person has been receiving is within a reasonable tolerance, we're not there to question the physics or question your medical opinion.

So there is a difference there. At first, I thought there wasn't and I didn't want to confuse it.

MR. BELLEZZA: Do you accept a prescription in terms of milligram hours?

MR. TSE: I think I can answer this. I think we do in the proposed regulation, but I think the case which John and Ed are talking about is involved more than prescribing the milligram hours. It involved much more.

If you read the definition in the proposed regulation and any physician -- some physicians, they are using milligram hours. Does that answer your question?

MR. BELLEZZA: In that one particular case, there was a separate review by a physicist and oncologist that were contracted by the NRC to look at this case. Their recommendations were very extreme; that they thought that this individual was not competent to be practicing medicine, so this is not just the analysis by the NRC.

Whenever we have these where medical discrepancies exist, people go in and study and look at the patient charts, look at the history and do an investigation. We look at their recommendations and then look at our recommendations.

That was a unique case. We don't have that sort of thing happening very often. Most people are doing a good job. There's just a couple of bad apples. According to our proposed definition, milligram hours prescription is permitted.

Second, if somebody prescribed milligram hours, the check would be a check on the milligram hours

calculation. That would be the check the simple check. If somebody prescribes a dose then some kind of calculation is needed to come up with a dose and the check involved would be checking those calculations.

If somebody uses milligram hours and you've already checked that and then, in addition, they want to make a calculation, I don't think this would apply, because you already checked the milligram hours that is the prescription on the dose. That's the prescription, but we will, as John mentioned yesterday, already noticed this point and we will have discussions with ACRS to see that your points will be considered also.

Now, any other questions relating to this section or this element. We can go to other elements if anybody has any problem with another element.

MR. BELLEZZA: Let me ask a question. Say a physician prescribes something in milligram hours and says, go ahead and do a computer plan. Now we do a computer plan and we do our check on the milligram hour calculation, so that's settled.

But he looks at the computer plan and says, this is too hot. That could have been wrong, or whatever. So, he adjusts his time, but he leaves it in and it turns out to be more than a 20 percent change in the milligram hour prescription. Is that a misadministration?

MR. TSE: No, if he authorized the change, re-prescribed. This is for 4.4 and is he permitted to change the prescription, but he cannot change it later if somebody finds out the calculation was of that magnitude and that would be a misadministration.

MR. JANICE: That's one of those unintended misadministrations.

MR. TSE: Unintended misadministration.

MOK: When can he change the prescription? Can he change it?

MR. TSE: In brachytherapy, he can change the prescription. He can modify the implant, even after he implants it.

MOK: Suppose, later on, people go back and find discrepancies. Can he change a prescription at that time?

MR. TSE: After he finds some error?

MR. MOK: Yes.

MR. TSE: I don't think so. It still might be a misadministration because, as a result of the error, he exceeds certain doses.

MR. MOK: There's a lot of difference if the dosage is over what he originally prescribed like 5000 rad and the prescription called for 4500 rad. It's not a significant change or damage to the patient and certainly he can change the prescription, so what's the difference that

he changes the prescription shortly after the implant or maybe a year later?

MR. TSE: Two items: one is that the 10 percent or 20 percent misadministration limit will be discussed this afternoon. Second; the difference from your example changed now/changed later, if you discover an error, an error somebody forgot to multiply by 2 and then the physician tried to change dose to take care of this error, that's not permitted.

But if the physician, because it's a problem, and it turns out the prescription would be changed, that's the physician can just make a note that says this is an update and I update my prescription because of these two sources that are supposedly changed by one --

MR. BENNETT: That is permitted.

MR. MOK: If the discrepancy is an error, can the physician change the prescription and it still causes an error, that is a misadministration? Is that how I understand --

MR. TSE: It depends on what you describe in your error. If your error is discovered after everything is completed and then they change the prescription, I think that's kind of a -- I don't know whether you could do that. If everything is completed and then you discover the fact that there was an error and you say, oh, don't worry about

it because I will change it to another prescription, but if during the process, you discovered the error and the physician notifies the physician that the -- we can't take care of the patient by lengthening the time or whatever -- then probably it would not be a misadministration because you discovered your error and you compensated for it in brachytherapy.

MR. MOK: It seems to me that you need to clarify that might someone might see which item --

MR. TSE: Misadministration will be discussed this afternoon. Here, we do not really say anything about misadministration. All we say is, 4.4 says we can change the prescription -- the physician can change the prescription.

MR. MOK: He can change the prescription shortly after -- an hour after the implant, after commencement of the treatment, can he change the prescription -- or, two weeks later, can he change the prescription?

MR. JANICE: All it says is he can change the prescription.

MR. MOK: It could be a year later that he decides, oh, I can give 4000 instead of 3500?

I would like to give you an example back to an implant, and then, after the initial calculation, there is a second check of everything. And then later on, I looked at

it, and I see, well, I missed a couple of sources here. I couldn't identify those sources initially. Now, those sources should be at this position instead of this position. And it changes the isodose curve by more than whatever percent.

Is that a misadministration? Can the physician look at that and say well, it doesn't make a difference to the overall prescription; can I just change the prescription, because it doesn't matter to the physician that much. It does the same thing for the patient. After the fact, after the treatment is completed, can you change the prescription?

MR. TSE: I don't think so, because when we talk about misadministration, misadministration is how many percent difference between the administered dose and the prescribed dose.

MR. MOK: The administered dose is over whatever the percent is?

MR. TSE: Right. The current regulation and also the proposed regulation we are going to discuss this afternoon do not say you have to have significant damage or impact to the patient. It just gives you the percentage.

MR. MOK: That percent, whatever percent it is, suppose the discrepancy identifies the source in my example is over the percentage? Can the physician change the

prescription?

MR. TSE: No. After the fact, it would still be a misadministration, even if you change it. But still, if you discove an error after the fact, if that error is greater than the threshold, then that's the misadministration already, regardless of whether you change. The prescription at the time you discover the error is the one you are going to use.

But you may make some suggestions this afternoon when we discuss misadministrations, how do you think that should be modified.

MR. MOK: Say maybe you want to suggest some changes.

MR. TELFORD: Let me understand this. You're saying that the physician just rewrites the prescription to cover whatever actually got delivered?

MR. MOK: It might not be that difficult.

MR. FELDMEIER: It wasn't really clinically significant. We were treating a couple of weeks ago, my residents were treating a spleen, for a large spleen in a patient.

There are a jillion different ways you can deal with that. We discussed the case. We chose to treat the spleen at 25 rads, two, three days a week. A lot of people treat with 50 rads. A lot of people treat with 100 rads.

You can probably go up to 200 rads, and probably not have any negative impact on the patient.

The technologist looked at the calculation, somehow or another misread the monitor units or something for rads. Instead of giving 12.5 rads from the front and 12.5 from the back, gave something like, I think the total dose ended up being like 60 rads, instead of 25. That's more than twice the prescribed dose. But it frankly has absolutely no significance whatsoever. In fact, some people we treat like that.

So I mean, strictly going by the percentage guidelines, we should have reported that as a misadministration, because it was more than two times the prescribed dose.

But on review, I mean, you look at it, and you say to yourself, did we hurt the patient? No. Was it corrected? Yes. I mean, I think that would be really making a mountain out of a mole hill in that situation.

So I think, I really think there should be some provision in there whereby you have percentage guidelines, because I think you need some guidelines, but I think that there should be a provision or a disclaimer that this amount of dosage difference should have some clinical significance.

MR. TELFORD: You bring up a very good point. When we talk about misadministrations, you have really two

ideas here.

First of all, did this extra dose exceed some threshold level; or secondly, did this extra dose cause some sort of harm to the patient, or deleterious effect? Keep those ideas, and we will deal with them this afternoon. But the idea of just rewriting the prescription to cover this, just won't cover it. We want to do the former. We want to do what you are suggesting in some way.

MR. FELDMEIER: See, the technologists will say, oh, my God, I gave 60 rads instead of 25. And you say, when you are approached by a technologist, I mean, I think you always have to fall back and say, well, you know, did we do the patient any harm. And if you didn't do the patient any harm, and if, strictly speaking, the regulation says you have to report this, I mean, I agree, I don't think we should do coverups; I don't think we should do anything to formalize the idea that things should be covered up. I think there needs to be some kind of a judgment implied.

MR. TSE: Okay. Any other comments? Any terminology problems in this section? Yesterday, after we talked about the technology problems, are there any terminology problems here?

MR. BENNETT: We're still on Section 4?

MR. TSE: Still on Section 4.

[Pause.]

MR. TSE: It looks like no additional comments. Any additional elements, or some alternatives?

Oscar?

MR. HIDALGO-SALVATIER: Can you summarize where we are on four?

For instance, what happened with 4.1?

MR. TSE: Nobody has made any suggestions on 4.1. today. 4.1. You said 4.1?

MR. HIDALGO-SALVATIER: Yes. 4.1.

MR. TSE: Well, we asked for comments for the whole section, and nobody made any suggestions today on 4.1.

MR. HIDALGO-SALVATIER: Okay. So I'm still of the feeling, and my physicians also, the physicians at my center, that NRC doesn't have anything to do with regulating the 4.1. I just want to make that statement.

MR. FELDMEIER: You are saying Oscar, that the medical use is indicated for the patient's medical condition?

MR. HIDALGO-SALVATIER: Yes.

MR. FELDMEIER: That part, just like we talked about yesterday?

MR. HIDALGO-SALVATIER: Yes. I just want to make sure that it is mentioned again today.

MR. FELDMEIER: Yes.

MR. TSE: Well, if we changed the regulation,

regulation objective as Objective 1, if we changed that, suppose we remove that one, then this one will follow.

MR. HIDALGO-SALVATIER: Okay.

MR. TSE: Any other points, Oscar?

MR. HIDALGO-SALVATIER: No others.

MR. TSE: Then we go to the next section, which is teletherapy.

Again, does anybody have questions or comments, suggestions?

MR. FELDMEIER: I was going to say the same thing about 5.1 as he said about 4.1, that the NRC really is not the appropriate regulatory agency to determine that. The medical applicability of radioisotope therapy has been looked at. And I think the way around it is to say something like, NRC assumes, or, it is assumed that other regulatory quality assurance organizations will review the appropriateness of the application of isotope therapy in patients, in any individual patient's conditions.

Because I think as sort of an introduction to the whole thing it makes sense to say we assume that the very first part of the whole process is to look at the patient and determine that radioisotope therapy is appropriate. I think we all agree that the NRC is not the agency to do that, that it should be professional peer review type of organizations.

I don't think it hurts to have a an informational point in there that you assume that that is being done by somebody else. I think that accomplishes what you would like to do is to remind people that that is the first step in the whole process. A determination should be made whether this therapy is appropriate for the patient. That's not within the purview of the NRC.

MR. TSE: The question is, is the referring physician and the authorized user involved in those cases?

MR. FELDMEIER: I hope so.

MR. TSE: So the idea here is to try to make sure that whatever the referring physician --

MR. FELDMEIER: Dr. Tse, I don't think anyone really objects to what is said. I think the objection is to who is saying it. The NRC, it is not within the NRC's charter to determine, to make a judgment as to whether the use of radioisotope therapy, teletherapy, brachytherapy, and iodine therapy is appropriate. That is for other medical professional peer review organizations, and is part of an overall quality assurance program, but it doesn't really come under what we see as the NRC's rule in this whole thing. It's something for the AMA or the ACR or ASTRO, or local quality assurance, or local credentialing committee. But not for the NRC.

I mean, somebody should be looking, somebody

should determine that a practitioner who is using radioisotopes, whether it is in a sealed source or whether it's an iodine pill, or whether it's cobalt teletherapy or brachytherapy, is applying that therapy appropriately. We're just saying the NRC should stay out of that and let organizations that are already in existence more properly have that charter. I hope you guys don't have problems with that.

MR. TELFORD: What if we said, to somehow put a little behind that, we say we expect that?

MR. FELDMEIER: I think it would be fine to say that you expect it, it is anticipated, it is assumed, that this will be done. But I don't think it should be written as if it's being regulated by the NRC. I think "anticipate" is a good word, "the NRC anticipates that the appropriate application of radioisotope therapy will be reviewed by the appropriate peer review organization.

I think this is meant to be a harmless statement. But I think it raises some flags with the professional medical community, because we don't think that the NRC should be in this position. There are already a bunch of peer review organizations that do this. I'm not saying it shouldn't be done. It's just a matter of who does it and who regulates it, and how it's written.

MR. TSE: Okay. Any other comments?

MR. BENNETT: I'd like to go on record as supporting that, and I know that our physicians feel the same way.

MR. FELDMEIER: I don't know if it is worthwhile taking some sort of a consensus vote or not. I don't know if that helps.

MR. TELFORD: No. We hear your logic. It's great logic.

MR. BENNETT: I have a comment on 5.2, if we're ready to go on.

MR. TSE: Yes, please.

MR. BENNETT: In the statement, "approve a treatment plan," if you are saying that that is a computerized plan or a manually-created isodose-distribution plan, I take exception to this.

If, on the other hand, it should read that the physician is thinking through a process of how he wants to treat this patient, and it is just his plan of attack for treating the patient, I can accept that.

But if you are talking about a computer plan, or a manually-created isodose plan, I don't think that that is appropriate. Especially before the first treatment.

MR. TSE: So you think it is okay to have the prescription?

MR. BENNETT: Correct.

MR. TELFORD: Doug, this just says a treatment plan. Could I get you to look at what it says that treatment plan shall include?

MR. BENNETT: I've looked at it, and I don't know what you mean by plan. Do you mean an isodose distribution plan, either computer-created or manually-created; or do you mean just a process that the physician is going through?

MR. TELFORD: It says total dose at specified location. It doesn't say isodose curves. This is a treatment to a point, total dose to a point.

MR. BENNETT: You are describing here then a prescription to include these things?

MR. TELFORD: This is the plan. It includes treatment mobility, treatment volume, or you could say treatment site, portal, or field arrangement, total dose at specified locations, and the dose for fraction and number of fractions.

MR. BENNETT: So a prescription.

MR. TELFORD: So where does it say anything about isodose curves?

MR. FELDMEIER: I think the word "treatment plan" has connotations in radiation oncology. You say, you know, has your physician approved a treatment plan, and everybody goes paging throughout the chart to look for the isodose printout, the multicolored isodose printout, to make sure

that the physician has initialled it. It's like a prescription, a treatment plan. I think that's the connotation that some people use on a daily basis. But if your definition of treatment plan is treatment modality, treatment volume, portal or field arrangement, total dose, dose per fraction, number of fractions, I think we can all live with that.

MR. BENNETT: I would prefer to call it something else. Plan is a word that doesn't settle, because it immediately tells me that there's a manual or computer-generated isodose distribution. So I would like to see it say treatment method, treatment approach, treatment design, or treatment scheme.

MR. FELDMEIER: Treatment course.

MR. TSE: I think I understand your point. It is that the treatment plan here does not say that only limited to those few parameters; the treatment plan says, including this, but could include many other things, too.

So if we say perhaps like a prescription and approved treatment parameters, as indicated, as included in those, would that solve your problem?

We're not trying to include all the details. It's just those parameters.

MR. BENNETT: Treatment method or treatment approach, I like.

MR. BRAHAMAVOR: You can resolve it by just saying the prescription includes an approved treatment plan, or that a prescription will include whatever the details of that plan are going to be.

MR. TSE: Our definition doesn't include a portal or field arrangements. I think our definition of prescription does not include all these things.

MR. BRAHAMAVOR: But that's how you're defining that, the prescription should include these things, because it doesn't include, you are telling them what it should include, in this particular .5.2.

MR. FELDMEIER: Just take out the phrase, "a treatment plan includes," and just say, "will approve the treatment modality, the treatment volume, the portal and field arrangement, the total dose, at specified location, dose per fraction, and number of fractions." I think you will accomplish what you are trying to say.

MR. TSE: Yes, just without these words.

But prescription is defined in the regulation.

MR. FELDMEIER: No one has problems with the prescription.

MR. TSE: He does.

MR. FELDMEIER: Do you?

MR. BRAHAMAVOR: But what I'm saying is if you have a problem with treatment plan, what is in the

prescription that includes? You are defining it so that you can remove it and approve the treatment plan. If you remove it, then you are just going to kind of define what that prescription, or that 5.2, that should resolve whatever the treatment plan issue may bring in.

MR. FELDMEIER: You want to personally make, date, and personally a prescription that includes --

MR. BRAHAMAVOR: That includes, that's all right.

MR. FELDMEIER: I can live with that.

MR. TSE: In that case then, with the term prescription, defined in the regulation, will also have to be changed to include all these things?

MR. BRAHAMAVOR: No, I don't think so. You are defining it here.

MR. TELFORD: The information that is asked for here in the treatment plan should be according to whatever we ask for in the prescription, as an alternate way to do this? Is that what you said?

MR. KLINE: I believe what you were trying to indicate is that the prescription is required and on top of that you should include these --

MR. BRAHAMAVOR: That's right. The prescription definition should remain. What you are doing for 5.2 is, you are specifying what the prescription for that 5.2 should include. So you are clarifying the prescription purpose

that was done for the case.

MR. KLINE: Maybe, would it be better to say, make a prescription, and shall also include the following? I know it sounds confusing, that we're now kind of redefining prescription.

MR. BRAHAMAVOR: No, we are not.

MR. TELFORD: We're not. But I don't want to confuse other people as we bring this point up.

I think the original intent of the treatment plan was to include these minimum things, but not the all-inclusive, meaning that some people will generate a computer treatment plan and have all this information on it; some people will manually do only a prescription with this information, not do a plan, of which the authorized user approves both.

So in essence, I think the intent here is you have to have a prescription, and the treatment course, Dr. Feldmeier, a word of that nature might be appropriate, a treatment course that includes the following, would not be strictly limited to that, in whole or in part.

MR. TSE: The word "prescription" in the proposed regulation as defined for teletherapy shall include proposal dose, number of fractions, and treatment site dose. Those are three things.

MR. FELDMEIER: You know, I think it can be

rephrased a number of different ways. I think the point that we're trying to make is that a treatment plan has specific connotations in the radiation oncology community. And there should be some alternative wording.

MR. TSE: Any other comments?

[No response.]

MR. TSE: Any other elements?

MR. FELDMEIER: 5.4 says after administering a dose fraction, a qualified person under the supervision of an authorized user will personally make, date, and sign a written record in the patient's chart, or another appropriate record, describing dose administered, et cetera, et cetera.

What we do on our daily treatment record is the technologist initials next to the day on which the treatment was given, and how many monitor units or how many rads per field or whatever, but it's not signed. There is an accountability in that the technologist initials it there, and there's a written record, but it's unsigned.

If you make an individual entry, you know, you're going to have a chart that's this thick.

MR. BENNETT: Yes. Our charts are massive enough. Initia[illegible] are all we need. We don't have space for full signatures on this. So I agree. Initials only.

MR. TSE: So the suggestion is to accept initials.

MR. BENNETT: Yes.

MR. FELDMEIER: M-hmm.

MR. JANICE: It is that the state regulatory comes in and views, and says whose initials are those, what they want to see is some statement signed by someone in authority saying Joe Blow has the initials of JB. So that they have to have it somewhere.

MR. BENNETT: Every institution is supposed to, every department is supposed to have on file within the department signatures and initials, and who that goes with. So you just put in a department manual someplace that Mary Smith, who is MS, as well as Mary Smith or M. Smith, or something like that, for signature.

MR. JANICE: What they actually want to see is a facsimile of that initial. They want to be able to distinguish that that "MS" equates to Mary Smith.

MR. FELDMEIER: Like the bank having a signature card on file, they want to have a memo on record saying that these are the true and authentic initials of Mary Smith.

MR. JANICE: Correct. Not just "Mary Smith" typed out and then "MS" on the side. They don't want that. They want to actually see what the "MS" looks like for Mary Smith.

MR. BENNETT: That is required by lots of other agencies.

MR. TSE: Okay. Any others?

MR. HIDALGO-SALVATIER: On 5.4, I think it is a good idea to add the time of delivery plus the dose delivery, the time of delivery plus the dose administered. It is more important to know what time the technologist set on the machine. The dose is a calculated value. The time is the actual setting on the machine. And that is more important.

MR. TSE: The time. Okay. So the time is how many minutes?

MR. HIDALGO-SALVATIER: How many minutes.

MR. TSE: I think do some people use that as a measure? I think [illegible] is equivalent to the dose administered, meaning was it a conversion factor.

MR. HIDALGO-SALVATIER: There is a difference. They can write the dose. But actually, they said something else in the machine. And the truth is what they said to the machine.

MR. JANICE: That's the dose delivered.

MR. HIDALGO-SALVATIER: Yes. Not the number, though, they're writing in there.

MR. BRAHAMAVOR: See, most of the chart, the patient's chart, includes the time that is set and the dose. Both the pieces of information are there in the patient's charts.

MR. BENNETT: Monitor unit, time, or monitor unit or time, plus dose.

MR. BRAHAMAVOR: Plus dose.

MR. TSE: In the cobalt-60 machine, do you write both numbers down, like time and dose? So if we have a dose administered that would be --

MR. HIDALGO-SALVATIER: It's not enough.

MR. TSE: It's not sufficient?

MR. MOK: You need both in there. Dose and time.

MR. TSE: Do you all agree?

MR. FELDMEIER: I think we routinely do it anyway.

MR. BRAHAMAVOR: It's done routinely, you can add it.

MR. BENNETT: Regarding signing a record, many facilities now are getting systems attached to their treatment units called "record and verify." Many of those also create a document that is computer generated as opposed to a manually-generated chart in that there is a computer generated initialling. Technologists have to type in their initials.

Will that be acceptable if we use this as our document in the patient's chart and if this is all typed out on a printer, plotter of some kind on a day to day basis?

Is that acceptable as opposed to a manually initialled?

MR. JANICE: I would think that if that's way it's written on their policy and procedure manual that they would have to accept that.

MR. MOK: They have always initialled that manually. Otherwise any technologist could put somebody else's name to it so the person who actually administered the dose, so if I would do it I'd have the dose and initialize it.

MR. BENNETT: The other thing is frequently there are two technologists working on a machine at the same time.

Very commonly the practice I've seen performed is that one will be documenting. The other one's working with it and both sets of initials are put in by the individual doing the documentation so that initialling may not be -- you know, Mary Smith and Nancy Jones might be working together and Nancy Jones puts the initials in of both people.

MR. MOK: I don't know but in our case we have two technologists on a machine.

I think one technologist's initials is sufficient. The purpose is you need the initials. You need to have proof that that person is actually there when he is doing the treatment.

If one person is there he or she can witness the other person.

That's my opinion.

MR. FELDMEIER: You need some accountability. If there's some problem you can say, you can come back and say who treated this patient.

MR. TSE: Okay. Any other questions?

MR. BELLEZZA: On that point --

MR. MOK: Can we go to 5.6 first?

MR. TSE: Okay.

MR. MOK: 35 percent prescribed dose for a very short treatment. That may not be appropriate. One or two times only so I think it should be something stating that with the exception of very short treatment like two days or so.

MR. TSE: If you have three fractions, when should you do the double check?

If you only have three fractions, let's say, after the first fraction?

MR. MOK: Well, the way --

MR. TELFORD: Did you say within two fractions?

MR. MOK: I would say within three working days for our institution. That's what my policy is. Within the third working day it's very possible the patient come in on Saturday. On Sunday the treatment may be already over so I think the third working day would be sufficient for that. You might want to put in there in my institution I will

specify in some cases if the dose is over a certain level like 400 rad I would require an immediate second check but for anything less than that amount I will allow them to go three working days without a second check.

MR. TSE: In those cases what would be equal to three?

MR. MOK: Three working days, so for example if you quit on Friday initially and for some reason you didn't get there on Monday you can check it on Tuesday.

MR. BELLEZZA: But does it still need to be done before the completion of treatment?

MR. MOK: Provided the treatment is over three fractions. If the treatment is over three fractions it would be over by Tuesday so you'd need to provide some leeway for some cases like that. I mean you do have cases like that. You don't want to come in on Saturday morning and do a second check.

MR. HIDALGO-SALVATIERR: But isn't it the three day that you're talking more restrictive than the 25 percent?

MR. MOK: Yes. You need to say 25 percent some special cases. For example, if the treatment only requires three fractions by the third working days like Monday or Tuesday when I come back it's already over so I would not be able to check that before the 25 percent dose. I would say

before the fourth working day.

MR. HIDALGO-SALVATIERR: Because we use in five days in Baton Rouge. The calculation has to be checked within one week, the first five days and we still have problems to do that.

MR. MOK: Yes. Sometimes we might miss the initial check but I think the three working days we have a couple of them and for some reason and for some reason we miss that, but I think the third working day would give me that requirement.

MR. TSE: May I ask you a question? Suppose you only have one fraction. Should you double-check your calculations before you administer the dose?

MR. MOK: It depends on the dose. If it's only 25 rad I wouldn't bother to check it. I would check it after the course of treatment.

MR. TSE: If it's a small dose.

MR. MOK: Below a certain dose -- if it is over 400 rad it would require a second initial before the treatment. If it's less than 400 rad, they could go ahead and do the treatment given it's only one treatment.

MR. TSE: But the problem is you don't know whether you're giving this patient 200 rads. It might be if an error was made, it could be 400 or 500 rads.

MR. MOK: Well, I mean you have to trust the

person who is doing the calculation.

MR. TSE: We always try to trust the person but as you said, you're asked to do a second check. A check is not indicating not trusting. It's just that sometimes you want a check.

MR. MOK: The thing is you mis-specify certain doses -- my policy is 400 rad in a certain treatment time, if it's not given in a certain treatment time for cobalt I would say maybe one minute, two minutes, depends on your dose rate.

If it's longer than the treatment time we will require a second check. If it's less than the treatment time, even if the person makes a mistake, the amount of error delivered to the patient is not going to be significant to justify to have a second check because you might be doing that Saturday at 11 o'clock. Where are you going to find a person to do a second check?

MR. TSE: Well, we have already said in one other case there was some suggestions that the person who might be able to check himself. Suppose that's the case.

MR. MOK: What's the purpose of checking himself?

MR. JANICE: The first time --

MR. MOK: We are talking about calculations. How do you check yourself on your calculations? You're supposed to check yourself anyway.

MR. TSE: That's the suggestion in this proposed draft.

MR. MOK: You are saying that a second check can be done by the same person?

MR. TSE: That is one of the suggestions here today is that in some small places, small institutions where they don't have people, what do they do?

MR. MOK: I would disapprove of that. How could you check yourself?

MR. BELLEZZA: I think there is a distinction between the situation in brachytherapy. With the teletherapy the calculations are much more simple and the technologist's treatment can do the trick.

You can train that person for bracytherapy calculation. It could very easily be that there's only, that the physicist is the only person outside who understands the calculation so I don't think you can. It's apples and oranges here.

As far as self-check here versus self-check in brachytherapy I'd say that in brachytherapy generally you do it by computers.

MR. BELLEZZA: Yes.

MR. TSE: The check's only checking inputs, not to see if somebody does understand what the heck is going on.

The physician can check.

MR. BELLEZZA: I don't think that's correct.

MR. TSE: But anyway, your comment on that doesn't apply here.

MR. BELLEZZA: That's right.

MR. MOK: For external calculations you need a second person and I think you should let the first treatment be done without a second check, not doing any harm to the patient, enough to cause any damage if it's less than 5 minutes. How many rad can you give to the patient?

The benefits you got with a second check compared with the course you were doing.

MR. BELLEZZA: My point is that there are two things I am always very nervous about, calculations being checked in a timely manner. On the other hand, I don't think that you can be effectively regulate for so many fractions or before certain circumstances.

I think as far as the regulation goes you might just say "before the conclusion of the treatment" and leave it up to the institution to decide what's effective.

I think if it wouldn't take too many times for an excessive dose to be delivered before the physician and physicist decide if we're going to do it every second day or something. I don't think you can really put a number on it. I think that's never going to get done. There has to be a certain amount of latitude within the institution.

MR. TSE: So your suggestion for this 5.6 again is to say "before completion" --

MR. BELLEZZA: And I think the institution would be well advised to have a policy that would be much more strict than that.

MR. MOK: What happens if you only have one treatment?

MR. BELLEZZA: You have to develop an internal policy to deal with it.

MR. MOK: Do you have to do a second check before the end of the treatment?

MR. BELLEZZA: Yes. I think that would be a good idea.

MR. MOK: It might be a problem.

MR. BELLEZZA: Let's say if it's compression on a Saturday, that comes under emergency.

If it's Monday morning and the patient comes in. This is somewhere else. The physician is doing the initial calculation or one of the technicians is doing the initial calculation -- the other technician can check, the technician on the machine can be trained.

If the technician is the person -- it's a real small operation and the technician does the calculation, the physician can do some sort of check. I think that's just good practice but I think that the timeline on it needs to

be done internally.

MR. TSE: Okay. Any other points? Any other elements?

MR. BRAHAMAVAR: You skipped 5.5(c). Does anybody have any problem? He can say so, whichever element.

MR. MOK: Are we going to order them?

MR. TSE: Does anybody have a problem on 5.5?

5.6 we've already discussed some of it.

Anything additional on 5.6?

5.7?

MR. MOK: On 5.7 when you say "using an accredited TMV service" what do you mean by an accredited TMV service?

MR. TSE: I think we might need to change this word. It would mean like M.T. Anderson and they would be approved.

MR. MOK: I think you need to specify.

MR. TSE: Any others?

MR. MOK: 5.8? About the transmission factor. We can also provide some way to calculate. Some material can be calculated or measured.

For example, we just measure the thickness of the lead and we don't measure every -- we just measure the attenuation that we use so if you have to measure every compensating filter it would be very time-consuming.

MR. BELLEZZA: Isn't that covered?

MR. TSE: It did not say individual. Any problem with the tray wedges? Anybody have a suggestion on those things?

MR. BELLEZZA: This may be nit-picking but as far as different stocks of material, a tray that you bought now versus a tray that you might buy in the future or something like that, how nit-picky does that get?

You know, it's lead. Lead is a quarter inch of acrylic.

MR. TSE: So your suggestion is that some of these may not be necessary to be measured.

If you have such a suggestion you may say so.

MR. BELLEZZA: I don't know. I just raise the question but at some point someone has to make a decision about how much stock, what mixing of different batches of materials is sufficient to cover whether somebody is -- I worry about the inspector in the field.

Am I just being very nit-picky?

MR. TSE: Let's go one by one. Should trays be measured?

MR. BRAHAMAVAR: Any time you change, you know your material is different, you have to measure before you start using it.

I'd say that's common sense. If you change your tray material, then before you put that and start using it

on a patient you have to check the transmission because the transmission is going to be different. It should not be annual. It would be immediate and you check that at the end of the year perhaps. That's what that means. That's how I interpret that.

MR. TSE: I think that's 5.9, 5.9 says that. If you have not been measured before you have to measure but 5.3 is the annual, each year you need to measure.

MR. BRAHAMAVAR: Yes, but in a year you might have changed your stuff so when you change the stuff you measure it again.

MR. MOK: What happens when you change your stock? If you use lucite we order continuous, probably several months and we order a whole bunch of acrylic trays. I don't think I need to measure every time when I order the same tray because we use a lot of trays and it would be a lot of work.

As long as I know the attenuation property of that tray, I only have to measure once. I don't have to measure it every time that I order the acrylic.

MR. BRAHAMAVAR: You don't have to measure it if the quality of whatever the material the tray is made your supplier is supplying the same thing, you don't have to re-measure it but if you have changed it, then you have to.

MR. MOK: I don't have to measure it every year.

That's what I'm saying.

Why do I have to measure it every year? We do as a good practice but I think shouldn't be a requirement.

MR. TSE: So the tray may not be necessary to be measured every time.

MR. TELFORD: Question. How about a sample of those trays?

MR. MOK: I think it is useful to measure samples of trays once a year just as a good practice. I thought it was -- some things we don't measure every year. If we know it's there we just calculate it.

The transmissions we don't measure every year.

MR. HIDALGO-SALVATIERR: When you think that measuring dosimetry might be important you might be able to detect if the source is not placed correctly.

MR. MOK: Yes, but you really have to measure the transmission once a year and of the lead and lucite or whatever material we use. That's a lot of work.

MR. HIDALGO-SALVATIERR: They should be done.

MR. MOK: Well, I don't think we have to measure the transmission with lead.

MR. HIDALGO-SALVATIERR: No, I was talking about symmetry. Flatness of the beam.

MR. MOK: I don't think so. That's us to us to decide whether it should be measured. I was going to bring

it up later on. This is a sidetrack from what we are doing, talking about now.

I don't think it's up to NRC to tell us what shall be measured and what shall not be measured. I think it's a profession. As a qualified physicist I should be able to determine what to measure and what not to measure.

I think the NRC, within the scope of NRC they can say you have to do it once a year. They have the right to do that but they shouldn't tell me how to do the calibration.

For example, in 5.10, this says I have to measure an open field in angles and I don't think it's up to the NRC to tell me to do that.

MR. TSE: Let's talk about that at that time.

MR. MOK: This is a sidetrack.

MR. TSE: We will talk about that when we get there.

Now 5.8, what should be include and have to measure?

MR. MOK: I think what you should do is if it would affect the transmission of the property being determined and if they would do the calibrations let the person who does the calibration decide whether that should be measured because he has this responsibility to decide whether it should be measured or not.

MR. TSE: What do you think should be measured?

MR. MOK: I would measure the sample trays. I would measure -- I don't think I would measure, you know, once a year, and the box, I don't measure the box once a year. The bolus we just measure it initially when we use it. If I decide to use a special bolus material I measure it but I don't do that once a year.

I don't know if that's the way you do it or not.

MR. TSE: So your suggestion is to say sample of trays and wedges.

How about retesting block material?

MR. MOK: It has to be measured once. I'm talking about annually.

MR. TSE: Anybody else has a view on this element, 5.8?

We go to 5.9 -- 5.9 essentially like you all said it is if it has not been measured before, either the field size of something or are they being modified? You should do so before 25 percent of the dose is delivered.

MR. BELLEZZA: Why don't we take out the 25 percent and make it "before completion."

MR. TSE: Any other comments?

MR. BRAHAMAVAR: How restrictive is No. 1, the field sizes of treatment distances that fall outside the range of those measured in the full calibration? How

restrictive that statement is? When you make a full calibration you are basically measuring the standard field sizes, 5 by 5, 8 by 8, 10 by 10 and go up to 25 by 25.

In real life when you treat a patient they are not square boxes. You are generally treating different rectangles and squares, and you are taking a rectangular field. As for this, it does not measure in a full calibration. We have not included 8 by 11. That means if it is an 8 by 11 field, do we have full calibration or do you measure that one before we take a patient?

MR. TSE: Well, the intention is if you can interpret inside your maximum. Maybe you do not have to measure. There's some charts or some data you can use to make it the interpretation but if it's an extrapolation outside the range. If you said 12 by 12, you go way beyond 12 by 12, this element suggests that we should measure it.

Now the physicist has to make a determination. If you change it one centimeter or so, the changes are small changes, or like you say, if a square you measure square and it become rectangular but obviously where you are going outside your measured range this element suggests that you should do a measurement.

Do you have a problem with that?

MR. BRAHAMAVAR: No, see if it falls within the minimum field size and the maximum field size, anything in

between we use it because it is not measured at the full time calibration level, full calibration. You can extrapolate, interpolate between the two and use it. That I think is fine.

MR. TSE: It says if it is outside the range of those measured in the most recent full calibration.

MR. BENNETT: What about extended SSEs? You measure a 35 by 35, you set a 35 by 35 field size, which is at 80 centimeters, but you go to 150 centimeters.

MR. TSE: What do you think? Should you measure? Would you be comfortable not measuring it?

MR. BENNETT: In my annual calibration, I verify that the inverse square log is appropriate, and I would have in the calculations the appropriate data to account for back scatter factor and other things.

MR. TSE: So, you would be comfortable, even though annual calibrations did not measure up to this large distance, you would be comfortable by using the inverse square log.

MR. BENNETT: Part of the annual calibration is to verify the inverse square log.

MR. TSE: Up to which distance?

MR. BENNETT: I don't know.

MR. BRAHAMAVAR: Part 35 says extended distances. So, it may be anything. Standard is 1,800. That's what you

measure.

So, if you go to 70 or 110, then you are really basically using the inverse square log, what he is talking about, which is not measured.

MR. MOK: For a calibration, you should measure the inverse square log when you do the annual calibration. I'd measure the 70, 80, 90 up to maybe 120 and see if the inverse square log works, and I think you would still be allowed to do that.

MR. BRAHAMAVAR: But once you proved that and your machine is there for 10 years, you won't have to do it every year then. If it applies once, it will stay.

MR. MOK: I don't know about other people, but I do the inverse square log for a check. The way they scatter can change. It may -- even in an inverse square, it may be off a little bit.

The source may drop a couple of centimeters; you never know.

For extended SSE, if I'm shooting 200 centimeters, I definitely want measured.

MR. BRAHAMAVAR: Yes. That you would.

MR. TSE: I'm not sure whether it's comfortable with the physicists or physicians just to use inverse square log to determine how many minutes to treat the patient.

MR. MOK: I think it's verified. If the inverse

square log is verified, I should be able to calculate, but it should be verified once a year. It's very easy to do, just like three or four measurements.

MR. TSE: Okay. Any suggestions for a change or modification?

[No response.]

MR. TSE: How about the second item? Items 5.9 says a beam modifying device, which essentially says if you have not measured it before, you should do it.

Any questions, comments?

[No response.]

MR. TSE: How about the items that you would treat? It says beam modifiers, except blocks, pumice and starting material. These can be accepted? You have no problem?

MR. HIDALGO-SALVATIERR: Why except blocks? That's when it's probably most important to check it. If you have a very irregular block or a very irregular fix, it's a good idea to check it.

MR. TSE: Okay. What do the physicists think? Should we not exclude blocks?

MR. MOK: We make blocks every day and they are not checked. I mean we don't check every block that we make.

MR. HIDALGO-SALVATIERR: But some block are very

irregular.

MR. MOK: According to what is said, any beam modifier, modifying device, you say you would exclude. You say you would take blocks out. That means you would have to measure every block and put it on the machine. I think you should leave it to us to judge whether it should be measured.

I mean, Oscar, there is a certain table to decide whether that block should be measured or not, and then I would measure it.

MR. BENNETT: I don't want it left in there that it implies that every single block that we create has to be checked. I agree that there are certain devices that we create that, sure, we should check that.

MR. TSE: But we can't determine that.

MR. BENNETT: We will determine if we've got some blocks that -- we call them polo blocks, but they're terrace blocks, and we have to verify the attenuation on those before we ever use them. But I don't want it to be implied that every single square or irregularly-shaped block has to be checked before it's used.

MR. HIDALGO-SALVATIERR: That's not what we're trying to imply, every block, but the output -- this 5.9 refers to the output, right? And there are certain blocks that are designed for special cases that is not

straightforward to calculate the output. I think, as a rule, we have to check both. You know, the block might be just a circular thing.

MR. TSE: I thought block is to stop the beam. To stop the beam, you have a very thick material. The transmission factor is almost zero. It's very small.

So, the reason we did not put it in is because there's not much we can -- it's pretty thick with not much changes.

MR. HIDALGO-SALVATIERR: We're talking about the output, isn't it?

MR. BENNETT: No.

MR. HIDALGO-SALVATIERR: A physical measurement of the output would be made.

MR. TSE: Yes. Is it important to measure output under the block?

MR. HIDALGO-SALVATIERR: No. That's not what I understand. That's not my understanding.

MR. BRAHAMAVAR: The output of the dose delivered with the block in, not the transmission of the block, not measuring the dose but the dose delivered by the irregular field that is created.

MR. TSE: I think I may understand your point on this output. I don't think we really mean that.

We mean that if you have a certain beam-modifying

device and you have not measured before, during your annual -- say you just bought it today -- if you have not measured before, you should measure the transmission factors before you use it, before 25 percent is over.

MR. HIDALGO-SALVATIERR: That's not my interpretation of 5.9.

MR. TSE: Okay. Perhaps we should change this to two sentences: ways to measure output associated with number one, and then, second is a measure of the beam -- of the transmission factor would be associated with number two.

MR. HIDALGO-SALVATIERR: But 5.8 is clearly the transmission factor.

MR. TSE: Yes.

MR. HIDALGO-SALVATIERR: But 5.9 is the output.

MR. TSE: What do you actually do if you have a beam-modifying device not used before? What do you actually do?

MR. HIDALGO-SALVATIERR: I measure the output. With most of the blocks, I'm not talking about the transmission of the block itself. I'm talking about the output through the opening in the block. The output will change according to the shape.

MR. TSE: So, you are measuring --

MR. HIDALGO-SALVATIERR: The output.

MR. TSE: You measure the dose to see how much

scattering you have with those, when you measure output.

MR. HIDALGO-SALVATIERR: That is my understanding of 5.9.

MR. TSE: Does that also apply to the other beam-modifying devices, like trays?

MR. HIDALGO-SALVATIERR: No, they're different. You measure the transmission of a block, of a wedge or a tray, but you measure the output -- you can measure the transmission of a sediment block, also, but when you talk about output, you don't talk about transmission. You're talking about the outputs of the machine through the unblocked area.

MR. TSE: No. My question is what do you do? Do you measure the output of the machine?

MR. HIDALGO-SALVATIERR: For blocks that are very --

MR. TSE: Irregular?

MR. HIDALGO-SALVATIERR: Irregular blocks.

MR. TSE: You do that.

MR. KLINE: Possibly, a better word for "transmission" might have been more appropriate. What Oscar might be talking about is that, in the past, there have been some machine designs that certain companies have come out with where you can form an irregular field with an accommodating system, and then you're talking about

measuring the output within the field, or if you interject a block that has a hole in it and measuring the output?

MR. HIDALGO-SALVATIERR: Yes.

MR. KLINE: I think the intent, when it was written, was to -- they were talking about solid blocks, not irregular fields, not field holes within blocks, just a regular solid block that used in the blocking trays.

I don't we got that specific as to irregular field or irregularly shaped in the head or in the blocking tray. But I understand your confusion, because output and transmission --

MR. HIDALGO-SALVATIERR: Are different.

MR. KLINE: -- are two different things.

MR. TSE: Now I understand.

So, the point is that we should measure the transmission factor of trays and wedges, if it's not measured before, so that the changes possibly here in 5.9 is to say measure the output with -- associated with item 1 and then make a second sentence; measure transmission factor of those beam-modifying devices. Would that solve the problem?

MR. HIDALGO-SALVATIERR: I don't know. That doesn't clear to me.

MR. BELLEZZA: The sentence construction is going to be awkward.

MR. TSE: I'm talking about the idea first.

So, we are really not intend -- at least in my thinking -- not really intend to have you measure the output of a complex or an irregular block situation. If you want to measure, because of your calculation, whether it will work, then you do it yourself, but it's not stated here, unless you want to add it. If someone is suggesting to add an element, that one could be added.

MR. HIDALGO-SALVATIERR: No. That was my interpretation of 5.9. I thought you were talking about output.

MR. TSE: Right. I understand. Thank you for the suggestion.

So, if I said, if we said for -- under this item, for beam-modifying devices not measured before, our suggestion is that you should measure the transmission factor of those devices, still except blocks, pumice.

MR. MOK: Can we adjourn for lunch?

MR. BENNETT: I want a clarification of one thing.

Would we meet the intent of this if we did a measurement in or on the patient during the treatment within the first 25 percent, by placing TLDs on the patient or diodes on the patient, to making measurements to verify that our calculated dose to those points is verified by actual measurements at the time of treatment, as opposed to doing this with open field, without the patient there, in the

evening or weekend or something like that?

If we do the calculation, if we do a computerized treatment plan, and we say, at the central axis, on this surface, or D Max, whatever, and then we actually make some measurements with TLDs or diodes, do we meet --

MR. TSE: We said a physical measurement. So, if you have a TLD measurement, you can use it to develop a transmission measurement.

MR. BENNETT: It would incorporate everything. It wouldn't break it out independently.

MR. TSE: Yes. That would be okay.

Anyway, we can continue this discussion after lunch, because you might want to think about it.

Perhaps we should stop for lunch, and we'll come back at 1 o'clock. When we come back, we'll finish a few things; then we'll go to misadministrations.

[Whereupon, at 12:04 p.m., the meeting recess for lunch, to reconvene this same day at 1:00 p.m.]

AFTERNOON SESSION

[1:10 p.m.]

MR. TSE: We're going to reconvene the discussion of brachytherapy.

Before break for lunch, we were talking about element 5.9, which talks about output, and we understand Oscar's point.

Any other discussions of points that were raised in 5.9?

[No response.]

MR. TSE: How about 5.10?

I really didn't know what you said last time in the workshop. What we're going to do is, for now, to ask you to forget about the conditions. Look at the intent. The intent is to make the calculation and verification of your computer output versus the measurement, how it's going to be done. You can also make suggestions of how you think it should be done. We're also going to have discussions with other associations.

But what do you suggest on when this should be done or should not be done or how you'd do it?

MR. MOK: I think the intention is very good. I agree with you. You need a check of the computer program.

What I think we should do, instead of having all those conditions, you should say according to guidelines

published by AAPM or whatever society you choose that is relevant to the computer program. It is there for you to specify the tests required to do.

MR. TSE: Okay. Any other suggestions?

MR. BELLEZZA: I second that. Unless you do that, you may as well just delete this, because I think to specify a specific measurement condition makes no sense at all, unless you just want the regulation for the sake of sentences.

You're trying to regulate specific measurements and enumerate them. It doesn't make any sense.

MR. TSE: But you also agree with the intent.

MR. BELLEZZA: Absolutely. The intent is fine.

MR. TSE: Okay.

MR. BELLEZZA: But it's not practical.

MR. TSE: Under these specific conditions, under those conditions stated here, you believe it's not practical.

MR. BELLEZZA: And I don't think that you can write a regulation that will include any specific conditions which would be practical. I think a task group could spend a few years on it. A graduate student could write a thesis on it. Unless some professional group or the AAPM comes up with a program and you say follow that program -- that's one thing, but I don't think you are able to come up with a

program.

MR. TSE: Okay. We could talk to AAPM and see if they have guidelines.

Any further comments?

MR. HIDALGO-SALVATIERR: My comment would be that the intent is good, but anytime you try to put specific methods, how to -- "how to" should not be in a regulation, because by the time the regulations come to be effective and everybody implements them, the technology and the methods and the standards have changed, and they should be left to either the standards societies, which establish standard protocols to be used for this purpose, or leave it to the institution and submit to you the plans how they are going to take care of this. There are two ways of doing it.

Let the institution develop their own plan on how to verify computer plans or those measurements or treatment plans or the micro-fields and submit those as their protocols in lieu of following the standard AAPM protocols.

MR. TSE: Okay.

MR. BENNETT: I think I'd only agree with the statement of intent and no specifics, and I don't think it would be even appropriate for an institution to submit specifics as to what they're going to do, because they're going to change, depending on new software, as its developed, or they change treatment-planning computers or

some things that are specific to one system, as opposed to the other.

So, I'm supportive of the statement of intent, but not the specific issues.

MR. TSE: Any other comments?

MR. HIDALGO-SALVATIERR: I agree with everything they say.

MR. TSE: Okay.

Any other comments?

MR. BELLEZZA: I'm a little bit fuzzy as far as, you know, if you make a statement of intent, then do I have to go back and do something about that to try to satisfy the inspector?

MR. TSE: First of all, let me explain again, these are the guidelines. Generally, the inspector should not say you must do it this way. But what we are concerned -- I did not mean to read earlier, because we are thinking about suppose an inspector says you must do this in what kind of a situation and then what should the licensee do?

And my thinking is that intent, if we say intent, we mean that somebody should do something like make a calculation, check the output to make sure they are close or match, so that when we go with the treatment program, at least for this particular check, it's okay.

If that's a good intention, probably we would

maintain this item, but we will change the conditions into generalized words or follow the suggestions, use AAPM or some other thing as standards, if it's available, and we cannot say it at this time, because we have to consider other people's comments and discuss with societies and so on. But we will take your suggestions into consideration and your advice.

We probably will not delete it, because your feeling is that the intent is good.

I cannot tell you exactly how it will be modified at this time.

John?

MR. TELFORD: Allow him to suggest a modification.

MR. BELLEZZA: I've thought about it; I can't come up with any. I'm to the point where I think it's better to delete it.

MR. TELFORD: You might say that after a source change.

MR. BELLEZZA: Ed mentioned earlier this morning something about setting up a condition where you would put a chamber in a phantom and measure that, compare that to what the computer will generate. That's only good for that specific situation. You don't have to change the field size, and you're using a totally different set of data in the computer, and you verify essentially nothing.

MR. TELFORD: Could we make the statement, without being specific, just say, in general, after a source change, make a comparison between the calculated output and measure it?

MR. BELLEZZA: Now you're mixing a few different things, when you talk about computer programs.

MR. TELFORD: Let's split this.

MR. BELLEZZA: We've got computers that do time calculations, on a personal computer or something like that, and you've got treatment-planning computers, a treatment-planning computer that may not be used or have in it all of the activity of the source decay. A source change or annual calibration gets rough because you're looking at different distributions and different treatments.

MR. TELFORD: So it's not the treatment planning. Is that what you're saying?

MR. BELLEZZA: Well, I'm not sure what you're really trying to nail down here. Are you trying to look at treatment-planning computers or dose-monitor calculations?

MR. TELFORD: It's real simple. It's like if you change the source and you forget to tell the computer that you changed the source.

MR. BENNETT: That may not apply. That may not even come into play, because there are some computers that you can do isodose distributions and it has absolutely no

basis as to what the output is of the machine. It just gives you an isodose distribution. Whether you create that in 20 minutes or 20 years doesn't make any difference. Source activity is unimportant.

MR. TELFORD: It's relative dose? It's all normalized?

MR. BENNETT: A hundred percent, 95 percent, 90 percent, that kind of thing. So, if you change the source, you don't change any information in the computer unless maybe it's the source size has changed. So, Penumbra has changed if it's on a cobalt unit.

MR. BELLEZZA: I think what you're trying to nail down are dose-monitor calculations, and I think you need to specifically state that without regard to relative distribution, just dose-monitor calculation, something about the output that's being used.

MR. KLINE: Do you feel that people, other physicists, will understand that term? Is there any feelings on what that means? Would you know what that means if that were in the reg right now? Is there a more generic term?

MR. MOK: I agree with David. Sometimes the isodose may not be related to the output from the machine. But on the other hand, I don't think it would hurt to check the computer isodose curve even if the output is not related

to the computer program. Now, the dose could change. I thought that may change afterwards, once a year.

You take a 10 by 10 isodose curve and compare it to your 10 by 10 measured, and I don't think it would hurt to do that. I think it's a good practice to do that.

MR. TSE: So, to change 5.10 to include the -- dose measurement where you change the source, in addition to checking the relative isodose curve, we can generalize there, saying that you have to check your computer program once a year.

MR. BELLEZZA: But if you start saying that we're going to check the relative isodose curve, where does it stop? So, you do that for a 10 by 10 field. That says nothing about 12 by 5.

MR. TSE: I agree. That is why, instead of having all of these conditions in there, we should check it according to the guideline of number so-and-so.

MR. BELLEZZA: Is there a guideline?

MR. TSE: I think it would be perfectly appropriate for NRC to go to AAPM and say we need to have the guideline.

MR. BELLEZZA: I don't know that there is a guideline.

MR. HIDALGO-SALVATIERR: There is the AAPM correlation to the quality assurance. There is a report,

report 24 or something. It was published only about a year ago.

MR. MOK: There is a computer committee on the AAPM. I think, if there is no guideline, AAPM should come up with one on quality assurance. It would be up to the AAPM to come up with one.

MR. KLINE: Actually, that's something we are considering with our dialogue today with AAPM and ACR, is to look at some of their proposed protocols and acceptance testing or however they define it regarding source changes, and it's not beyond the scope of the NRC to reference a document of that nature within the Federal regulations, as they do now in Part 35. So, it can be done that way. They're quite detailed in their software analysis. That's one viable option.

MR. TSE: Let's look at the intent of this particular section, of this element. The intent is to make a simple check, not a comprehensive software check.

So, on the book, we have another so-called comprehensive QA, and that addresses the comprehensive software check. But here, in the basic QA program, we just want to make sure that if it's a change of source, we need to ensure your computer code, the source is modified accordingly.

MR. BELLEZZA: Then I think if you just write

something very narrow addressing just the source strength in the computer program.

MR. TSE: I think that's what we have, is the intention to have one simple check before you first use that computer program and after changing source strength.

You can make a check of the computer calculations versus actual measurements.

MR. BELLEZZA: You need to specify that the computer program that uses the source strings.

MR. TSE: We have the parenthesis here for embodying relative calculations. If you have a computer that doesn't expose it so that you can check against the measurement. So for -- you still need to make a calculation, plus your additional calculations will give the dose rate. But it's supposed to be a simple check, not a comprehensive software check.

MR. BELLEZZA: And the problem is that even what's in parentheses can be interpreted as being a very large project.

MR. TSE: Okay. Maybe from that we might want to modify it to make it more clear that it's not that -- that it's not a comprehensive check; unless you have some suggestions? And we will take your comments, and when we consider -- do you have any suggestions?

MR. BELLEZZA: I don't know how to run the

language narrow.

MR. HIDALGO-SALVATIER: Let me add some more to what they said.

To begin with, I've never see anybody testing a computer program following point number one or 5.10. Where did it come from?

MR. TSE: Okay. Let me state it again. Assuming these are there for today's discussion, we will ask you how to do it, or we'll ask APM how to do it an so on. And we may even put the generic statement like was suggested. Where this has come from -- they are coming from a meeting with ACR, some people suggested that, so we --

MR. HIDALGO-SALVATIER: Number one, is to test the computer to deliver a dose at dosing error, it just doesn't make since. I don't what committee was that, but -- MR. TSE: Okay, it's coming from some discussions. But we're going to --

MR. HIDALGO-SALVATIER: The intent is good. What you'll have is an acceptance testing on a computer program and a periodic quality control. But one, two and three -- I will eliminate them all.

MR. TSE: We had that. Next time we may -- we may let them know. Okay, any other point on 5.10?

[No response.]

MR. TSE: How about 5.11 -- I don't think anybody

has made a comment on 5.11?

[No response.]

MR. TSE: Any other additions or alternative method which you used in any section in the teletherapy portion?

[No response.]

MR. TSE: John, I think it's your turn.

MR. FELDMEIER: Thank you.

MR. TSE: Thank you.

[Brief pause.]

MR. TSE: Thank you, we're up to the point of talking about the proposed 35.33 -- the proposed diagnostic record keeping and reporting environments. And I'll put up some viewgraphs, but keep in mind that the exact words you'll need to refer to on page 1447 of the proposed rule in the Federal Register Notice -- 1447. 1447 is the actual language, 1442 was merely the descriptive portion. So there's probably going to be a discernable difference.

Now, on the screen on the right, I just want to start by saying these are the current requirements. I'm told by the State Agreement Program folks that as of April 1st this year, the agreement states are now -- agreement state licensees are now obligated to report these mistakes and misadministrations.

Okay, number one is the wrong source, number two

is the wrong patient and number three is the wrong route and four is when the administered doses, diagnostic test is 50 percent different from what was prescribed and number 5 is when you have radiopharmaceutical therapy, and the administered dose is 10 percent different than what was prescribed, and number 6 captures both teletherapy and brachytherapy, and it is when the administered dose is 10 percent different than what was prescribed. Those are the current requirements.

I'll leave those over there for a little bit -- stand over to that viewgraph. But in 35.33, we have proposed some new reporting requirements on diagnostics. The (A) paragraph here, we're going to define things we're going to call events; (B) we going to define things we're going to call misadministrations. Events are those kinds of things that are not as bad as misadministrations. That's the overall scheme here.

So we have, in (A) we have the events and (B) we have misadministrations, and (C) that says who's going to do what and (D) that says under what conditions. If you meet or exceed these thresholds, you'll have a report. And Ian says you'll keep these records, that's the overall scheme.

So let's start with A -- Part (A) events. The intention here is to have an internal feedback loop within the licensee organization that reports these things so that

-- and correct reports that you steer along and be aware of the fact that you may have a bunch of little things -- maybe they're little this time because you were lucky; next time they may not be so little. So we have to have feedback loops so you can figure out if you want to make corrections.

MR. JANICE: (A)2.

MR. TELFORD: (A)2.

MR. JANICE: We did have, during this trial period, well first off, we're going to go oral referral as well, depending on the -- what the final outcome would be.

MR. TELFORD: We'll have some kind of new defined referral mechanism that we will try -- we, the staff, will try to write a referral mechanism that starts with something like having what we described yesterday, as an oral referral, where somebody on the referring end is reading from a chart or off the information on his form. And you're talking to a person on your end and they're writing it down -- all the pertinent information.

Then, if that allows the technologist to follow a standard order like a standing order, like in the procedures manual, then you're doing what the authorized user is telling you to do; but if there's a departure, you go back to the authorized user. So assume that something might exist.

MR. JANICE: During the trial period what took

place is that we did have patients that came without prescriptions or referrals for a procedure. We recalled the office and verify again that that's really what they wanted. We would go ahead and tell the office, if they had a fax machine, to fax us the prescription, if they didn't.

After the injection and the waiting period, we would go to the office and pick up the prescription there. Would that still hold water?

MR. TELFORD: If we modify a referral -- if you get a patient who didn't come with a written referral so you could confirm the information by phone, ask them to read from their chart, or their form and put it on your form. If both made sense to you, and you could follow a standing order from the authorized user, then you'd be okay.

MR. JANICE: The problem I can see with it is what David was saying yesterday. His people are so hostile out there. Patients get stacked up in the hall.

MR. TELFORD: He has the alternative of going to the authorized user and saying, should we do this? In essence, write a prescription. He has his choice. He can delay or have it written.

MS. ROY: Wouldn't it be covered by the footnote that's at the bottom of the third column here, 1447, where it says, "an oral instruction may be acceptable, but a written record of the information specified in 35.2 for

prescription shall be made in the patient's record within 24 hours." And that's a footnote to diagnostic referral.

MR. TELFORD: If you declare it to be an emergency.

MR. JANICE: Who declare --

MR. TELFORD: On the rise to -- so if you want to declare that an emergency -- a diagnostic test is an emergency, okay.

MS. ROY: That's what it's referring to is a diagnostic test. It depends upon it is --

MR. TELFORD: Like a lung scan. A person comes into the emergency room. An auto accident?

MR. JANICE: The emergency room is going to have the orders written on the emergency room chart, signed by a physician or a telephone order -- signed by someone -- from the physician.

MR. TELFORD: I guess I was imagine something where it happens a lot faster than that. Somebody comes in very quickly and somebody says we've got to have a lung scan, stat, so the patient is whisked off into the diagnostic test area. That's why that is intended to capture -- to allow that -- to notice to allow handling a patient under conditions like that.

MS. ROY: Okay.

MR. TELFORD: Truthfully guys, we didn't intend it

to allow how much of other things.

MR. JANICE: I don't know.

MR. TELFORD: If your authorized user wants to declare those are emergency cases, okay. That's a medical judgment.

MS. ROY: Okay.

MR. HAMMOND: Before we move on, for the record, if we're talking about delete, modify or retain -- I would agree to this remaining -- to remaining in there as long as we change the diagnostic referral definition. If we're not going to change the diagnostic referral to include oral, then I think we should remove it because we're only going to be reporting multiple things that we can never change.

MR. TELFORD: Okay. Any recommendations on whether we should delete, modify or retain all of (A) or anything in (A) -- go ahead.

MR. HAMMOND: If we're going to move on -- in (A)3, according to what's in the Federal Register, when we're talking about diagnostic medical use, why do we have the administered radiation dose, when what we're actually talking about is the radiopharmaceutical dosage administered, not the administered radiation dose. That's not the normal calculation for diagnostic medicine.

MR. TELFORD: That's a good point. Before we close the door on (A), let's see what happens if we have

(A), an event here that says that you'll have the RSO investigate and make a record if one of these happens.

Now, is an RSO the proper person that we're suggesting the RSO's action appropriate? Would you like to delete, modify or retain that?

MS. ROY: Appropriate action -- you've got example to investigate and report that could be as simple as you can have a prescription slip.

MR. JANICE: What is he going to say, next time, make sure you have one?

MS. ROY: Let's just make sure you get it -- is that enough?

MR. TELFORD: In the exact words it says, "an RSO shall promptly investigate its cause and make a record -- obtain a record and notify the licensee management." That's on page 4248. So, the cryptic message here is investigate and make a record.

MR. HAMMOND: The third part is notify the management. He's got to do all three.

MR. TELFORD: Correct.

MR. HAMMOND: Personally, I think the RSO is the appropriate person. In most cases, at least in the state, the RSO is the authorized user for nuclear medicine. I mean, the RSO, that's what he's there for, whether he's the authorized user or not.

MR. JANICE: It looks like you're fishing for something there.

MR. TELFORD: Let's go back to (B) and pick up diagnostic misadministrations.

MR. JANICE: I think David brought up an interesting point the other day. We can -- if we can classify -- is it misadministration?

MR. TELFORD: Meaning, you just blew it? Here you have, number one, you have wrong patient, or wrong radiopharmaceutical or wrong route.

MR. JANICE: You had the right patient, the right radiopharmaceutical, and you hopefully have the right route; but something happened.

MS. ROY: But then it would come under (B) -- you're using more than 50 percent of the prescribed dose in your clinical manual -- procedures manual, it would only indicate three millicuries for a liver scan. You could end up giving them six. Is that a misadministration?

MR. JANICE: We're opening a can of worms.

MR. TELFORD: Look on page 1448, the third column. Now, wait a minute, I'm sorry, that's therapy, excuse me, let's back up. Back up to -- it's 1447(b)(1). An incorrect medical use would include treatment of the wrong patient -- how about wrong organ or side?

MR. JANICE: No, it wasn't the wrong side.

MR. TELFORD: Via an unintended route -- you're going to irradiate that arm, so you've got the wrong site. That's what I was looking for. I think it's there. Do you want it to be there?

MS. ROY: Is it every time you blow a dose, you've got to report it?

MR. HAMMOND: I don't want it to be there. I think it should probably be reported as a diagnostic event and it ought to be reported somewhere, but not as an administration.

MS. ROY: I think the RSO ought to know if you've blown a vein or something.

MR. HAMMOND: In the normal course of things, I think it should be --

MR. KLINE: Who wants an infiltration? That's not considered -- that's not a diagnostic misadministration.

MS. ROY: Infiltration -- what if you get a dose -- what if you give them another dose, prescribed dose, clinical procedures manual?

MR. KLINE: You have to document what happen and you have to put in your procedure, in your dose log.

MR. JANICE: Not according to what that piece of paper says.

MR. KLINE: Maybe I didn't hear it all.

MR. TELFORD: Page 1447 (b)(1). It says, "all

radiation to the wrong organ or site." Okay, if you radiate an arm, you certainly didn't intend that as a site. And there's a second problem, as Terry points out. You can double the dose.

MR. KLINE: I thought the question was infiltration -- whether or not that was a misadministration?

MR. JANICE: That's what the question is. You're saying it's not, I'm saying it is.

MR. KLINE: I don't know if we're talking about the same thing. The wrong side.

MS. ROY: You ended up irradiating a side -- you're not radiating the liver or lungs, you're irradiating the arm.

MR. HAMMOND: If this thing read like diagnostic instead of therapy, we wouldn't be there in the first place, because what happens when you read (b)(1), it needs to be changed, because it says -- where it says wrong -- source, you're not going to use sealed source and diagnostic radiology. So, that needs to come out anyway. And when you take that out, then you're going to take the site out, because site, more or less, would tend to be a therapeutic term, as opposed to a diagnostic nuclear medicine term.

Your misadministration, most often, is going to be a result of using the wrong radiopharmaceutical. Instead of radiating the liver, you can irradiate the kidneys, you can

get the wrong organ as opposed to the wrong side. But if we're going to claim that an infiltrated dose and reinjection is a misadministration, then we'll leave site in here. That's the only way you can justify it.

I don't personally think that misadministration -- I mean, a misadministration is not necessarily -- is an unintended deviation. I think that most people realize that -- all things being equal that once and a while, you're going to have an infiltrated dose, from a diagnostic nuclear medicine procedure, and it's really -- it's not a desired deviation, and it's not what we would call a an unintended deviation -- it's going to happen.

It's not necessarily, in most cases, it's not the fault of the person doing the injection. You may have an older patient with poor veins or whatever. You know, there's not much you can control; but it would be a diagnostic event as opposed to a misadministration. It should be reported to management, but there's no reason to report an infiltrated dose to the NRC in an agreement-stated program.

MR. KLINE: Just to make sure, we're correct on this. Cases in the past have been reported to the NRC regarding infiltrations that say a collapsed say or something where the dose was not injected into the vein, is not considered a misadministered, because this happens with

patients commonly, and on patients in the aging group.

MR. TELFORD: You're talking in reference to current requirements. We ought to be talking in terms of proposed requirements.

MR. KLINE: Okay.

MR. TELFORD: We're going to find out how to modify these. I think he's got a good point; that if we're going to write something here and capture things like wrong organ or wrong site, wrong organ may be okay because maybe you've got the wrong chemical and it went to the wrong organ. But, if we write something that could be interpreted like site, where it's the arm, instead of the organ, then all they're saying is put it up here, an event.

MR. KLINE: As an event, not as a misadministration. Okay.

MR. TELFORD: I believe that we would be better off to scratch out the site, because if you don't, how you define infiltration. The way I understand from the conversation, everybody assumes 100 percent of the dose is infiltrated. How about from 20 millicuries -- infiltrated just one -- it's still usable, but it's an odd spot in the arm, which you can see almost 90 percent of nuclear medicine studies. There's an injection site, and it's almost unavoidable.

If you come up with a definition, if you put it

in, it will open up another can of worms. You will use a wrong organ and take out wrong site.

MR. JANICE: If we don't, we've already got two strikes against us.

MS. ROY: Take out radiation from a wrong source.

MR. HAMMOND: Also take out diagnostic referral in (b)(1) because the medical use is going to be dictated by the authorized user, and a clinical procedures manual is going to be the governing thing in use.

MR. TELFORD: Yes. We said that yesterday, but we said we needed it because the patient could have been given a liver scan, according to the procedures manual. But gee, whiz, what was really requested was a thyroid scan. So what you say is true, as long as you take the right scan.

Well that's a good point about (b)(1). Any other comments or suggestions on (b)?

MR. JANICE: If infiltrations arent' considered to be a misadministration, then we don't have to worry about them, because it ought to take care of that.

MS. ROY: Foster just a technicality. If you leave (b)(2) the way it is, maybe that could still be interpreted like -- like Terry mentioned, if you had three and you needed six, it could be -- I would suggest that the prescribed dosage by more than 50 percent to the target organ or whatever. That way, it would prevent any

misunderstanding.

An intended administration?

MR. JANICE: We've got two different things going.

MR. TELFORD: We have a prescribed dose.

MS. ROY: Right.

MR. TELFORD: Or you could say what's in the clinical procedures manual is the prescribed dose.

MR. TELFORD: So is it always the case that if you gave twice the dose, is it always going to be the target organ that gets the overdose? Do we need to specify that to say target organ?

MR. HAMMOND: That would take care of what we're talking about, talking about the target organ receiving greater than 50 percent. That would eliminate any misconception about infiltration being a misadministration.

MR. TELFORD: Okay, that's a good point.

MR. BENNETT: That assumes, though, that when you say 50 percent, you're saying plus 50 percent, not minus 50 percent.

MR. HAMMOND: Right, we're talking about reinjection.

MR. TELFORD: The administered dose differs from the prescribed dose by 50 percent, which means either plus or minus. Do you think it ought to be that way?

MS. ROY: It says more than.

MR. TELFORD: That the administered dose differs from the prescribed dose. That means it could be plus or minus. The threshold is 51 percent or more.

MS. ROY: Okay, I've got it.

MR. TELFORD: You said it should be that way, should leave it plus or minus?

MR. BENNETT: Yes.

MS. WOOD: If it was 50 percent there may be occasion when it didn't have activity when you do a study. So it might be half of what you would normally use. That would be a misadministration.

MR. TELFORD: That says that you if give --

MS. WOOD: It's followed by your procedure and you give 3 or 2-1/2, that's 50 percent.

MR. TELFORD: Make it 2.4.

MS. WOOD: If you do less, it's not necessary.

MR. TELFORD: Okay, modify. If you modify the referral at the prescription to say that in this case it's okay to give 2.4, even though your procedure manual says 5, it's still all right.

MR. JANICE: Your prescription must say that you're going to a liver scan on a patient, it doesn't say how much you're going to be giving him or her.

MR. BENNETT: Correct, but if you modify that in those special instances where you don't have enough but the

doctor -- the authorized user now says -- I would assume that the technologist would go to him and say, doctor, I don't have 5 milicuries for the study, but we've got 2.4, will you authorize us to do that? And he says, yes, that should be enough activity for this patient. Then you just modify the referral from liver scan indicating 2.4 was authorized or something like that. And that's not very often and it's a special case that you address individually.

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

MR. FOSTER: It's just my opinion. I don't think it's necessary to report or even have to change anything for a diagnostic procedure if it's under the prescribe dose. An example we came up with, it was a bone scan. Let's say we infiltrated it. That was given 20 and I only got in 9. I'd probably still do the bone scan. A whole body table would take that much longer. I would go ahead and reinject it. But if we do the minus, I would have to report it or it would be changed.

And so I don't see -- you know, for therapy I could understand because it may change the patient's medical condition if you only give him half of the treatment, but for a diagnostic procedure I don't see where it's necessary to do that. As long as it's read in the report as being somewhat objective, I don't see where you have to go changing referrals and all that.

MR. TELFORD: Okay. What you're suggesting then is to only say if it's greater than?

MR. FOSTER: Yes, for diagnostic.

MR. TELFORD: Not less than?

MR. FOSTER: Right.

MR. TELFORD: Okay. What happens if you had somebody that was making a lot of mistakes, a technologist, and they were making a lot of mistakes with diagnostic administrations, so now you're only going to count those that are above?

MR. FOSTER: I understand.

MR. TELFORD: A large error below? You're lucky if there's no harm, but the next time it's a large error above. Are you saying that you would rather have the ones below reported "appears to have been" so you could find out about this person?

MR. FOSTER: I don't think the ones should be reported as an event that is below. If you're getting a technologist who is always misadministrating or infiltrating, that should be an internal quality control thing that you should be handling. It shouldn't have really anything to do with the NRC. I think that could be controlled by your own internal mechanism, by quality control.

MR. TELFORD: Okay, but what do you do with it?

How do you get back into the internal loop, take it out of here and put it up?

MR. FOSTER: You're talking about only for more than 50 percent?

MR. TELFORD: For discussion purposes, let's say that we had greater than doses and misadministrations, we had less than doses.

MR. FOSTER: I think greater than 50 percent would -- that could possibly be put in the report, that would be in the record.

MS. WOOD: That could possibly be put in that report.

MR. FOSTER: I think greater than 50 percent should be a misadministration, because I think that's important.

MR. TELFORD: How about less than the dose?

MR. FOSTER: My opinion is to forget about the less than for a diagnostic procedure.

MR. HAMMOND: Less than is going to end up being an event by default, because if your RSO and everybody else is doing their job, you're going to make a record of the administered dose or the RP dosage given to the patient, so there will be record of the 2.4 in there, and as part of their on-going review, somebody's going to notice. If it's an isolated incident it's going to happen, but if it's a

continuing thing you're going t ve documentation for it.

It may be that cumulatively you have an event where one is a fluke or whatever, but if you've got a continuing problem with the tech, the RSO in his normal review of the action will find it, an. I think it should probably -- underdosage should be a diagnostic event and overdosage should be a misadministration.

MR. TELFORD: Pat?

MS. WOOD: I agree with that.

MR. TELFORD: David?

MR. DADARI: I agree with Ray, I agree that internal medicine relies on statistics. If you say your dose is 20 milicuries and you administer, you can get a perfect diagnostic test and there is no harm to the patient and the patient has still got the same amount of radiation. I believe that the NRC should be concerned with over-radiating the patient rather than giving less radiation.

MR. TELFORD: So this suggestion is to take the underdosages and make them vents and make the overdosages misadministrations?

MR. DADARI: Why do you want to make it an event? I will still have a perfect scan. I don't see any reason to make it an event. I'm supposed to do a bone scan and give one injection. I've got my bone scan and the statistics are there to prove that I got 600k for every image. I doubled

my time.

MR. HAMMOND: Because you had an event that was unintended occur while the patient was in the department. You had an infiltrated dose.

MR. DADARI: The problem with making it an event is how are you going to clarify where is that 50 percent of infiltrated dose? Who will decide that's 50 percent or 40 percent or 20 percent or 1 percent? Who can define it?

MR. TELFORD: This is to the target organ?

MR. DADARI: If you care about quality care and diagnostic care -- well, it won't happen all the time but it will happen pretty often, small doses. It would be real hard. I can take 1 milicurie and put under the camera and take it for 3 minutes and it looks like 100 percent of the dose, but it's not real. Or I can have my injection site right on the wrist, which is not in the field of view whatsoever. Then you wouldn't even know it. So what I'm saying is to not have it as an event, the less than 50 percent.

MR. FELDMEIER: I agree with David. Unless the situation happens where you would get motion or something, you would have to repeat the study and then it becomes a bit of a radiation safety concern, because then you have to repeat the study and you have to dose the patient again.

MR. TELFORD: So you have to dose the patient

again? Should that be an event?

MR. MOK: What David is saying, you still get a good scan and no harm is done. Why do you want to make it an event? You get a scan, it's what you want, you don't overdose the patient. So why do you want to make that event? This regulation wants to give benefits to the patient and the patient has received no loss of benefit.

MR. TELFORD: It's true that the situation is, the technologist made a mistake, but because we use a longer accounting time, we get what we came after.

MR. FELDMEIER: I don't think it's a mistake if a vein infiltrates. I mean if we want to compare this to other medical specialties, it's like a surgeon. He puts two units of blood on hold for a patient he's taking to surgery, but he uses 4 units of blood because the patient bleeds more. Are we going to ping that surgeon for a quality assurance item and make him write the referring physician and the administration of the hospital because he uses 4 units of blood instead of 2?

I think the fact is that some of these infiltrate if it's a nuclear medicine study. There's a dose and the infiltration doesn't get into the circulation, it stays in the tissues. There you have to adjust if you get enough doses to the circulation. If you didn't, then you have to adjust. You're going to have to repeat the study and you're

going to have to test the patient again, and maybe that's a safety concern at that point. Or at some point maybe it becomes a safety concern.

MR. TELFORD: Let me see if I understand what everybody is telling me here. Let's say that we've got a 50 percent underdose. You've measured that dose and you've made a record, as Bruce was saying, and the RSO periodically checks that, as they probably would do anyway. They want to know what's happening. So there's no need to make it required to be an event because you've already got the record. But if you have to dose the patient twice, and you have something that occurs, would that be an event or a misadministration?

MR. SHAFFER: If you're dosing them twice, it's going to be a 50 percent dose.

MS. ROY: But not to the target organ.

MR. FOSTER: That's why you need to say target organ.

MS. ROY: Make that second dosing an event?

MR. TELFORD: You had to dose the patient twice. Make that an event.

MR. FOSTER: Not if it did not exceed 50 percent to the target organ, that would be my opinion.

MR. TELFORD: It is not a misadministration. It might be 100 percent of the first dose just went right into

the muscle, the second dose was required, it went into the vein, and so that would be called an event, not a misadministration.

MR. FELDMEIER: Can I ask a stupid question? What if a nuclear physician does a patient and the camera stops, what do you do?

MR. JANICE: You're up the creek.

MR. FELDMEIER: Is that a misadministration?

MR. JANICE: I wouldn't call it a misadministration.

MR. TELFORD: We have to make it an exception.

MR. FELDMEIER: I shouldn't have said anything.

MR. TELFORD: It's an event, so it's not that big of a deal.

MR. HAMMOND: A misadministration is out of the ordinary occurrences.

MR. TELFORD: Yes.

MR. HAMMOND: Equipment breakdowns are ordinary occurrences, infiltrations are ordinary occurrences. When you administer to the patient above 50 percent, that's not an ordinary occurrence. That's life, it just happens. We can create enough paperwork to keep you guys in Washington for years just reading reports if we want to report every time somebody has a machine breakdown, but it's not going to prevent quality of care and it's not going to do anything

except leave a paper trail that really justifies a regulation, which you probably wouldn't need in the first place.

MR. TELFORD: Okay, greater than 50 percent to the target organ. What about the second dose?

MS. ROY: If it's more than 50 percent to the targeted organ.

MR. FELDMEIER: And that point the nuclear physician becomes involved and determines whether it's in the patient's best interest to have the second study, and essentially what you're doing is changing the physician's assessment in these situations, and he's making a prescription in writing giving an indication. The second study is indicated, so I don't think it becomes an issue then.

MS. ROY: You mean on a down camera?

MR. JANICE: If there's a down camera there will be a report made of the fact that the camera is down and the patient is to be rescheduled for a study.

MR. FELDMEIER: The patient is going to sign it. He's going to indicate that it's necessary to repeat the study so that you have a prescription, but you have a revised prescription and then if it doesn't become an event or an occurrence, a misadministration.

MR. FOSTER: And there won't be more than

50 percent to the target organ by the time you wait until the next day.

MR. JANICE: Okay, that takes care of that.

MR. TELFORD: Okay, that's B-1 and B-2. Would you be willing to move to C? Let's see what happens to these things. We treat the misadministrations like we treated in A, so we have the SRO investigating make a record. Now we look at B, because if we have one of these thresholds exceeded, then you have to make a report to the NRC, so let's look at these thresholds and tell me if you like to delete, modify or retain these thresholds.

MR. HAMMOND: The second threshold is five-fold area epidosage. At the risk of sounding careless, I think that -- I want borrow one of Mark's phrases -- if it's clinically significant, if you had a prescribed dose for a thyroid of 10 microcuries and the patient received a 50 microcurie dose, it's not going to be significant and you still do the uptake. So the five-fold variation in prescribed dosage would not normally require written notification to the NRC within 15 days, but it's not clinically significant to the patient. If you're expecting the patient to get 20 milicuries for a bone scan and you give them 100, then it could be clinically significant.

MR. TELFORD: Maybe you should focus on the clarification of this, because what this says is if you have

an organ dose greater than 2 rem, and you're 50 microcuries, wouldn't that be 50 rem under the thyroid? You're going to exceed that.

MR. HAMMOND: These aren't "and" statements or "or" statements.

MR. TELFORD: You are greater than 50 percent? I'm not sure about that.

MR. TSE: They all are.

MR. TELFORD: If you exceed 50 percent and then you report, is that the way it should be?

MR. JANICE: You've got to have all three of them before you report.

MR. TELFORD: Just as 50 percent and that 2 rem, you're supposed to report.

MR. HAMMOND: You could exceed the 50 percent with the thyroid dose of 50 microcuries and five-fold and still not have a clinically significant event.

MR. TELFORD: Yes, but you would exceed this 2 rem.

MS. WOOD: Would your procedure manual give you some latitude?

MR. HAMMOND: Well it depends on your procedure manual.

MR. DADARI: If there's no regulation, it will limit your use of any item. You've got to go to the doctor

and ask him for the specific prescription for uptake. If you limit the maximum to 30 microcuries a prescription, you shouldn't have that.

MR. TELFORD: Let me give you an example of less than 30. The diagnostic scan, 10 microcuries. If we gave 16 and we exceeded the 50 percent, it goes to the organ and is greater than 2 rem. Should that be reported?

MR. DADARI: I don't think so, especially in the I-131. Our institution uses a cap. We can't do anything to the cap. The cap comes, it's sealed and we cannot open it. So we have a range of 10-20, and usually it's in that range, and if it's over, I don't have a choice.

MR. TELFORD: You're supposed to give 10 caps, but the technologist gave 20 caps. Instead of 10 and 16, use 10 and 20. It exceeded the 50 percent and this 2 rem. How would you propose modifying these thresholds?

MR. DADARI: I would take out the organ dose because it's just a matter of nobody can basically tell how much of the I-131 goes to the targeted organ. Are we talking about functional study or biological study? The usual uptake is 5-20. A 5 percent uptake is almost nothing. If you double it, it's still nothing, it doesn't matter. But if you're talking about a grave disease, the patient has a grave disease, it doesn't matter because he's going to be treated with the I-131.

MR. TELFORD: You said take off dose to the organ. What if we just exceeded the 50 percent but didn't quite exceed that? Let's see if we can forget that for a moment. What's a good example here? You were supposed to give 10 microcuries, you gave 45 microcuries. You exceeded the 50 percent and you just escaped that. How many rems to the thyroid, 45?

MR. DADARI: I would consider that a misadministration.

MR. TELFORD: I didn't catch it, I would have to be report it.

MR. DADARI: It's more than 50 percent.

MR. TELFORD: You only have to report if it exceeds this. I didn't exceed that.

MR. JANICE: You're still within the guidelines.

MR. TELFORD: I'm just asking a question. If you took the organ dose away, then what happens? Let's say that we only wanted to report things that are clinically significant. How could we structure these to capture those?

MR. HAMMOND: If we have the scenario you described, it doesn't change the fact that where you had a misadministration, you did not need to have a misadministration. So it gets reported. Should you report the clinically insignificant 45 microcurie administration to the NRC or is it essentially a misadministration that

requires action by the RSO? Then it should not require notification to the NRC. the patient's family, the referring physician, the local newspapers, and everybody else. It's something that happened and the RSO should do what's in paragraph C and he should probably investigate the cause, make the record and retain the record as directed.

MR. TELFORD: Let's go with that for a minute and see what happens. We would have to take this off, or otherwise you'd be giving 45 rem to the thyroid. So if you took this off then you wouldn't have to report to the NRC because this has not been exceed. So the question is, is this a sufficient threshold? Should we partition those events into those that should be reported and those that should not?

Organ doses take two rounds, whether or not you may want to increase that, but I don't know what the cutoff is.

There's two choices. We can follow the suggestion and say -- and David's suggestion -- and delete the "if" and rely on the fivefold error to catch those things that should go to the NRC. The things left go to the licensee.

Now, the other alternative is to increase this dose.

FOSTER: That's what I'm thinking, that if you take away the organ dose, you're only left with the fivefold

error. I mean, you're getting really megadoses in some bone scan of like 100 megacuries instead of 20, and that could be significant. There has to be something in between a fivefold and a target dose. There's going to be some kind of record.

You don't want it too high and you don't want it too low. The organ dose might be -- what, I' don't know, maybe 5 rem.

MR. HAMMOND: What about taking out the organ dose and decrease the fivefold? That's too high if you don't have the organ dose, because like you said, a hundred millicuries is astronomical. Make it two or three, if you double the dose. That could be clinically significant and there should be some reasonable standard. Get the two rem stuff out of there.

The stuff you're going to deal with daily is dosages you give the patient, not how many rem did the patient's organ get or how many all body rem did the patient get, unless you go to the physicist and say, what do you do? The immediate thing that's going to be evident to the person in the department is the dosage the patient received.

Can you waive the organ dose of two rem and add rem to the total body and decrease the fivefold to two or threefold so that you've got something that's reasonable that you can deal with that's not going to cause you to

report every time you turn around?

MR. FOSTER: I'd like that. The idea is good. It would decrease the paper work. But if you use a twofold error, if you gave 20 to the thyroid, you run into a problem there.

MR. TELFORD: What if you made it three and you'd have to check the limit because the Iodine 131 would put you at the limit for a prescription on 10 microcurie dose?

MR. JANICE: The other thing we have to remember too is that most of our radiopharmacist- have on record and they fill that enough of our prescr[illegible] so know that if you're going to say, I've got Joe Blow for a bone scan and I want a hundred millicuries, they're going to question that and should question it.

MR. TELFORD: Dr. Feldmeier's made an analogy that we can make to teletherapy. For instance, if a thyroid were an organ -- but you would only treat the tumor close by and you were, as a result of giving this dose, you would stop short of giving x dose to the thyroid --

MR. FELDMEIER: In neck cancers, we treat the thyroid which just happens to be unfortunately invaded by six or seven thousand rems. We treat the pituitary with doses like that. I have trouble relating to this, because we're giving factors a thousand times more in doses than you guys do.

I think it's a different thing. We're treating patients who already have malignancies. In terms of carcinogenic effects of radiation, it's a matter of risk and benefit. You know, you guys don't think a dose of 45 rems to the thyroid is significant. I think it is in its carcinogenic potential.

MR. TELFORD: Over the next five or ten years.

MR. FELDMEIER: Or twenty years.

MR. TELFORD: It increase the probability of cancer.

MR. FELDMEIER: I don't have a feel for this. I really can't say anything that would be helpful.

MR. BRAHAMAVAR: Was the two rem just an arbitrary number?

MR. TELFORD: It's currently in 10 CFR, these numbers, currently in Part 35. We merely used it again. The fivefold times an error -- but my understanding from the organ doses, not taking into account any occurrence from A, B, or C which encompasses injecting the wrong pharmaceutical, I mean someone was supposed to get 20 millicuries of technetium and might get 19 millicuries of gallium, that's not fivefold -- five times more than the dose of the radiopharmaceutical, but it is going over the 2 rem for the whole body dose.

It's saying that any occurrence described in A or

B above, if it involves fivefold error of dosage, but the dosage means to me, millicuries. You're not going to give 19 millicuries of gallium as opposed to 20 millicuries of technetium, unless you have the rem dose. I would be reporting that.

MR. TELFORD: So you may need the organ dose when you have the wrong pharmaceutical.

MS. ROY: Wouldn't the wrong radiopharmaceutical come under B because it wouldn't be following the prescription in the procedures manual?

MR. SHAFFER: It is a misadministration, but under D, it's according to which of those misadminstrations you have to report. I don't think you should report that, but without the rem, it's not reported.

MR. TELFORD: Well, we could write it that way. We could say that -- as well as in the previous discussion, if there is a 50 percent increase, it would be a misadministration. You could put a threefold on top of it and the exceeded dose, and you could go to the NRC. If you didn't, you'd go back to the user, the licensee and you could leave something like this in the case of the wrong pharmaceutical.

How about a wrong route? Are we going to get some organ that you didn't intend to get?

MR. HAMMOND: If what we're trying to accomplish

is that the NRC gets notified of the wrong dose to the wrong patient and the wrong radiopharmaceutical to the right patient, to the two most common misadministrations, then let's just put that in, indeed. If B-1 or B-2 have, and you have either a non-authorized byproduct material, a threefold error in the dosage or the wrong patient gets the right radiopharmaceutical or the wrong radiopharmaceutical to the right patient, that gets reported.

That's what the intent of all of this was in the first place, is to report misadminstrations. Those two things under B-1 are clinically significant. A different route is not necessarily clinically significant diagnostically.

MR. TELFORD: Let's explore that. Does that mean that this really ought to be an event and not a misadministration, the wrong route?

MR. HAMMOND: It depends on what it is.

MR. DADARI: I can't think of an event which would end up like that.

MS. ROY: It would be clinically significant if it was the wrong route? I'm trying to think.

MR. TELFORD: Does anybody know any horror stories here, the worst stories about the wrong route?

MR. FOSTER: I've never seen it happen, but I think it probably could happen if somebody interpreted the

wrong order for a patient. You can give oral sulfur colloids for a reflux study instead of a liver scan for somebody. It would have to be significant because that's the stomach and the esophagus and whatever.

MR. TELFORD: Therefore, that should be reported.

MR. HAMMOND: If you give oral DTPA for the same use -- that's real stupid, but it could have happen. Any other modifications you'd make here?

MS. ROY: Are we still on D?

MR. TELFORD: Yes, we're still on anything up to A, B, C, D. Are you willing to move to E?

MR. HAMMOND: No. Let's talk about the part of D that isn't up on there.

MR. TELFORD: All right, let's look at D on page 1448?

MR. HAMMOND: Yes. When you get down about halfway down that paragraph, that long paragraph, it says that for a diagnostic event or misadministration in which notification of the patient is required -- whether the licensee informed the patient or the patient is responsible and all that kind of good stuff, the report to the NRC must not include the patient's name or other information that would lead to the identification of the patient.

It identifies only one circumstance in which you have to notify the patient. That's for iodine only, more

than one millicurie when one microcurie was ordered or microcurie amounts were ordered. Then you've got to notify the physician, the NRC, the patient's -- and all that good stuff.

I don't think the NRC or anybody else should sit out here and tell the physician when they've got to notify the patient or a patient's family. I think it's up to the authorized user to assess the potential damage to the patient, in conjunction with the referring physician and for them to make a determination of whom is going to be notified, when and where.

I believe this for a couple reasons: One is that when you have an event that's that significant, it's going to be reported in the hospital to the QA committee and all that kind of good stuff. The medical staff is going have to take some action on it at some point in time.

Secondly, if you report it to the NRC, it's now public record and now it's on the Morbidity and Mortality Reports and in the Public Health Service for everybody to peruse and the local newspaper and t.v. folks to take you to task on it, when the actual clinical significance to that patient may or may not be that great, depending on the patient's age and this kind of thing.

I don't see that it's going to serve any useful purpose to bypass the physician/patient privilege and notify

the NRC and the patient directly.

MR. TELFORD: Maybe we didn't do that. There's a built in --

MR. HAMMOND: It reads that way.

MR. TELFORD: Let me ask you to read this carefully, because we went over this several times. The way it's supposed to work is, you notify the patient if or unless the referring physician, the patient's primary physician says no, because it will do more harm than good to tell them.

There is one safety valve in that the authorized user can say -- or the primary care physician -- should this patient be told? Now, if that person says no, you don't have to do it. If the person says yes, you still have to do it.

MR. HAMMOND: But if you're going to leave that in there, you're not required to notify the patient or the patient's responsible relative without first consulting the referring physician and you're going to allow the referring physician -- now you're going to allow the referring physician who may or may not be versed in nuclear medicine and the effects of radiation to make the decision and if you've got an environmental activist for a referring physician who says, oh, yes, we're going to tell the patient, and it may not be that significant, now you're

letting the referring physician decide whether a significant event occurred, instead of the authorized user.

MR. TELFORD: Is this the place where we were suggesting before to put in something about clinical significance?

MR. TSE: In some other workshop.

MR. HAMMOND: My point is, don't put in there at all, unless the NRC is willing to assume part of my risk management responsibilities. If you want to jump on the bandwagon when they sue me for an event that will play well in the newspaper and play well on the television that did not significantly alter the patient's life, but I'm going to end up paying a couple of million bucks for it, don't legislate to me what I have to do with the patients.

MR. TELFORD: I believe you will discover that we've got a slight difference in wording between diagnostic and therapy. In one place or the other, we said that if it's clinically significant. I believe that in a prior workshop, it was suggested to us to say report those -- tell the authorized user to go to the primary care physician, but it will require reporting to the patient if it's of clinical significance.

MR. HAMMOND: But you asked us to comment on what's here. That is an there.

MR. TELFORD: If we did that, is that a sufficient

safety clause? That would give you two safety valves. You've got one with the primary physician and the second one being the clinical significance. That's a medical judgment.

MR. HAMMOND: If you're bound and determined to leave some language like this in the regulation, I would want the clinically significant in there. Preferably, I rather you take all this out.

MR. TELFORD: I think we have a legal problem here.

MR. HAMMOND: You may have some legal problems if you leave it in.

MR. TELFORD: Yes, I understand. Well, I'm trying to say that we have this -- our attorneys are advising us that we may be duty bound to leave something like that in there because the patients have this legal right to know.

Now, if we can put conditions in there that go to the primary physician and say, okay, do you really want to tell them or not? Put that safety valve in there. Put a second safety valve in and say, is it clinically significant? That may be something that this part of the staff can deal with.

MR. HAMMOND: I think I'd agree with that, if the referring physician safety valve was there and the clinically significant.

MR. TELFORD: Does anybody else have any feeling

on that or some horror stories or --

MR. FELDMEIER: So what you're saying is that you would allow the nuclear physician to report to the referring physician and to the NRC, but not the patient? I have some problems with that because I think that once you report it to the NRC, that becomes public information, becomes discoverable and I think that a physician would be ill advised not to inform the patient.

I think the best thing to do is to inform the patient, you know, that there was a misadministration. We've reviewed the situation and have taken corrective action and this has no clinical significance as far as your situation is concerned, rather than, you know, down the road, -- especially if this is an inpatient or something and the primary care physician puts a note on the chart saying, I talked to Dr. James Smith today in Nuclear Medicine and he tells me that he gave the patient three times more iodine than we should have and we discussed it and decided not to tell the patient.

The patient's record is discoverable, too. I really think that in terms of legal liability that that would be worse, not to tell the patient but to have a referring physician and primary care physician know and having the NRC receive the written report.

MS. KELTY: Doesn't the NRC report not identify

the patient -- no name or identification?

MR. HAMMOND: The NRC is not going to identify the patient.

MR. TELFORD: That's how a legal point to protect your own assets. As far as the reporting requirement goes, the safety valve of going to the primary care physician is currently in the regulations in Part 35. We left it there. You have advised us or suggested to us that you'd like to see something close to this. I think we can work with this.

Any other suggestions for A through D? Are you willing to go to E?

MR. JANICE: I enjoyed the three years after the administration, but my local state fellow tells me that my unit dose scrips have to be kept till they rot in a jar because that's also my record of disposal.

MR. TELFORD: Okay, you've met the three years.

[Laughter.]

MR. JANICE: What I'm saying is that the three years means we can ditch them after three years.

MR. TELFORD: As far as the NRC is concerned, yes, but as far as your state, maybe not.

If we're going to tell the states, You have to be this good or this tough, or however you want to look at it so that the state cannot say, Okay, you only have to keep your records for two years, that wouldn't work.

MR. FOSTER: I was just thinking, on number three, the report of each occurrence, like if you had a small occurrence in '80 that you didn't report to the radiation safety officer, we keep most of our reports. If we gave the wrong dose or something, that would be put in the medical record of the patient. In our state, it's only required for seven years, and if we had to keep that for ten years, I would recommend that we change that to seven years.

I think that's the usual form of states, to keep any patient records that haven't been seen seven years. This way, you would have to keep duplicate records to make sure that, in case this patient can come back in seven years and say you didn't do it right, in case you wanted to inspect it eight years from now, or whatever. So I would just recommend we change that to seven.

MR. KELTY: I think for pediatrics --

MR. FOSTER: We keep certain things forever. Mammograms, we keep for ten years to be on the safe side. So I'm saying seven years. That's my recommendation. I know pediatrics you keep longer.

MR. TELFORD: What's your inspection frequency?

MR. FOSTER: From the state, usually every five years or so.

MR. TELFORD: Five years? Let's work with that example, every five years. You had an occurrence, you have

a report. That happened in year one. The inspector comes out in year five and says, Okay, what are you going to do? You have a little glitch here; you need it fixed. You suggest a fix, and they accept it.

The inspector comes back in year ten and says, Gee, I don't think you quite made it. What was the original problem, anyway?

MR. FOSTER: The original problem would have been in the first inspection that you would have had at least documented. So you would have had the record in there from the first inspection. So it would still be -- they inspect every five years. It may have been seven or eight years have come about since we were inspected.

MR. TELFORD: Our smaller licensees are inspected every three years, so you've iterate a couple of times that you can get past six or seven pretty easily. There is another kind of a fly in the ointment, as the Federal Government has these standard recordkeeping requirements of three, five and ten. So if we went to OMB and said, We want seven, they would say pick one -- five or ten.

MR. HAMMOND: So you did.

MR. TELFORD: If we have to iterate a couple of times with the licensee that we're inspecting every three years, we can easily get past five, therefore, we need more than that. Let's ask another question. How much of a burden

is this? How many of these things are you going to have?

MR. FOSTER: It's not that much of a burden.

MR. TELFORD: What you guys are saying, you only have one of these every five years, so you only have one of these to save?

MR. FOSTER: I'm not saying it's an added burden. You just don't want to not have that report available when someone comes in ten years, and I just don't want that situation to occur. But it's not that big of a burden unless they report somebody to the Radiation Safety Committee, and that's usually kept forever. So I guess you probably wouldn't even come into that problem. Those people don't have a radiation safety committee, like a smaller patient clinic. That's what I'm looking at.

MS. ROY: One occurs every three, four years. I mean, you can have files that have two pages in them for ten years. I don't see a problem with it.

MR. JANICE: Maybe somebody will walk by and say, "What are these files for?

MS. ROY: Yes. Office files.

MR. TELFORD: Does anybody else have any comments on all of 35.33 A through E?

MR. DODARI: I have one big problem with E2. We constantly change our procedural manual, and basically, it's in the computer, and we rarely print it out. Sometimes we

do, and we do have a hard copy, but any new pharmaceutical comes in, we add additional pages in the computer. They are almost constantly in change.

MR. TELFORD: Visualize that you have a manual, and this is when you take out a page and you replace a page. This says, Keep the old page for three years. You've got your's in the computer. What if you took all the old pages and you copied them onto a floppy, and you kept the floppy for ten years?

MR. DODARI: It would be fine, but there is a very close area with the MRI, a big one, and it might wipe my whole floppy out.

[Laughter.]

MR. TELFORD: How do you protect your real manual, then?

[Laughter.]

MR. HAMMOND: I don't really view that as an issue. I mean, Dave, if you go to talk to the risk management fellows, they're going to tell you, Don't throw them away, because if you had a patient event occur today and five years from now, that patient sued, they're going to subpoena the diagnostic procedure manual, and if you've updated your manual to 1995 standards, well, that's what they're going to take to court with them.

If you can hand them the 1990 manual that said the

current practice in the industry was A, not A plus five years, it's different. According to the '90 standards it was not clinically significant, and according to the '95 it is clinically significant, your best defense is that old procedure manual.

So you shouldn't throw them away. You shouldn't throw any procedural manual away for a period of time. So I don't see that three years on a whole procedural manual is a problem.

MR. TELFORD: Okay. Any other suggestions on 35.33? Anybody object to taking about a ten-minute break? Come back at 3:05, please.

[Recess.]

MR. TELFORD: Let's go back on the record. We're now going to look at the proposed recordkeeping and reporting requirements for therapy. This is 35.34. It has an almost identical format. We have the eight paragraphs and we have events. So these four things are events. Since you're familiar with the format -- it's the same as 35.33 -- we just went over that -- so we can go right into looking at the things we call events. Would you like to delete, modify, or retain these?

[Pause.]

MR. TELFORD: Does somebody want to comment about A1? Any suggestions there? How about the and? We have a

prescription for the therapy. Do we need this "and," "and a prior review"? Is the description sufficient, or do we need both? This is the radiopharmaceutical.

MR. JANICE: You don't need both.

MR. TELFORD: You don't need both? What would you do there? How would you modify this?

MR. MOK: The more and more I think of it, if you're going to do grave disease you're going to need to preview the patient's chart. You're also going to need to review the patient's chart. You need to review the patient's chart before you come up with a prescription. I would hope that anyone just looking at the plan wouldn't say this is what we're going to give.

MR. TELFORD: You would say you have a prescription. You already have the review by definition?

MR. HAMMOND: No.

MR. TELFORD: Not necessarily? Okay. So you need this for certain pharmaceutical therapies. Oscar, do you have any suggestions here?

MR. HIDALGO-SALVATIER: I would think that this applies to brachytherapy?

MR. TELFORD: Teletherapy, brachytherapy, all therapies?

MR. HIDALGO-SALVATIER: I will delete "and a prior review of the patient's case by the authorized user."

MR. TELFORD: For teletherapy and brachytherapy?

MR. HIDALGO-SALVATIER: For both.

MR. TELFORD: Okay.

MR. HIDALGO-SALVATIER: Teletherapy and brachytherapy.

MR. TELFORD: Okay.

MR. HIDALGO-SALVATIER: There shouldn't be any treatment without a prescription, period.

MR. TELFORD: So prescription is sufficient for you?

MR. HIDALGO-SALVATIER: Yes.

MR. JANICE: Prescription doesn't necessarily mean that you know what the patient has.

MR. MOK: This would be the responsibility of the physician to find out.

MR. JANICE: In essence, if you do that, you're going to review the chart, if you're talking to the physician that's going to review the patient's case.

MR. FELDMEIER: I don't have any problem with that. I mean, I think the physician is going to have to know what he's treating and review the case in some fashion by examining the patient, reviewing diagnostic studies, reviewing the chart, discussing with the current physician. I mean, those are all reviews of the patient's case, and I think that's necessary before you write the prescription for

therapeutic dose of radiation, whether you do it by radiopharmaceutical, or you do it by cobalt machine.

MR. TELFORD: How about the daily reporting of the dose? You do that anyway, don't you?

MR. FELDMEIER: With radiopharmaceuticals, do you record the daily dose?

MS. ROY: It's recorded daily.

MR. HAMMOND: The way it actually reads in here is somewhat different from what's capsulated over here. It says, "Daily record in the appropriate record the administered radiation dose or a radiopharmaceutical dose." If you gave one dosage of I-131 for therapy, you're going to have to record that dose.

MR. JANICE: But you're not going to dose a patient today with 20 millicuries and say you're going to get 20 millicuries today, but come back tomorrow, and tomorrow you're going to get 18 millicuries. You're not going to do that. You're going to send the patient away with 20 millicuries, and see when comes back in six weeks.

MR. TELFORD: You just record it once, so it says In the appropriate record -- do you measure that, keep a log of what you measure, the dose?

MS. WOOD: Yes.

MR. FOSTER: That's a requirement, isn't it?

MR. TELFORD: That's a record, isn't it?

MR. HAMMOND: You're not going to have a daily dose. You're not going to have a daily dose on an iodine therapy. You're going to give the dose one time.

MS. WOOD: I think "daily" is the word we have problems with.

MR. TELFORD: Okay. A little glitch there. David?

MR. BALLEZZA: About that word "daily," we're just focusing on item 131. Well, how about if you have P-32 treatment for leukemia?

MR. HAMMOND: Then you'll have a daily record. Each time you administer a dose, anyway, you are on a dose calibrator, and you will have some record.

MR. FOSTER: As a technicality to this, I would take out just any therapeutic use without regard to the administered dose.

MR. TELFORD Okay.

MR. FELDMEIER. You know, sometimes in teletherapy, we're treating patients two to three times a day, so it's probably not adequate to report it on a daily basis. It is to be reported on a per-dose basis.

MR. TELFORD: How about the single fraction here? Would you like that to be an event?

MR. HIDALGO-SALVATIER: That's what I was doing. When I read carefully the definition of "therapy event," it

says we need a record and a report. It will be recorded in the patient's chart, and it probably will be reported at the end of the chart as a dosimetry note. Will that be enough?

MR. BRAHAMAVAR: Through management.

MR. MOK: It's supposed to be reviewed by the administration, so just recording in the chart may not be sufficient. You might put it in the report, turn it in to your QA committee, and have them look at it.

MR. HIDALGO-SALVATIER: That's what I was trying to make clear, you know.

MR. MOK: If you look at the definition of "event," if I can find it -- it's here somewhere --

MR. TELFORD: Page 1448. It starts at the bottom of the middle column. This is A3.

MR. FELDMEIER: It says "A record is required in the report to licensing management."

MR. MOK: So you would have to report to the Radiation Safety or QA Committee.

MR. HIDALGO-SALVATIER: It doesn't make sense to me because we see that every day. Instead of 100 monitored units, they deliver 150, and they can correct it. You see, radiation therapy is not a direct line. I mean, a doctor prescribes this, and you can follow it perfectly. You have radiation constantly, and we had to steer the treatment.

MR. TELFORD: Is 20 percent too small? Is that

what you're telling me?

MR. HIDALGO-SALVATIER: I think so.

MR. TELFORD: Okay.

MR. HIDALGO-SALVATIER: Twenty percent to run to the administration and report it in a fractional dose?

MR. MOK: When we set up the quality control program before we start this, Dr. Feldmeier and I and a couple of other people have talked about this. I think you just said larger than 20 percent error. What it means is if you give 200 rad and you deliver 140 rad or 160 rad, you have an event. So we have to look at the purpose of this regulation here. Each item, as you are aware, is if you have an overdose to the patient. So if we give the patient overdose this day, we would give the patient underdose next day. It's not what we want, but it's not so bad because we can make up tomorrow. We do it all the time; we make up the dose tomorrow.

So maybe we should change that sentence in a couple of ways. First of all, instead of just larger than 20 percent, we can say the dose is over by a certain amount, and then to look at the total dose instead of the daily fractional dose.

MR. FELDMEIER: You know, we treat bone metastases. A fairly common way of treating metastases is treating 300 rads a day for ten treatment days. Some people

treat bone metastases 400 rads a day. If the patient were to be get 400 rads rather than 300 rads for one fraction, I mean you're talking about a 33 percent error. It's probably not clinically significant, and you can adjust. You can make adjustments, adaptations, for subsequent treatments. I think there should be a disclaimer in there that says, at the end, "is clinically significant."

MR. TELFORD: Well, clinically significant what?

MR. FELDMEIER: I think it's very hard, when we're talking about percentages or doses, in terms of hard and set numbers, I think it's very, very difficult -- I think impossible, really -- to come up with a number or percentage that is reali.ng to represent a clinically significant event in every circumstance.

I mean, I can think of cases, like I mentioned earlier, where the dose was off by a factor of more than 200 percent, and it wasn't clinically significant. In a case where we're treating the spleen, we gave 60 rad instead of 25 rads.

MR. TELFORD: Let's change the question slightly, then. Is there any occurrence that involves a single fraction that's an overdose that you want to go internal to the licensee organization?

MR. FELDMEIER: The origin -- I mean, I just don't know how to put that in a simple declarative sentence so

that, you know, it will fit every circumstance, because there are some cases where 20 percent is highly significant, and there are some cases where maybe 200 percent is not.

I think it's a clinical judgment. I think it should be discovered, and maybe it should be discussed with the Quality Assurance Committee. We're talking about something that's kept internal here, so I probably could live with that.

If we have to have something that you can express in a simple declarative sentence, I could probably live with that as long as it's kept internal and all we say is that quality assurance means, well, this patient got 160 rads instead of 200 rads. We evaluated the situation and made sure that the technologist was wearing her glasses when she read how many minutes the cobalt shutter should be open the next day, and determined that it wouldn't have any impact on the patient's overall management, or, for the next two days, we added 20 rads per fraction or something like that.

I think at this level, keeping it within the institution and taking it no higher than the administration of the institution, we could probably live with that. I have no problems with the other viewgraph.

MR. TELFORD: Okay. Did you have your hand up?

MS. ROY: Yes. Not that this is anything -- that I, you know, know anything about the field, but maybe the

wording could be something where if the dosage was more than clinically significant to the health of a patient, differing with the total dosage, the prescribed dose, but put the patient's health in there if it would be damaging to their condition if they received clinically significant more, instead of having this 20 percent here.

MR. TELFORD: Is that any organ?

MS. ROY: Item.

MR. TELFORD: And not the treatment volume? Is that whole body, or --

MR. FELDMEIER: It's one of the things that has been brought out as we've discussed this. The way this whole thing is configured, it talks about percentage and dose, or, you know, relative dose level. It doesn't talk about missing the tumor; it doesn't talk about the field being too big or too small. So, you know, this is only part of the whole story, part of the whole quality assurance program.

MR. TELFORD: Well, would you rather see this to be 33 percent or 50 percent?

MR. HIDALGO-SALVATIER: I'd like to see 20 percent of the total dose.

MR. TELFORD: We're not at the total yet. This is the single fraction.

MR. HIDALGO-SALVATIER: Yes, well that number is

just not unrealistic.

MR. TELFORD: What would you like to see? Fifty percent?

MR. HIDALGO-SALVATIER: No. The dose reality is if you didn't give it today, you compensate tomorrow. If you exceed today, you reduce it tomorrow. So if you made a mistake one day, then it has to be done twice because the next day, you're going to have even less.

MR. JANICE: Well, Oscar, when does an error in any fraction occur or does it ever occur?

MR. HIDALGO-SALVATIER: Oh, often. It's common.

MR. JANICE: What?

MR. HIDALGO-SALVATIER: It's common.

MR. JANICE: What would you consider an error?

MR. HIDALGO-SALVATIER: If they're supposed to deliver 200 rads, and they deliver 250 --

MR. JANICE: But you just said the next day, you're going to compensate by only giving them 175.

MR. HIDALGO-SALVATIER: Right. So it doesn't matter to write a report and go to administration and --

MR. JANICE: That's what I'm saying, that, in essence, an error never occurs if you're going to compensate the following day, right?

MR. HIDALGO-SALVATIER: Not according to the way it's stated.

MR. JANICE: No, that's what I'm asking you. When does an error occur?

MR. HIDALGO-SALVATIER: On the total day, I would say so.

MR. JANICE: Well, then on the total, maybe that's what you need on the total. But you're not going to be able to get it on the total dose, so, in essence, an error never occurs if you compensate one day for the next.

MR. FELDMEIER: It's not that simple.

MR. MOK: It depends on what you mean by error. It's not because we practice bad medicine; you just get in situations where it happens. Like Oscar says, you deliver 100 rads a day, and you deliver 125 rad tomorrow, you just gave some deferred rad to compensate that because the patient is going to have further treatments.

MR. JANICE: That's where we're stuck with that 20 percent.

MR. FELDMEIER: The reason it's not so simple is it really depends on, you know, the wording, where the wording is included in the radiation treatment. I mean, if it's lens in the eye, a couple of rads makes it high and a significance difference. If it's the spinal cord, it might be very significant. If it's muscle tissue or connective tissue --

MR. TELFORD: How many rads to the spinal cord?

MR. FELDMEIER: We start getting concerned and we're fairly conservative, but I think that the practice of radiation oncology in the United States is a few people exceed 4500 rads to the spinal cord. Some people I've seen go for 5000. If it's a primary spinal cord tumor, sometimes they'll go 5000. But a ten percent error there is probably significant. A ten percent in 4500 rads is 450 rads. You get up around 5000, and that becomes significant. That's why I'm saying it's very hard to put this in a simple declarative sentence.

MR. JANICE: Maybe we need to talk about the organ rather than this straight point.

MR. FELDMEIER: Well, it would be -- no one would ever read this regulation because you virtually have ot list every organ in the body and say, Five percent error is okay; 15 percent error; there is 17 percent; 25 percent. It's really difficult to do, I think.

This, again, is a report that's kept within the institution and doesn't get boosted about, and you're not required to tell the patient and the referring physician maybe 50 percent in that case is more reasonable, because if I prescribe 200 rads and the technologist gives 300 rads, I think that's significant, even though I can adjust for it a bit.

It's probably not going to have any impact on the

patient's overall management in the long run. But I like to make sure that there is corrective action taken, so maybe 50 percent is a more realistic situation.

MR. TELFORD: Anything else on one through four? Are we willing to go to B. These are misadministrations. How about number one. Wrong patient, wrong source, wrong site, wrong route. Any suggestions there? How about -- this is radiopharmaceutical. It differs by 10 percent.

MR. DADARI: Again, I'd like to refer back to my statement yesterday. The dose calibrators vary from one to another and 10 percent variation is very common. And I would increase that number.

MR. TELFORD: This is therapy now.

MR. DADARI: You are not talking about radioisotope therapy?

MR. TELFORD: This is radiopharmaceutical therapy, but this is a therapy dose that you're going to give -- maybe it starts at 1 millicurie or 2 millicuries, or something -- 5 millicuries.

MR. DADARI: 15 millicuries -- that's what a license -- and I don't have any authority to exhaust that. And I see 10/15 percent variation from my dose calibrator to the pharmacy's dose calibrator.

MR. JANICE: You ought to go back to the user and say this shows 12, what do I do? You go back to the user.

MR. DADARI: But it's not significant. The 10 percent is not significant, if you're giving 15, 16.5 or 17 millicurie doses, 15 is not that significant.

MR. TELFORD: Are you saying you don't have a problem?

MR. DADARI: I would have a problem with 10 percent.

MR. TELFORD: That's the current requirement. Do you have a problem today?

MR. DADARI: No.

MR. TELFORD: Let me be sympathetic. Let's say 10 percent is too low. But tell me a number and tell me some logic, why it ought to be higher. I don't think you can get away with putting the basis of your logic that your dose calibrator is crumby -- you've got to get that calibrator -- your dose calibrator has got to be fixed. The pharmacy's dose calibrator has got to be fixed, or both of them have got to be fixed. That's not any good.

If it's not 10 percent, what would you like?

MR. DADARI: I would prefer 20 percent.

MR. TELFORD: Can you make the case that 20 percent difference is not a substantial difference to the patient?

MR. DADARI: I don't think so because the way to calculate the amount of radioisotope, especially for the

thyroid, it's based on the thyroid uptake -- we do thyroid uptake first. We say this is 20 percent, 30 percent. And if we inject this month, it will go that much, and we'll radiate this much. So there are so many approximations in the end calculations.

MR. TELFORD: Let's choose a rule of thumb here. Let's say that we have a 15 millicurie dose and we overdose by 20 percent. And that's 3 millicuries, that's 3,000 rads to the thyroid.

MR. JANICE: It depends a lot too as who where you nuclear physician is coming from as to how they've been trained and how they want to treat Grave's disease. If some that are conservative in treating Grave's disease; and others they say, where the patients has Grave's disease, let's put him on thyroid replacement. But again, it goes back to your institution.

MR. FOSTER: My comment too. I don't see anything really wrong with that. If you have a capsule that's delivered in 6 millicuries and the doctor orders 5, and change in prescription to 6, you don't have an error.

MR. DADARI: That's kind of fixing the problem. Are you talking about mishandling the submission. If I'm legally to -- it's that much significant, I have to report to NRC or no?

MR. TELFORD: He's saying before the fact. And

the authorized use approves it, then you have zero percent.

MR. DADARI: Usually we do it that way. As I mentioned earlier, this varies sometimes with the physician. Some physicians prescribe 7 millicuries and the other prescribes 15 millicuries. It's just -- usually nobody refuses to rewrite the prescription.

MR. FOSTER: So there's no error.

MR. TELFORD: Does anybody use liquid? Do you use liquid, Mark Shaffer? In the medical center it's liquids. What's your comment, on 10 percent? Is that a substantial change from what was prescribed?

MR. SHAFFER: I don't think so. I would be more inclined to be closer to 20 percent, personally. But again, it's better obviously, in capsules, than with the liquid. In liquid form it doesn't come exactly what you order -- very rarely. If you order 50 millicuries, it comes in 53. You have no way of adjusting. Chances are you're going to be getting less than that to the patient. And anyway, especially in liquid form, as opposed to capsule, you have to keep adding water and liquid to it -- to the source.

MR. TELFORD: If you're under 50 and you've got 56, now you're exceeding 10 percent, so you need to come back to the authorized user and say, should I give this? All right, that's what we do -- comes in that particular case. The authorized user rewrites the prescription

basically, before it's administered.

MR. JANICE: If you're giving a patient 50 millicuries and you get plus or minus 10 percent, you come out with 55 and you measure 56. What's one more millicurie going to do when we're giving them 52 to begin with.

MR. TELFORD: So, if we said plus or minus 20 percent, then at 50 -- you got a 60?

MR. JANICE: I don't think you'd have that much variance in what you would be getting in liquid. I think 53 millicuries would be more standard; plus or minus 10 and 60. I think if you go up to 60 millicuries, then you need to talk to your radiopharmacist.

MR. SHAFFER: If we get 50 millicuries, as opposed to 60, when I put in the dose calibrator, we're going to question the pharmacy anyway.

MR. TELFORD: That's if we're talking about large doses. Or even, what if we're talking about doses that are sort of on the threshold, down around maybe one, one millicurie?

MR. JANICE: I don't think anyone would ever treat Grave's Disease with one millicurie anyway. Chances are, if you give one millicurie to the patient, you'd be taking a body scan, because they've already had their thyroid removed, and you're seeing if there any metastases.

MR. TELFORD: Can you give me an example? Maybe

you're giving 100 microcuries.

MR. JANICE: Microcuries?

MR. TELFORD: 100 microcuries.

MR. JANICE: Of I-131.

MR. DADARI: Oh yes, we do have that -- some of the nuclear physicians do require that --

MR. JANICE: I don't have that.

MR. DADARI: It's common practice if you've got linear accelerator, you use 100 microcuries.

MR. JANICE: I've heard of giving 100 microcuries of 123.

MR. SHAFFER: We give 100 microcuries of 131 is relative.

MR. JANICE: That's a high dose for a normal thyroid.

MR. SHAFFER: With the rectal linear, that's very normal -- 100 microcuries is normal.

MR. TELFORD: Let's check out the logic here. We've looked at the 20 percent. Let's look at the 20 percent on the low end, 100 microcuries.

MR. JANICE: I think the requirement of -- of having a prescription for anything over 30 microcuries is going to fill the bill.

MR. TELFORD: We have a prescription. Now, let's look at any consequence here. If we put that in 20 percent,

now you've got 20 microcuries.

MR. HAMMOND: We're talking about a therapeutic dose of the order of 100 microcuries of 131 -- you're still going to have a prescription, but it's going to be a diagnostic prescription, not a therapeutic prescription.

MR. JANICE: Therapeutic dose would not start with anything less than 5 --

MR. SHAFFER: or 10.

MR. HAMMOND: Aren't we talking about here a therapeutic use that's greater than 10 percent, where you have them come back and get the prescription changed?

MR. JANICE: There's nothing wrong with that.

MR. HAMMOND: You're not ever going to report anything, if you've got a reasonably competent technologist or a physician, and they get 56 millicuries when they ordered 50, they're going to come back and say is this okay, and the doc is going to say yes, he's going to sign off and now you have a new prescription and this is a moot point.

MR. JANICE: That's right.

MR. TELFORD: In a suggestion earlier, I just wanted to grind through it. Okay, are you willing to move to three then, (b)(3) -- teletherapy? Oscar?

MR. HIDALGO-SALVATIER: What is the difference between three and one, I'm having a hard time distinguishing?

MR. TELFORD: This is total dose. You're going to give 5,000 rads total dose. You're going to give 25 fractions at 200 rads each. You've given 10 fractions at 250, instead of 200, so you look at this one. You're plus or minus your margin of error here is 10 percent of the total, so that's 10 percent of the 5,000 or 500. So you've got 10 fractions that were each 50 rads too much. So 10 times 50 is 500. If you give the 11th fraction at 250, you exceed this -- this is a cumulative total as you go along.

This allows the adjustment that you were talking about. This 10 percent of total is a current requirement -- a factor of 2 of any fraction is a lot larger than what we were talking about here. This is like twice as much than the 200 percent error on the high side. But let's say that you were less than this and this were 50 percent over here; then you could give the 250. Let's say on the 10th fraction, you discover that you've been giving 250 for 10 fractions; you would say, okay, no problem, my less fraction will be less.

Number (iii) just says look at this 10 percent as you go along and stay within that. Initially, the first fraction, for instance, you're going to give 200 rads the first fraction -- it's plus or minus 500. We've only given 200 the second fraction. You've given another 200 -- it's still plus or minus 500, so it doesn't really come into play

as being very restrictive, until you move towards the end. If you're going to give 25 fractions, you've got to get past 10 or 15 fractions before it means anything.

But, would you like to delete, modify or retain these things?

MR. HIDALGO-SALVATIER: It's almost equivalent to number I -- very similar to that.

MR. FELDMEIER: What did you say, Oscar? You said it's too tight?

MR. HIDALGO-SALVATIER: It's a little similar to I.

MR. FELDMEIER: I think 3 -- sub I there is a little too tight. Consider we do all body radiation as part of one marrow transplantation, actually we shoot for homogeneity of about 10 percent. So, already we have, in that situation, a 10 percent error -- in homogeneity at least. I may treat a prostate to 7,000 and my private practice colleagues may treat it at 6,000, that's a thousand over 7,000 rads, that's more than 10 percent difference. I really think that if we're going to have a percentage, it needs to be more generous than 10 percent.

You know, an average parallel would probably have a homogeneity being factor of -- might disagree with me, but maybe 3, 4, 5 percent.

MR. TELFORD: You mean this one or this one?

MR. FELDMEIER: I'm kind of with Oscar, I don't understand what the difference between (i) and (iii) is. I mean, they're both 10 percent of the total dose.

MR. TELFORD: This would imply you don't have to apply this to the --

MR. FELDMEIER: Right.

MR. TELFORD: -- this says you have to do it has you go along.

MR. FELDMEIER: You have to do it dynamically as you go along.

MR. TELFORD: After each fraction.

MR. FELDMEIER: If you say that by three weeks into the treatment you should be at 3,000 rads, you're treating a thousand rads per week, and you're at 350 rads -- I'm sorry, let's start all over. At three weeks, you should be 3,000 rads.

MR. TELFORD: The total is five -- it should be 5,000, so your window here is 500.

MR. FELDMEIER: Well let's say you're at 3,600 instead of 4,000, you'd have to report that.

MR. TELFORD: Right.

MR. MOK: I think that's a little bit too tight.

MR. TELFORD: It's a little too tight until the last dose. On the 25th dose, if you're given 25 fractions at 200 each and the total is supposed to be 5,000, and this

is going to get applied on the last dose, are you saying that this ought to be larger, up to the N minus 1?

MR. MOK: I really don't see the purpose of triple (iii). If it's over 10 percent, there is a misadministration.

MR. TELFORD: That's a different comment.

MR. MOK: Why do you need (iii)?

MR. TELFORD: Turning it around, tell me why you can throw it away?

MR. MOK: I don't see that it's any different than (i).

MR. TELFORD: Are you saying that you don't have 10 percent on the total that you don't apply to the end -- and the only thing I'm applying each fraction is this factor of two? And that's good enough until you get to the end.

Dave?

MR. BELLEZZA: I think you're interested in the final outcome and how to encourage that. I think to be concerned with what's happening along the road, to get to that bottomline, it just would generate too much of having to be reported and it doesn't make any difference, once you finally get to the desired clinical result. So, I would delete three.

MR. TELFORD: Okay. I'm a little skeptical about two. An example -- 5,000 rads is the total, let's throw

away (ii) and (iii). Somebody gives 2,500 rads, one fraction -- have I exceeded (i), not yet -- not to the total yet. Is that a substantial departure from what was prescribed? We're supposed to give 200 rad fractions. Someone gave 2,500 rads.

MR. BELLEZZA: The physician is going to look at what's delivered, and he's probably going to stop the treatment based on that; so the total -- total dose is going to differ from the prescription.

MR. TELFORD: Well, you can stop at any point, in theory. You've got this example of 25 fractions at 200 rads each. You get to the 20th fraction and the physician can say that's enough. If we don't need the last five, the physician can say, stop treatment, change the prescription, no problem. You don't see any problem with giving 2,500 rads in a single fraction?

MR. FELDMEIER: Using your example, John, let's say you give the dose, instead of twice the dose on a given daily fraction. It has absolutely no clinical significance at all. You can just kind of throw that dose away, or you can make it up. Instead of giving 200 rads per day, let's say you give 20 rads one day, using 2 up there, three sub 2, that would be a misadministration, reportable to the NRC.

MR. TELFORD: Therefore, we can get rid of the underdosing for a single fraction.

MR. FELDMEIER: I think so.

MR. TELFORD: How about the underdosing for a single fraction?

MR. FELDMEIER: I think there has to be something -- 2,500 rads, even though we would be in concurrence with 3, sub 1. You probably need to have some guidance, in terms of an overdosage on a daily basis, or on a per fraction basis.

MR. TELFORD: Is 200 percent -- are we in the right ballpark?

MR. BELLEZZA: It depends on it.

MR. TELFORD: You've got one wage and a single fraction, is it by a fraction of three?

MR. BELLEZZA: Not usually.

MR. TELFORD: Would anybody like to make a suggestion or modification?

MR. BELLEZZA: If you leave it in, you might want to be more generous.

MR. FELDMEIER: I think I'll take three out and leave one and two in, increase one to 20 percent, probably increase two to three times.

MR. TELFORD: A factor of three.

MR. FELDMEIER: Five times.

MR. MOK: If it's less than five times, it's going to be captured in an event. You don't want to have too many

misadministrations eventually.

MR. TELFORD: If you changed this to 50 percent, then anything over 50 percent, but less than a factor of three would be an event.

MR. FELDMEIER: I think that what we're aiming for -- we have to drop back and remind ourselves of what we're looking for.

We want to wait to identify and address the policies and procedures that are routinely causing errors. And a physician is going to have justify, a technologist is going to have to justify, a physicist is going to have to justify if you have an error of more than 10 or 15 percent, it's going to be in the quality assurance meeting minutes somewhere and it's going to be addressed. Someone is going to sit up and take notice, and there's going to be corrective action. I don't think that we necessarily have to air all our dirty laundry in the bright shining sun, for something that's not clinically significant in and of itself. If it identifies a trend or there's a systematic error or something like that, it can become clinically significant over time. But I would, as I said, keep one and two in -- make one and two more generous and put 50 percent over in -- three.

MR. TELFORD: This catches the trends and the systematic errors over here, and you can correct that

internally. So if you increase these, then you're pretty sure that you've got something that's more clinically significant.

Okay, any other comments on three? Oscar?

MR. HIDALGO-SALVATIER: I still have problems even with number one. If you prescribe 1,000 rads to the patient, and we deliver 1,101, I mean, are we going to run to NRC and confess our sin every time we do that?

MR. FELDMEIER: I said I'd increase that to 20 percent.

MR. HIDALGO-SALVATIER: It's okay if we keep the physician informed -- we have to keep the physician informed, he has got to know; but to run to NRC every time that happens --

MR. MOK: Unfortunately, that seems to be the way it is.

MR. BELLEZZA: Talking about percentages is really meaningless, unless you're talking about it in a dose category standpoint.

MR. FELDMEIER: Maybe it should say something like 20 -- more than 20 percent, or at least 500 rads or something like that. If you're talking about 20 percent of 100 rads, it is 20 rads; that's not clinically significant in any instance that I can think of.

MR. TELFORD: Greater than 20 percent and greater

than 500 rads.

MR. FELDMEIER: What do you think about that, Oscar?

MR. HIDALGO-SALVATIER: I still have trouble having to run to NRC every time. I don't have trouble reporting to the physician and reporting to administration; but it's not going to happen that we have to report to NRC every time -- it's just --

MR. FELDMEIER: How many times can you think of where you're off on your total dose by 500 rads? I can't think of too many times?

MR. JANICE: Have we got an agreement state?

MR. TELFORD: April 1st 1990 -- it just happened not too long ago.

MR. HIDALGO-SALVATIER: What do you think, Ed?

MR. MOK: I think it's fine to leave it there. I don't like it.

MR. HIDALGO-SALVATIER: Ten percent of the 500 rads.

MR. FELDMEIER: Twenty percent, don't say 10 percent.

MR. MOK: Twenty percent over -- under dose.

MR. TELFORD: In total?

MR. BRAHAMAVAR: In total?

MR. MOK: If your prescription says 5,000 --

4,500, is that a misadministration?

MR. TELFORD: Well, it is currently, but if you intended to give the 4,500, why wouldn't you just amend your prescription? You're at -- let's see, you're giving 200 -- 200-rad fractions, you're going to have a hard time stopping it at 4,500 -- 22 fractions -- I have 4,400. So let's say I wanted to stop there, then you could say -- you could amend the prescription and say stop. But, if you truly intended to get 5,000 and you had some problem that you didn't know about and you -- you gave 4,400 --

MR. MOK: So that would be a misadministration?

MR. TELFORD: Your suggestion is 20 percent here and it exceeds 500 rads; how about here? This is a factor of two, do you want to put it exceeds a certain number of rads here?

MR. FELDMEIER: I think so. That's what David Just said.

MR. BELLEZZA: That was an aside. Say a factor of three and so many rads.

MR. FELDMEIER: One-hundred rads, 200?

MR. TELFORD: A fraction by 200 or 300 rads.

MR. FELDMEIER: A rad only comes -- the total rad and clause would only come into play if you're dealing with dose as a factor of three -- would come into play if it was 200 rad fractions, and that gave 600 rads, then the three

would make that a misadministration. It has to be both.

MR. TELFORD: Oh, I see. If it's a 200 rad fraction and it exceeded a factor of three, you have to to above 600, but if you're at a low dose, 50 rads --

MR. FELDMEIER: You give 150 or 200 --

MR. TELFORD: Then you've exceeded it by 200; so do you want something larger than 100 here, say a factor of three, and exceeds a certain number of rads? How can we get into trouble there? How could you -- If you're going to -- you're treating something and you're going to overdose and are not in the treatment problem?

MR. KLINE: I think also you might want to consider large doses per fraction, large treatment areas and you get back to the critical nature of the organ -- how much can the organ tolerate. But, if you're talking maybe 500 rem limit and you administer half the body 500 rem, you'd have a real problem.

So it's very difficult without getting into putting up tolerances of different tissues. But you might want to consider the unusual cases. When you administer a large fraction at one time, how that might affect the misadministration reporting.

MR. TELFORD: You had you hand up, Oscar?

MR. HIDALGO-SALVATIER: Not yet.

MR. TELFORD: Okay, I take that back then.

So, we have a suggestion to make this 20 percent greater than 500 rads, and then it's just a factor of three -- don't put rads on this.

MR. FELDMEIER: I think we should put rads on that -- probably 200.

MR. TELFORD: Two-hundred, okay. Exceeds 200, do you follow that, Oscar?

MR. HIDALGO-SALVATIER: Is that greater than 20 percent? Every total dose are more than 500.

MR. TELFORD: And -- okay, are we willing to move to four?

We have a brachytherapy source that is leaking or lost.

MR. FELDMEIER: I think we should accept that as it is.

MR. TELFORD: Okay. Any other comments?

How about number five, brachytherapy administration?

MR. MOK: You need to be careful. It's not unusual to have a dose -- it's not unusual that once it comes out, that's inaudible.

MR. TELFORD: Do you know what happened to it?

MR. MOK: The patient went home? And he passed it went in the sewage.

MR. TELFORD: So what if we said unaccountable.

In this case, you could account for it. It was passed in the urine.

MR. BELLEZZA: This speculation as to whether or not that happened? You're hoping that it went down the toilet?

MR. TELFORD: Is this seed, by itself, is a hazard to anybody?

MR. FELDMEIER: It's unlikely. I mean, if it happens right after the implant and it's fairly hot -- and if you're keeping a philosophy -- as little -- as large as I guess it is, it's a minuscule risk, perhaps.

MR. TELFORD: We're not going to apply the part 20 limits to that single seed. It didn't go in the toilet -- maybe it's in the patient's house someplace? You look for the health and safety questions here and say, is it a problem to the patient, or is it a problem to some innocent bystander who might be in the patient's house?

MR. BRAHAMAVOR: When you send them home, you've already determined that radiation levels cannot be more than 500 over a period of one year, when you discharge them from the hospital before they go home.

MR. TELFORD: Does the seed stay in the patient?

MR. BRAHAMAVOR: The -- discharging them after the level is reached for the safe release of the patient from the hospital, so the health issues don't come when the

patient is in the home.

MR. TELFORD: Ed, would you like to suggest a modification to this?

MR. MOK: Maybe we can say that after the patient is discharged -- the patient is discharged -- it is no longer our responsibility.

MR. TELFORD: How do you know about that -- you planted the seeds and the patient goes home?

MR. MOK: He comes back for follow-up and we can do x-rays or do dosimetry.

MR. TELFORD: If you did lose the seed, this loss is not due to you.

MR. MOK: That's right.

MR. JANICE: What's wrong with the word "unaccountable?"

MR. TELFORD: It's not unrecoverable because of something you did. You put the seeds in there, you know they're there, the patient went home. Upon re-examination, one of them is gone.

MR. HAMMOND: The way you've got it written there, the patient went home and lost it. The way it's written here, it says, during the brachytherapy treatment -- if the treatment is continuing, you've got to be responsible for it, even after the patient is gone.

MR. TELFORD: Should this say, treatment within

the hospital clinic?

MR. HAMMOND: Have it say what it says on the overhead.

MR. TELFORD: Don't say, during the treatment?

MR. MOK: I would amend that sentence then -- having recoverable sealed source before the patient is discharged. Once you discharge a patient, whatever happens, it's no longer my responsibility.

MR. TELFORD: Okay.

I think that covers the intent here. Any other comments?

MS. ROY: How can you have an administration of a lost or unrecoverable source? How can you administer something that's lost?

MR. TELFORD: You lost it when you were trying to plant it. You went to the OR with 40 seeds and you put 27 in and you only came back with six. Where did they go?

MS. ROY: So, it's during the administration process?

MR. TELFORD: As Ed was saying, it happens before the patient leaves the hospital.

Any other comments on four? Are you willing to go to five? This is when the brachytherapy administration is 20 percent different from what was prescribed.

MR. FELDMEIER: I think the spread being a little

more generous, in terms of our intolerance, since brachytherapy oftentimes is inherently more precise and we need to up that percentage to probably at least 30 percent.

MR. TELFORD: Okay. Is there a comment we can make here about harm to the patient -- deleterious effects? Most errors would not occur if they were greater than 20 percent or 30 percent, if they're likely to cause any harm to the patient.

MR. HIDALGO-SALVATIER: The calibration of the sources is no better than 10 percent anyway.

MR. TELFORD: Okay.

MR. HIDALGO-SALVATIER: So right there you have -- beginning with 10 percent error, 10 percent uncertainty. You're allowing only for 10 more.

MR. TELFORD: It's inaccurate by 10 percent. You have a number for it, you just don't know if it's that number or not.

MR. HIDALGO-SALVATIER: Say that it can.

MR. TELFORD: You have a number for this source, it's activity.

MR. HIDALGO-SALVATIER: You're talking just about cesium capsule, right?

MR. TELFORD: Any.

MR. HIDALGO-SALVATIER: Talk about gall seeds. If I measure the activity of gall seeds, I'm going to have a

range of 18 percent -- between one and the rest.

MR. TELFORD: I don't mean that for each seed you have a number for each seed.

MR. HIDALGO-SALVATIER: Would they -- plus or minus?

MR. TELFORD: You just don't know where it is within that plus or minus.

MR. HIDALGO-SALVATIER: I've got a number with a plus/minus rad.

MR. TELFORD: You've got a number and you think you're going to be giving a certain dose to the patient, based on those measurements of those seeds.

MR. HIDALGO-SALVATIER: That's what I was saying, and I'm already beginning with uncertainty. It's uncertain.

MR. TELFORD: Nobody will ever know what that number is -- what the true value is.

MR. FELDMEIER: Chances are you're going to use isotopes from the same batch. You're going to order your gall seeds, so they're going to be coming out of the reactor at the same time. Let's say that's two weeks after you do a gold seed implant, the manufacturer calls and says, gee, we found out that we had a problem with our dose calibrator and those seeds were 25 percent hotter than the activity -- we shipped them to you advertised at.

I think that what I'm saying is that if you have

an uncertainty, that it might be a consistent uncertainty -- it might be consistently low or consistently high.

MR. TELFORD: But your example is not your fault in what we're talking about here -- is you put in 25 percent more seeds than what you were supposed to have, or you left them in 25 percent longer than you were supposed to leave them in. So your 10 percent uncertainty on the value of the seeds is really irrelevant?

MR. FELDMEIER: As to the patient.

MR. TELFORD: But neither you nor the patient knows what the true value is and you have to accept whatever the dose calibrator says. Who are you going to believe, your's or the pharmacist's? Because you're going to calculate your dose based on one or the other.

You're going to start with -- call it an assumed value for each seed.

MR. FELDMEIER: So you don't see that as an under or over dosage?

MR. TELFORD: Nobody can define what that under or over dosage is; how are you going to do it? You've got a value for a seed. You put in x number of seeds and you leave them for a while -- hours. You put in too many seeds, then you don't do what was prescribed. If you leave them for too long, you don't do what was prescribed.

So let's talk about real mistakes here.

MR. HIDALGO-SALVATIER: What do you mean by a 20 percent error in dose; what is the meaning of that?

MR. TELFORD: Okay, in here it will say, administered dose is 20 percent different from what was prescribed, just like we said in teletherapy.

This says underdose or overdose.

MR. HIDALGO-SALVATIER: But the fact is that you can prescribe a dose, but it has an uncertainty, you don't know if it is --

MR. TELFORD: Why didn't you say that back here?

MR. FELDMEIER: Because I think we have a much better control over external beam therapy than we will over brachytherapy.

MR. TELFORD: The same claim could be made about radiopharmaceutical therapy, brachytherapy, teletherapy. To me that's not the argument you ought to be making. You ought to be making the argument that I can't get the seeds, in the treatment plan I can't locate the seeds as well as I think I could. And you implanted a certain number of seeds. Now, you cam out of the OR and the seeds are there, and you can determine how many are there and the location. Now it is just a question of watching the clock. Or are there other questions?

MR. MOK: To give you an example, when you do a cesium implant, you want, let's say, 4,500, and that's the

prescribed dose, after you put them into the patient you might get over the 4,500 rad on one point, because maybe the source is closer to that point. However, you don't want to pull it out early, because you have to look at the other side. You don't want to underdose the other point. So according to what you said, you might even be overdosing the patient.

MR. TELFORD: On the A point, but you are willing to overdose the A point because you don't want to underdose the B point?

MR. MOK: Whatever point you want to dose.

MR. TELFORD: Maybe you could embellish your example a little bit. Could we exceed the 20 percent easily?

MR. MOK: Well, --

MR. TELFORD: What is the prescribed --

MR. MOK: 2,400 would be 3,000.

MR. TELFORD: 2,400 rads to Point A?

MR. FELDMEIER: If the lady has tumors such that when you put the appliance in it is pulled over to one side, and you want to control your dose at both Point A but the one Point A is running 60 rads per hour and the other is running 45 rads per hour, that's an extreme example, but you are off by more than 20 percent in that case. So you know, you look at the situation, you look at all the doses, and

even though the original prescription might have ben 2,400 rads to point A to give 2,400 rads to Point A, if you control it at the 45 prior point, you have going to have 50-some hours; control it at the 60-rad Point, you are going to have to give 40-something hours.

MR. TELFORD: So your plan said do 50 and 50 but when you come out, you are doing 45 and 60, so would you change your prescription?

MR. FELDMEIER: Change the prescription.

MR. TELFORD: That's not even an error.

MR. FELDMEIER: I think the problem really comes in with permanent implants, for the reason, you go in with a preplan, and you want to give the prostate with iodine 15,000 rads or something like that, and you put your iodine seeds in, and place them as well as you can, and you don't give them 15,000, maybe you give 18,000, maybe you give 12,000. I think that's more than 20 percent. You could easily get more than 20 percent error in that case.

The other thing is --

MR. TELFORD: You went into the operating room with the pre-prescription to plant so many seeds and you found out that you could implant that many seeds or you could implant more seeds and you chose to do one or the other, you came out, could you just change the prescription?

MR. FELDMEIER: You can, if the NRC or the state

regulatory agencies in the states where states have control are going to allow that type of largess in terms of interpreting regulations, yes, you could do that.

MR. TELFORD: We're building that into the intention here.

MR. MOK: Would that be a loophole if you just happened to be larger than 20 percent, the physician could just change the prescription?

MR. TELFORD: It's when you come out of the OR, now you write your final prescription, now you know how many seeds you put in in another location. If it's a permanent implant, you have already decided that's the number of seeds you are going to put in. So the 20 percent wouldn't occur until many days later. So you are just changing a prescription because you are saying that is all I can do.

But if it is not a permanent implant, and you put in, let's take the GYN application here, we thought we were going to treat 50 and 50, but we came out treating 45 and 60.

You had a plan when you went in, but you found out you couldn't do that. So when you come out, you should change your prescription to reflect the fact that those are the two dose rates and now you are going to maybe recalculate your time to determine how long you are going to leave those in. So at the time you change the prescription,

that's what you should do, because then no error would be created. You just have to account for the fact that it was offset, but if you waited until after the fact, you just let it go and then after you had pulled out the sources, then you said, oh, gee, I've got a 20 percent error here, I'd better change my prescription, well, that's a coverup, you can't do that. That is fully the intention here.

MR. FELDMEIER: John, your interpretation is that for a temporary implant any time up to and including the time you pulled the implant, you have the opportunity and the advantage, the right to adjust the prescription?

MR FELFORD: Well, something like within a day or some reasonable time after you came out of the OR, you are fully knowledgeable that that's what happened in the OR, and if you have the offset of the device, as you mentioned, then you would need to do some recalculation to determine how long you could leave those in there so that at one point you give the minimum sufficient dosage, without overdosing the other point. So at that time you do the recalculati and then you amend the prescription. That's what you should be doing. That should be no error.

MR. FELDMEIER: If it is a permanent implant, you would have to live with what you get. You get 20,000 instead of -- let's do it the other way, you get 10,000 instead of 16,000, and you realize that you can, if the

implant is cooled, you can make up for the difference by bringing the patient in and giving them a few fractions of external beam. You can live with that as long as there is a thought process, a rationale, and some reasoning behind the adaptation of the overall treatment course.

MR. TELFORD: The uncertainties that you guys should be worrying about I think is the location of the sources. Are they, how close are they to where you think they are? How much can you be off, just due to a source error, I mean a location error? Is this 20 percent big enough to accommodate that, or is it big enough to accommodate "reasonable variations" in the time you leave them in?

MR. MOK: I don't think it's enough --

MR. TELFORD: You have to adjust right after you come out of the OR.

MR. FELDMEIER: After you see the plant, after you see the dosimeter, you know what you are working with. Especially with a temporary implant. If you are shooting for a 50-rad hour dose rate and you get a 40-rad hour and you want to give 2,500 rads, it is a fairly easy matter to just leave in the implant ten more hours or something.

MR. TELFORD: So if you are worried about location and time, is the 20 percent enough?

MR. FELDMEIER: It probably is. It might be

better to see a 30 percent. That might give you a little more leeway with the permanent implants, where, because of uncertainty in where the seeds ultimately end up, your dose can't be off by that much.

MR. TELFORD: Okay. What do you think, Oscar?

MR. HIDALGO-SALVATIER: Well, what is going to happen if the doctors are going to begin prescribing a range, instead of a number, a range. And they are going to say 4,000 to 5,000 to Point A.

MR. MOK: What happens, if it is not a prescribed dose? What are you going to do?

MR. TELFORD: That might not be a dose.

MR. HIDALGO-SALVATIER: Tell that to the doctor.

MR. BRAHAMAVOR: 6 to 6,500. 6,000 to 6,500 is prescribed, the range. Even now it is done.

MR. HIDALGO-SALVATIER: It's done, yes.

MR. BRAHAMAVOR: On most of the charts we see it.

MR. HIDALGO-SALVATIER: They write the MEs to deliver to this point in the lung between 5,000 to 6,000.

MR. TELFORD: Why is that? Is that the best you can do, or is any dose within that range okay?

MR. HIDALGO-SALVATIER: Physicists don't question the prescription of the doctor.

MR. FELDMEIER: I personally don't write prescriptions like that, as I do my dictation, my

consultation, my history and physical, I might say we'll deliver between 5 to 6,000 rads to this patient. And then, since it's a dynamic process to evaluate the patient's response and the patient's tolerance, during the treatment you might adjust that up or down. When I write a script on a patient's treatment sheet, I don't say 5 to 6,000 rads.

MR. MOK: For brachytherapy, you need a specified dose during a period, write down a specified dose.

MR. TELFORD: Any other comments on Part B? Are you willing to move to the rest of these, C, D, E, and F? These are very much like we had in 35.33, if we make the same changes here as we made before. Do you have some suggestions here?

[Pause.]

MR. FELDMEIER: There is no requirement in here to inform the referring physician or the patient for any of these misadministrations?

MR. TELFORD: Yes, there is. The same requirements as before, in that very long paragraph.

The A4 is the therapeutic use unauthorized.

The paragraph in question is on Page 1449.

MR. JANICE: It starts actually at the bottom of 1448 and goes all the way across.

MR. TELFORD: Yes, there are a couple of lines on 1448.

MR. JANICE: It still has the same thing as the other.

MR. TELFORD: With the same safety valve, Point 2B, referring physician.

MR. JANICE: The patient's name not being on the report.

MR. TELFORD: I believe in one of these we have the phrase "clinically significant." See, John, I think they are the same. The diagnostic and the therapy wordings under those two separate sections are about the same.

[Pause.]

MR. TELFORD: Okay. Any comments or suggestions for C through F?

Oscar?

MR. HIDALGO-SALVATIER: I've got only five minutes. So let me mention the position of the physicians at my center is that it is not within the realm of NRC to tell them who to refer to. That's the way they feel. And I was supposed to transmit that opinion to all of you.

MR. TELFORD: The NRC is not supposed to tell them to whom to report?

MR. HIDALGO-SALVATIER: The NRC is not supposed to tell the doctor that they have to report to the patient or to the referring physician.

MR. TELFORD: Oh.

MR. HIDALGO-SALVATIER: That some other organization is supposed to tell him what to do.

MR. TELFORD: Oh. Okay. That's the long paragraph that says you're supposed to tell the patient if the referring physician agrees, the patient should know. Okay. I understand that.

Any other questions on or comments on 35.34?

[Pause.]

MR. TELFORD: Okay. Let me kind of give you a little individual air time again, for some of the remarks you would like to make.

MR. JANICE: Ask if anybody needs to leave to catch a flight.

MR. TELFORD: If you need to catch a flight right away, then go ahead and leave. But If you are still here, I am going to let you speak individually, and you can make any observations or comments you would like. You can make any observations or comments you like about anything we have talked about for the past two days.

So let's start with Terry.

MS. ROY: Comments about anything in the last two days?

Diagnostic referral, I think it will be fine if you can put in something about the oral, just giving us a little bit of leeway there, with the attempt, for the

written prescription, at all times, or written referral.

The notation about the auditor, auditing procedures, the ones that can be amended for diagnostic nuclear medicine. I don't see any problems with diagnostic nuclear medicine, at this point in time.

I've enjoyed being part of it. And I hope that our participation in the workshops help everything go through smoothly.

Thank you.

MR. TELFORD: Thank you. Oscar.

MR. HIDALGO-SALVATIER: I would like to say that I am really happy that I had the opportunity to participate in this meeting. I think it has been really fruitful. Also, I want to congratulate all of you for trying to do this, which must be very hard, very difficult.

It also has given us an opportunity, because in QA, it is helping us to improve our quality control programs. It is helping a lot.

Thanks to these pressures, we have been able to put pressure on our institutions, also.

So it has been very, very fruitful.

But we have to be careful. We have to consider the opinion of the physicians. And if we want the program to succeed, if we want the regulations to succeed, we have to make them practical and everybody has to agree with the

regulations, not agree, but to contribute to what we are doing.

That's it.

MS. LaFRANCE: I'm just glad to be here. Listening to everybody's opinion, things have cleared up for me. My fellow panel members have answered questions about everything that I was questioning myself, and more so. So a lot of things have been cleared up. And I am glad to see some changes will be made, especially in the brachytherapy and teletherapy.

MR. BRAHAMAVOR: I think the aura, the intent of these discussions and workshops and the programs seems to be a good one. How it will finally end up, I think I am not able to predict at this point. But the real difficulty I think you will find as you start implementing this is going to be the described dose and radiation therapy, that there is always a change, unless that changes to 10, 15, 20, 40, percent, whatever numbers you put are not going to be really applicable. So something has to done for one number, when you talk about the percentage, it has to be one number, not a range. And when there is a range, the whole thing is go out the window.

So you may find some difficulty there. And I hope you try to foresee that and do something about making it to be practical, not just a paper document.

Thank you.

MS. WOOD: I don't have anything to add to what everyone else has said. I have enjoyed and appreciated being part of this. I'm anxious to see what the regs finally come out to be.

MR. TELFORD: Dave.

MR. DODARI: I enjoyed this meeting. I appreciate the NRC giving us the chance to say what we feel about these points, and listening to us.

I would like to point to the few issues, which in my own opinion, are the most important ones. As we discussed everything, and I am basically concerned if these positions are going to make any difference for NRC or not. But I would like to make a few points and highlight.

I believe regulations should be broad enough to fit everybody, in any different situation, and that regulation should not make specific rules for a city.

And regulations in isotope treatments I believe are the most important ones and most useful ones, and almost have been narrowed down for perfection.

That part I believe should be left untouched and emphasized very largely. Because nuclear medicine, almost more than 99 percent of malpractice lawsuits come form iodine treatment and treat isotopes. So this regulation should take care of that point.

On the diagnostic part, I believe the emphasis should be minimized, because we have been singled out because we use isotopes. Other modalities, like CT, expose the patients a lot more than we do. They don't even count their mistakes. We are obligated to count our mistakes and record it.

It should be minimized, so we will be able to compete with those modalities. So we shouldn't be singled out.

And I believe -- this is my last point; I'm taking too much time -- over-regulation should be avoided. If you emphasize more paperwork, I'm going to worry about reporting, documents, and all that stuff, and my valuable time should be spent in patient care. That's the primary purpose of all this situation, patient care. So by minimizing the paperwork, you are giving me more time to take care of my patients.

Thank you.

MR. NELSON: I would just like to thank everybody for coming and thank you for your comments. I think the NRC will look at all these comments and hopefully provide a rule that everybody can live with.

MR. TELFORD: Ed.

MR. KLINE: Again, I would like to thank everybody for their candidness and their being able to make this

workshop, all the workshops very interesting. There are a lot of different viewpoints, and all of them are documented and all of them will be reviewed. We take that very seriously, and we have a number of people looking at it. We will have a number of other people outside the NRC look at it. And also, we are going to have quite a few societies look, four or five, that are going to look at these comments.

So you are looking at a new method by which the NRC is approaching the rulemaking process. It's never been done before. This is all ad lib. This is not something that we are used to doing, either. I think it is a good avenue for opening up a door of rapport between the NRC and the medical community.

The NRC has historically been primarily a reactor-based agency. They've been regulating the nuclear power industry. The medical industry is something which has over the years become more and more prevalent, and the NRC has placed a little more emphasis in that area, and this rule-making process is part of that. But I feel that having a performance-based rule, we might be able to have somewhat of a reasonable rule generated that meets the intent of patient care and safety, and satisfies what we would like to get out of the rule and hopefully satisfied what you in turn might be able to get out of the rule, so everybody will be,

somewhat, like I said earlier, will be author to this rule. And there will be parts in there that you might be able to identify later that were your opinions, and might come directly from your statements.

And I don't know of any other Federal agency or rulemaking body where you can directly see this sort of impact. If it is, it has been watered down. It's very hard to hear what individual people have said that would affect the rule.

So in summary, I think it is something that we are all happy to be involved with. And I hope people here felt that this was worthwhile and they got something out of it.

I think it is, and I appreciate your time, taking two days away from the hospital to come here to do it.

So I thank you for being here.

MR. TSE: I really appreciate your comments and input. I hope this is not the end of our discussions.

If you have further suggestions or comments that you want to convey to me, just give me a call. My address is in the notice.

MR. KAPLAN: It's been a pleasure working with you. I want to thank you for being forthright and sending me your completed questionnaires. Now we have to sift and sort through the testimony, the proceedings, and the information. As Ed said, we hope that you can actually

someday see your contribution to this entire process.

MR. MOK: Well, I want to thank NRC for inviting me to come to this workshop. And I am very happy to come. And I think -- I hope I didn't keep my feelings hidden and that my comments can be useful.

I think that I want to congratulate the NRC for doing this kind of workshop and that they begin to consult other medical and professional societies before they finalize their proposal of the regulation.

Again, I am real happy to be here.

MR. TELFORD: John?

MR. FELDMEIER: I think this meeting and the pre-study meeting were both very productive. It seems to me that you gentleman have a better feel, at this point in time, for what our concerns were way back in the pre-study period. I congratulate you on your attention to those kind of things.

I think you kept your ears open during the whole process. I am confident that you're not just allowing us to ventilate and that you are going to apply the recommendations that have been made these past few days.

I would like to congratulate the other participants for being very active, very forthright, and very precise and perceptive in their comments. I'm a little disappointed that there weren't more physicians, because I

think it's important to have physician input. That's the reason I'm here.

I hope that, as I spoke with you yesterday, I think a good follow-on to this would be an opportunity that after the Part 35 has been implemented for a year or so that we sort of have a get-together again and see where we are with implementation and, perhaps, by that point, people would have to live under it for a year or so. There will be some interest in terms of having impact on it or, at least, a critique of what it is doing to the practice of medicine.

I think, all in all, it's been a very productive process, and I'd like to congratulate Brookhaven, the NRC, and the participants.

MR. JANICE: There's been many things that we've gone through in the last two days. What I've heard is that most everything in 35.35 was already covered in one way or the other.

The problem seems to be centering around these crucial peripherals, that it's a basic, standard-operating-procedure document. It is limiting in many areas, particularly in the therapy area.

It has been very educational. But when I look back at it, I see here, over the last 2 days, that we have, as a group, have said many things, but I really don't know what consensus we reached.

We said this would look good, this would look good, this would be this, and this would be that. So, I really don't know what we decided on as a group.

I would really like to see what this group has finally said about 35.35. I would really like to see the finished product of 35.35, before it goes to somebody's signature, saying this is law now.

As for myself and my institution, we're happy to take part. We appreciate NRC asking us to be a part of it. And we look forward to doing some more in the future.

MR. HAMMOND: I would like to add my thanks to the NRC for our participation in the program. It's been very beneficial for us. Hopefully, we had something to add.

Some comments about 35.35, in general: I still question somewhat the need, particularly in diagnostic nuclear medicine, for the assumption that the majority of the impetus for this came from misadministrations with an error rate that's quite low. I question the need for a lot of these diagnostic guidelines.

Again, I would like to raise my concerns about it being called a QA program. I think it raises too many -- I think, in some ways, if the misadministration was the reason for it, that some of the conclusions in NUREG-1272 weren't addressed, such as what role radiopharmacy plays in this misadministration problem.

I would particular like to urge the Commission and the staffers to consider the non-urban facilities, the smaller facilities, where on a per-case basis, any cost impact is going to be dramatic. If you're doing 6,000 procedures a year as opposed to 600 procedures, your per-unit cost is going to increase dramatically.

I have one other area of concern, and that's was Tony's aside earlier when he said that there was on the table a comprehensive QA program. I'd like to hear a little bit more about that one.

But I'd like to thank the NRC for our participation.

MR. TELFORD: Ray?

MR. FOSTER: Again, I'd like to thank the NRC and Brookhaven for this unique opportunity get involved in the decision process.

I don't really have any significant comments to make that were not already made. I am anxious to see the report and take a look at it before it goes into a formal publication. But that's about it.

MR. TELFORD: Let me thank you for your comments. Let me congratulate you. I think, in total, you gave us some very good comments in this workshop. I can almost assure you that you will see some of them in the final rule. You may be surprised to find your suggestions there, but

don't be, because that's the purpose of these workshops.

I believe I need to respond to a couple of comments over here: The one about the consensus -- we pointedly did ask for a consensus. So, we didn't expect nor did we want a consensus. We want advice from each individual volunteer, based on their professional experience, and that's what we got, and it was very good.

As to seeing the final product, the staff has somewhat of a problem, usually, in being able to show publicly its final draft. There may be an out in this situation.

I believe that our Advisory Committee for the Medical Uses of Isotopes is going to want to see the staff's proposed final, which we probably will do. It probably will be a public meeting. So, there will be a transcript of that. And if that's the case, I really don't have a problem with giving it to you, so that you can see what the staff has finally proposed.

The comprehensive rule: Back in the fall of '87 or early '88, the Commission said -- I think it was the fall of '87, when they said give us a rule that takes care of most of the problems now. That's the basic quality-assurance.

We'll save everything else and put that in the comprehensive rule. So, it's still sitting there on the

shelf as something to do.

Perhaps we can use Dr. Feldmeier's suggestion: Let's implement this rule for maybe a 2-year period, then have a review of the results to see if that's sufficient. It could be that it's not, in which case we'd need to dig into other areas. It could be that it is, in which case we don't need that rule. But it's still sitting there.

We haven't done anything with it, and we won't do anything with it until this rule is out, and I personally think it's a good idea to look at the results of this rule before we do anything with that one, because this is a big step up, it's a big change from where we are today. But once again -- did I miss something?

MR. TSE: Yes. We want to mention that it's not a proposed rule; it's an advance notice. So, it's not even on the stage, but we are thinking about it.

There was a Federal Register notice published about October of '87.

MR. TELFORD: Once again, let me congratulate you. I really enjoyed this meeting. I thought, in particular, yesterday was almost priceless. It was a very good discussion. The comments you made today were also very good.

I really enjoyed it. Thank you.

[Applause.]

[Whereupon, at 4:48 p.m., the meeting was adjourned.]

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DOCKET NUMBER:

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