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

BEFORE THE

U. S. NUCLEAR REGULATORY COMMISSION

In the Matter of:)

)

PILOT PROGRAM WORKSHOP)

)

Conference Room

Ramada Inn-Airport

1419 Virginia Avenue

Atlanta, Georgia

Friday, April 6, 1990

The above-entitled matter convened at 9:03 a.m.

ATTENDEES:

On behalf of the Nuclear Regulatory Commission:

JOHN TELFORD

ANTHONY TSE

LLOYD BOLLING

ED KLINE

SHER BAHADUR

RICHARD WOODRUFF

On behalf of Brookhaven National Laboratory:

EDWARD KAPLAN

KEVIN NELSON

On behalf of Pilot Program Participants:

GARY WAYNE LEE	THOMAS A. WHITE	TOM CLARK
STANLEY GIPSON	SUE GOODWIN	JONETTE ROBERTS
HAROLD W. BERK	ROY LANDERS	JEAN RHODES
A. R. PULCRANO	KENNETH FRYMAN	TERRY ROY
NEIL CANADA	BOBBY BARNETT	DAVID GARRISON

PROCEEDINGS

MR. TELFORD: We'll go on the record.

Good morning, my name is John Telford. I'm from the NRC, Rockville, Maryland. I'm the Section Leader of the Rulemaking Section that is trying to develop this program.

I want to welcome all of you, very happy to see you here. This is our third workshop. The first one was in New York, the second one was this Wednesday in Chicago and it's real nice to be in Atlanta, in the sunny south.

Does everybody have a copy of the agenda?

First we'd like to go through a little introduction to let each of you introduce yourselves. Then I'm going to rearrange the two topics here for the morning session. I'll reverse the order of those.

When you introduce yourselves, let me ask you to state your name, position, facility, hospital that you're employed at and what combination of brachytherapy, teletherapy or nuclear medicine that you hospital does. We assume that you're representing all three of those. If you're not, say so.

Let's start with this gentleman over here.

MR. LEE: Gary Lee representing Forest General Hospital in Hattiesburg, Mississippi, a roughly 550-bed facility. I'm the Manager of Radiation Oncology and representing brachytherapy, teletherapy.

MR. TELFORD: Excuse me, I did forget something. Please tell us if you're an urban location or a rural location.

MR. LEE: I guess we're both, small urban, about 60-65,000 population.

MR. GIPSON: Stanley Gipson from the same institution Gary is from and I'm Manager of the Diagnostic Imaging Section.

MR. BERK: Harold Berk, I'm from the University of Virginia Health Sciences Center in Charlottesville, Virginia, about a 750-bed hospital. I was radiation safety officer there for 12 years and now I'm a professor of radiological physics in the Department of Radiology and primarily doing radiotherapy work. I was the one who volunteered to come to represent our institution. Of course we have a large nuclear medicine program and a large brachytherapy program, treat about 100 patients a day with teletherapy, gamanite. We're one of the few institutions that has a gamanite. Also have a linear accelerator that does theriotactic radiosurgery.

Charlottesville is a town of about 100,000 people.

MR. PULCRANO: Tony Pulcrano, I'm with the Naval Hospital in Portsmouth, Virginia. I am the radiation safety officer. We have teletherapy, brachytherapy and nuclear medicine, I'm representing all three.

Naval Hospital, Portsmouth is about a 600-bed hospital and we service a large area from Yorktown, Virginia Beach, Norfolk, Hampton, whole big area.

MR. CANADA: My name is Neil Canada, I'm from Hamilton Medical Center at Dalton, Georgia. Our hospital is about 300-bed, I'm the nuclear medicine tech there representing nuclear medicine. Dalton is about 20-30,000.

MR. WHITE: Tom White, Baptist Medical Center in Columbia, South Carolina. I'm a radiation physicist and radiation oncology. We have teletherapy and limited brachytherapy and nuclear medicine departments and I represent all three. Columbia is urban, population of about 250. The number of beds is about 450.

MS. GOODWIN: I'm Sue Goodwin, West Georgia Medical Center in LaGrange, Georgia, which is just south of Atlanta. It's a medium-sized town, I guess you'd call it, about 50,000. The hospital is 250 beds. I represent radiation therapy and nuclear medicine. I'm the Director of Radiation Therapy and Nuclear Medicine. We have linear accelerators and limited brachytherapy.

MR. LANDERS: I'm Roy Landers from Sarasota, Florida representing a private physician group called Sarasota Oncology Center, we do teletherapy, brachytherapy in one of the major hospitals in Sarasota. We do a small amount of Group IV radiopharmaceuticals in our office, which

is a small urban area on the west coast of Florida.

MR. FRYMAN: I'm Skip Fryman, I'm from Hollywood, Florida, Hollywood Memorial Hospital, about 700 beds. I'm the radiation safety officer representing all three departments. The area has around 250,000 people.

MR. BARNETT: I'm Bobby Barnett, I'm a radiological physicists, I represent Rockdale-Newton Radiation Therapy Center. It's a free-standing teletherapy radiation oncology center. It's in suburban Atlanta.

DR. TSE: My name is Anthony Tse, I work for the NRC in its Rulemaking Section, I'm the task leader of this group.

MR. BOLLING: My name is Lloyd Bolling, I'm with the NRC State Agreement Program.

MR. KLINE: My name is Ed Kline, I'm with the NRC based out of Region II in Atlanta and my involvement is somewhat of a temporary nature in a rotational assistance assignment with our headquarters group. And I guess the evolution of the pilot program.

MR. CLARK: My name is Tom Clark, I'm from Southeast Alabama Medical Center in Dothan, Alabama, we're approximately 400 beds. Dothan is 50-55,000 population and we're kind of a regional referral center for the southeast -- southwest Georgia down, north Florida and southeast Alabama. I'm a nuclear medicine tech. We do teletherapy

and brachytherapy at the hospital and I'm here to represent the therapy department but I do not do the therapy.

MS. ROBERTS: My name is Jonette Roberts, I'm a nuclear medicine technologist at Riverside Hospital in Jacksonville, Florida, which is approximately 400 beds, urban location. We do I-131 therapy. I'm not sure what the population of the city is, it's urban.

MS. RHODES: I'm Jean Rhodes, I'm the quality assurance coordinator at Valdese Hospital and I'm feeling a little bit out of place, I'm a registered nurse. I hope we don't talk about technical things.

(Laughter.)

MS. RHODES: Our hospital is licensed for 170 beds but we operate about 75 and we're in a rural area. And please don't ask me about brachytherapy and teletherapy.

MR. TELFORD: You're representing all three?

MS. RHODES: Well I guess I am.

MR. TELFORD: In other words, your institution is participating to the extent of all three services?

MS. RHODES: That was my understanding.

MS. ROY: Terry Roy from Bradenton, Florida. I represent a small out-patient cardiac center, free-standing. We do out-patient only, just nuclear medicine, I'm the chief tech there. We do anywhere between 75 and 100 procedures a month. I represent an out-patient facility

where we'll be looking for patient identification and the diagnostic type things.

MR. GARRISON: I'm Dave Garrison, Arlington Hospital, 350-bed hospital about two miles outside Washington, D.C. I'm representing nuclear medicine and radiation oncology.

MR. TELFORD: Let me call your attention to the agenda. The next item on the agenda is review of proposed 35.35 -- oh, I'm in too much of a hurry this morning, excuse me. Let's go around to the interested parties in the back here.

MR. MERRILL: My name is Neill Merrill and I'm with the Georgia Radiological Health Section.

MR. HILL: I'm Tom Hill with the Radiological Health Section, Department of Human Resources.

MS. DRINNON: I'm Elizabeth Drinnon, I'm with the same group.

MR. COCHRAN: I'm Pat Cochran, I'm with the same group.

MR. FURR: I'm Walter Furr, I'm the radiation safety officer at the Medical College of Georgia in Augusta and for the VA Medical Center in Augusta, combined having about 1000 beds.

MR. BAHADUR: I'm Sher Bahadur and I'm Branch Chief at U.S. NRC and my branch is responsible for the

workshop.

MR. NELSON: My name is Kevin Nelson, I'm from the Brookhaven National Laboratory and we're assisting the NRC in the pilot program.

MR. KAPLAN: My name is Ed Kaplan. I've spoken to many of you, thanks for coming, I'm from Brookhaven National Laboratory.

MR. WOODRUFF: I'm Richard Woodruff, I'm with NRC in the Region II office here in Atlanta.

MR. TELFORD: Now I would like to take the second item, review of proposed 35.35 and put it after discussion of the pilot program. There are several things that I need to tell you about; namely, how we got to where we are today, what we're doing and how we're going to go about it. Right now I assume that everybody's a little bit nervous, they don't know quite what to expect, but let me just reassure you it's not going to hurt very much. It will become clear in an hour or two that it won't hurt very much.

I've put up a background slide to let you know that we've been working on this rulemaking topic since 1987, in the fall. Originally we had what we would call a prescriptive rule that we took to the Commission and then the medical community came in and said we really don't like this prescriptive rule. One of the things we object to is you telling us exactly what to do and how to do it. We

think we know how, so why don't you let us figure out how.

So we went back to the Commission and proposed a rule that was performance based. We had various meetings with medical associations and our ACMUI, Quality Assurance Subcommittee of that group, gave this proposed rule to the Commission, they deliberated on it for several months and in December of this year we received what we call a staff requirements memorandum that says what to do in order to make it acceptable to the Commission so it can be published in the Federal Register, and it was published January 16 of this year.

A point I wanted to make was that we have a performance-based rule, it says basically what to do in the form of eight objectives. It does not say how to do it.

As part of this effort, the Commission said that we should have a pilot program which would in essence try this out and see if we can make it better before we go final.

I realize that most of you here are from an agreement state and this rulemaking will be a matter of compatibility. As soon as it becomes final --

THE REPORTER: Excuse me, Mr. Telford, I can't hear you back here. Would you speak louder please?

MR. TELFORD: Where should I stand?

THE REPORTER: Anywhere as long as you speak nice

and loud.

MR. TELFORD: Okay, the acoustics must be real dead in here.

As long as we have a rulemaking, the agreement state will then come to you and say we're going to do the same amount and the agreement state has the option of course of making it more stringent.

So most people would assume that when you see a proposed rule, that it will become the final rule with very few changes. That's not the case here. We're running the pilot program to discover how best to write the final rule, what modifications to make to it. That's, I realize, probably a little bit of a credibility gap for you right now, but by the time we get through the next couple of hours, I hope you believe me.

The pilot program -- this is a little overview of the whole pilot program. To start off with, we have about 2000 NRC licensees and 4000 agreement state licensees across the nation. So since we knew that this rulemaking would affect all 6000 licensees, in the pilot program, we wanted to be able to proportionately represent all NRC regions, all agreement states, all classes of licensees, all types of facilities and locations whether they be urban or rural. You'll notice I think that there's a good representation here this morning from all those various combinations and I

would like to congratulate Ed Kaplan for having done a great job.

He set out to get 24 NRC volunteers and 48 agreement state volunteers. We have 22 NRC and 46 agreement states and it took quite awhile, about two months, to do that. But it was very necessary so that within the pilot program we have the input from all possible types of licensees and all combinations, so when they get their input in, we can represent them in their comments and suggestions.

Overall, the way the program works is you have a month to develop your quality assurance program. For some folks, you already have a quality assurance program, so it will be a minor change for you. We have assumed the worse and said you have a month to implement the program. A month to implement, implement means the time period after this workshop which you can modify your daily procedures and do any training that you need to do, if any. Then there will be a two-month actual test period, a 60-day trial, and then a month to collect the information for the evaluation.

Here's where we are now, at the first set of workshops, where we will discuss the ground rules, develop an understanding of the proposed 35.35.

After the actual test period, we will discuss results and there's a lot of things that we can discuss and those workshops will be two-day workshops right back here in

Atlanta. I'll tell you when a little later.

And I'll expand on this fourth item of how we want your input on what we think of your written programs and what we think through the site evaluations.

Now I've just put down some objectives of the whole pilot program -- let's go off the record for a minute.

(Discussion off the record.)

MR. TELFORD: In order to understand these objectives, you have to visualize that what we're doing is like a giant experiment. We have a proposed rule -- it's really proposed. It's something to work with, we have to start somewhere, this is the best we can do. I believe that through your help we can do a lot better.

So when we say that we want to understand how licensees develop their specific programs, that's one of the purposes. We're going to, in part, turn you loose and let you tell us how you would develop your program at your hospital to meet these objectives. So we really will learn from you.

Now by number two, I mean by the phrase "in actual practice", our QA team will visit 18 sites. Now that's 18 out of 68, so we can't come see everybody. I know that breaks your heart --

(Laughter.)

MR. TELFORD: We really would like to come see

more of you, but we don't. I'll talk more about that in a minute.

Now three, we want to determine if our performance objectives, these eight objectives, are any good. Are they any good at preventing or catching mistakes that you might make during the planning process or during the routing process before misadministration happens. So this would be like precursor mistakes. And then lastly here, we'd like to determine if these objectives are any good at doing what we want to do; that is, provide high confidence that mistakes in medical use can be prevented. Now I'll say more on that in just a minute.

What I'm trying to do is get you through a certain amount of information here so that you can calibrate everything and put it all into perspective before we start talking about the proposed rule.

I've said something about number one before, but this is the outline of a few more details of how the pilot program is envisioned to work. It took us until March 9 to get all the volunteers rounded up. The second item here is that the volunteers will review the proposed 35.35 and make a determination that their program meets the proposed rule or modify their program to meet it, and during March and now we can say part of April. Then here's the list of pre-tests, pre-trial period workshops. We're at April 6 and

April -- excuse me, March 29 was New York, April 4 was Chicago, April 6 is Atlanta, April 18 will be Dallas and -- that should say April 20, that's San Francisco.

We have asked volunteers to bring a copy of their quality assurance program to this workshop. If you haven't done so, we will give you another opportunity.

Number four here is that the volunteers during April, up until the actual start of the 60-day trial period, they can develop written instructions or modify their day-to-day programs and do any training, if required. In some places, you're probably ready to do today.

The 60-day trial period we would like to start on May 14 to July 13. Now to retain specific records, let me just say it now and say it again later, the only records that we need to keep you're probably already keeping; namely, our prescription, our referral, the administered dose or dosage and a clinical procedures manual. You probably have all those in the patient's chart or in your in-house referrals, so that's thought not to be a big deal. We'll talk a little bit more about that when I go through the proposed objectives.

As I told you, we'll be visiting 18 volunteers for a one-day site visit. That's a no-fault kind of visit where we're there just for one day at your hospital and looking only at your quality assurance program, nothing else. We

will have experienced NRC inspectors and if one of your institutions is chosen and it happens to be an agreement state, we will do everything we can to get someone from the agreement state to come with us.

The sixth item is the post-test workshops. It will be after July 13 -- we envision something like a two-week period for you to fill out your evaluations, and I'll say more about that later. But at the post-test workshops, we want to hear from the volunteers. After all, they have tried out this proposed rule. We expect that you would have, in addition to your evaluation, you would have some suggestions for improvement to the proposed 35.35. We want to hear about these objectives and reporting requirements, which I will get to in the afternoon. But maybe these objectives aren't any good. Maybe one of them or two of them or three of them we don't need. Maybe something is missing and after you've tried them out, I fully expect you can tell us what to do with some of them; replace them or get rid of them or add to them, because you will have the opportunity to implement these proposed objectives and you will have figured out how to minimize the impact to your institution because you can custom tailor your program to your hospital.

So cumulatively, we will get a lot of suggestions and that's what this is all about. We want to know how to

do this better. I'll be the only person in the room that will claim that these objectives are any good. And I'll do that just for the sake of debate so that somebody can defend them and I'll tell you the intentions of them. But they're not cast in concrete. We really want to hear from you on how to improve them.

Now during the post-test workshops, this NRC QA team, which will be four individuals from NRC, will give you some inside information on what criteria we use to evaluate your programs. We will evaluate every QA program, all 68 of them. Now the 18 that we evaluate with site visits, we will talk about those first at the workshop, so that you'll learn the criteria used to evaluate the programs and the results from those. You'll learn the criteria used to evaluate the sites and the findings from those.

Now that may be of interest to the agreement state folks because the state may do something similar, but you will get an inside look at how we do business. That's intended to be helpful to you.

MR. CLARK: Could I ask -- on item number five, the dates appear different there than they do on the handout.

MR. TELFORD: Yes, this date is correct. This is an old handout. Can we go off the record for a minute?

(Discussion off the record.)

MR. TELFORD: The purpose of the site visit is so that we can visit your site in a very no-fault manner and find out the answer to the question, are you implementing the program that you say you're implementing, because we will have reviewed a vast number of -- 68 -- programs on paper, so we would like to review some sites to see how you're doing it.

By the way, the evaluations that you'll hear here, these results, what we will say to you is we looked at your program; here are the strong points, here are the weak points, here's what needs work. We won't say it's deficient, give you anything about deficiencies, but it'll just be strong points and weak points and what needs work, purely as feedback to you. And a similar thing on site visits.

We might say your program says you're doing this but when we went looking for it, we had difficulty finding it. It may be there, but we had trouble.

MS. RHODES: After the evaluation of your program, is that information shared with anyone?

MR. TELFORD: For the 18, it'll be shared here. It's designed that way so that all of you can look at a minimum number, get feedback from a minimum number.

MS. RHODES: I was thinking about other agencies.

MR. TELFORD: Other agencies?

MS. RHODES: Uh-huh.

MR. TELFORD: We have no intentions to.

MS. RHODES: Okay.

MR. TELFORD: But what we talk about at both of the workshops will be public record as part of the rulemaking process. That's an advantage to us because we can use everything that's said as if it were a public comment. And it's an advantage to you because if you wanted to comment on the rule, you have until April 12, I think, to send in a written comment to the Secretary of the Commission. However, because you're in the pilot program, anything you say today or anything you say in the next workshop, we can use. So that gives you more time.

Now this is what we expect of you. I've gone over most of these, but you develop a program or modify your program to meet proposed 35.35. You attend the pre-test workshop and you provide any instruction or training that's necessary to prepare for the 60-day trial. Try out this modified program for 60 days and evaluate it and provide suggestions for improvement and you attend the post-test workshop.

I just want to reinforce these ideas of what you can expect. We want you to understand the criteria that we use to evaluate all the programs and to learn the

evaluations, so we'll share the evaluations with you and you will get an evaluation of your program. We want you to understand the criteria that we use for the site visits and to learn the results of those.

We want to listen to you very carefully in your evaluation of the proposed 35.35 because want to learn how to do it better and we want to listen to your suggestions on how to improve all of the rulemaking, including the reporting requirements.

Let me stop for a minute and tell you that we've completed a discussion of those three items that are listed before lunch. So I'm going to pause and give you a chance to make comments or ask questior . Incidentally, as we go along, if you have a question, feel free to ask, but let me let you collect your thoughts for what we've accomplished so far.

Any questions so far?

(Brief pause.)

MR. GARRISON: I have a question. You're suggesting that now -- do most places have a written procedure in their procedure book that's addressing this now? I don't. I mean I have bits and pieces that pretty well cover. If a patient comes down to our department, the chart will be checked, they'll be asked their name, that kind of thing. But to put all this together into one --

maybe I'm not following you.

MR. TELFORD: I think you're asking a two-part question or please allow me to break it up into two parts. The first part might be are most licensees conducting a quality assurance program today that might meet these objectives. And the second part is do they have a written program that's altogether in one manual. Based on our previous meetings, not just the workshops but the meetings we had in January of '89 with 18 licensees, we were told back in January and have been told so far in these workshops that most people are doing 90 percent of this already. So that -- my answer to the first part of your question is yes, I think the vast majority of licensees already have a quality assurance program in some form. They're probably doing the vast majority of what the objectives ask for.

But the second part is whether or not the program is compiled into one nice manual -- maybe not. I know of some licensees that have a manual that's an inch and a half thick and they have a very elaborate quality assurance program. That's over and above anything we're asking for here, but the pilot program, you don't have to write a manual, all you have to do is make copies of what you've got. And after we go through the eight objectives, I'll try to remind you that all we want is like a road map that says section so and so of my plan meets objective one. Another

section meets two. That's it, just a road map. We don't want to put you to any more effort than you have to, but we want to be able to read through the thing so that if you had copies of sections of six different -- out of six different manuals in your hospital, that's good enough.

Let me say a word about need for this r. omaking. I won't go through the slides that I have on the problems that we expected unless I get a lot of questions there, but we've looked at the misadministration reports for the last eight years. When we were developing the prescriptive rule back in the fall of '87, we did an analysis that was a retrospective analysis. It assumed that if what we were proposing in the prescriptive rule, if that were really carried out, I believe we determined that 80 percent of the misadministrations that have been reported over the past eight years would have been prevented. So the objective of the proposed rule, and indeed the final rule if that ever happens -- the objective will be to prevent mistakes in medical use. I'll use the phrase "with high conflicts".

Now we realize that not all mistakes can be prevented. However, I believe that some of them can be prevented. I won't even fool with what percentage, just some of them can be. And the other thing I'm finding is that everybody would like to prevent them if they could. Nobody really likes it, it's just difficult.

So what we're trying to do is structure some objectives that will be useful in prevention of misadministrations. So we're really not after zero defects. That's the objective, but we don't know how close we can get. We just want to set out some useful objectives that will work towards that end.

Proposed 35.35, if you saw it in the Federal Register, basically requires each licensee to establish a written program. The primary objective is to provide high confidence that errors in medical use will be prevented.

Now I've switched to talk about the eight objectives and there's a handout that's useful. It looks like this, it's called "Enclosure 1" on the front.

Can we go off the record for just a minute and make sure everybody has this handout?

(Brief pause.)

MR. TELFORD: I'm going to talk about the eight objectives, but let's think of the proposed rule as having three parts. The first is the paragraph that requires the written program. The second is the eight objectives and the third is -- let me just jump forward to the -- what I could call the feedback group where we're planning that every year the licensee conducts an audit. Some hospitals today these audits are done every month.

What you do is you find out what went wrong or

what went right. And you have an evaluation and then the licensee management will determine that the program is effective or that it has some flaws. If it has some flaws, then the proposed rule says make prompt modification to prevent reoccurrence of those mistakes.

So in the proposed rule we have an annual audit. I want you to understand that there's a feedback loop so that you can, as you're conducting your program, each year you have a chance to go through it and find out -- do your own audit, and we don't mean an outside independent audit organization by the way, we mean anybody who's qualified to do the audit ca do the audit. If you have two hospitals nearby, you maybe can trade RSO's or maybe you can have one designated person from one department to do the audit. What we would really like not to happen is that you audit yourself. You did the work, you know, you audit yourself so naturally you come out great.

Let's talk about these eight objectives. Now I'm going to be the only person that's going to claim these are any good, as I said before. So don't feel bad about beating on them, that's just fine. We've already heard that some of these are not so great and we know how to fix them, so far. So we're learning a lot just by these pre-test workshops.

What I want to do is go through these eight, tell you the intention of them. Now the words on the screen are

not exactly as you have on your handouts. So I will refer to the handout.

The intention of the first one is to make sure that a thought process has taken place. The ideal case is the authorized user physician has decided that the procedure is necessary for this patient and is indicated by the patient's medical condition. So under your program, you would just say how you do that or under what circumstances you would not do that. When we get through number two, we will have talked about a prescription. For instance, you may say in your program that the authorized user has signed a prescription that certain ensures that that person thought about it and thought that was the necessary procedure for this patient. You may want to figure out -- excuse me, I don't want to say what you want to figure out -- retract those words -- you may want to say in your program what you do with referrals, be they from another department or from an out-patient group.

Any questions on number one? Yes?

MR. LANDERS: Are we just in essence going to write down that yes in fact our physicians see the patients and review the case before they decide to do anything, or are we supposed to ask the physicians if they in fact did this?

MR. TELFORD: No, you're just describing your

program. The element is to do what you just said. You don't have to do any checking. You're just documenting a procedure. See, when we evaluate the program, we'll be looking for how these 68 volunteers do it in their institutions, how they ensure number one.

Now when we go to the 13 site visits, then we might come around and say, oh, take these patients and we trace them how they get into your system. Okay, these had prescriptions, that's clear. These had referrals, did anybody look at those. What does your program say that you do with referrals. We'll just see if you did it.

MR. CLARK: For condition number one, we have our physician either talk to the patient or the consulting physician or look at the patient's chart. That's a condition of our license.

MR. TELFORD: Okay.

MR. CLARK: We do that and I'm not real sure on item number two as far as a prescription, are you saying that our doctor has -- if we get a chart down that the physician wants a radioactive iodine uptake and a thyroid scan, we have a dose schedule in our department that for that procedure this amount of isotope is indicated. Do we have to have a separate like written prescription from our authorized user that says yes, we will give this patient five microcuries of iodine for an uptake? I'm confused

about that word prescription.

MR. TELFORD: Let me take your question when I get to number two, but the reason I was smiling when you said what you did about the way you take in your patients is that's what's in our regulatory guide. So let me get to your question in a minut

MS. ROY: I have a note to file in my procedure manual and it lists different diagnosis of a patient that would be appropriate for the reason for testing. Would that suffice to cover number one? When I have a patient come in or a referral physician call over and I ask the diagnosis and they say cardiomyopathy and that is listed in my procedure manual as one of the diagnosis for testing.

MR. TELFORD: That sounds pretty good. You're the one with all the out-patients, right?

MS. ROY: Right. So that would cover number one?

MR. TELFORD: Yes. All we're telling you is the intention, the ideal case and then you put into your program what you do, such that you're convinced that you've met the objectives in your own fashion.

MS. RHODES: Would you define authorized physician?

MR. TELFORD: Authorized physician?

THE REPORTER: I'm sorry, I can't hear you. Did you say something?

MS. RHODES: I asked him to define authorized physician.

MR. TELFORD: The phrase I used was authorized user --

MS. RHODES: Yes, okay.

MR. TELFORD: The authorized user is a nuclear medicine physician.

MS. RHODES: Okay.

MR. TELFORD: We use the term authorized user because that person is usually listed on the license.

MS. RHODES: Okay.

MR. TELFORD: Sometimes it's even the licensee. Is that right, Ed?

MR. KLINE: Yes.

MR. TELFORD: Okay, Tony.

DR. TSE: The intention of this particular item, number one, is not to question the judgment of the authorized user physician. The intention is to try to look at the referrals, referral physician generally is not an authorized user physician, he's not generally expert in nuclear medicine or therapy, brachytherapy area. He might write something which is probably -- may not be appropriate for that particular case and then the licensee, which includes the authorized user, has a responsibility to make sure that these are correct indications. That's the

intention of this item.

MR. TELFORD: I think the intention will become a little more clear once we get through number two and number three.

Number two is for therapy; it's for teletherapy, brachytherapy or nuclear medicine. So the ideal case here is to have a prescription for any therapy. However, we've noticed a lot of cases in which the patient was supposed to get ten microcuries of 125 or even 123 or .31 and the patient got ten millicuries or 100 millicuries of I-131. So we wanted to pay special attention to I-125 and I-131, so what we came up with is for all cases, even if they're diagnostic cases, if it involves more than 30 microcuries of I-125 or I-131, the ideal case is to have a prescription. Now that's first of all to prevent the micro to milli switch without somebody trying real hard, and second so that every time anybody handles I-125 or I-131, they're doing it under a prescription and we want them to think about it just a little bit harder.

MR. KLINE: Maybe I'm speaking on behalf of some other individuals here, you might want to explain what defines a prescription.

MR. TELFORD: Good suggestion.

So far, I've used a term "prescription". In three, I'll use two other terms that I will also want to

define. On page two of your handout we have a definition of prescription. Maybe you don't like this term, but that's okay. We may change that term for the final rule, we may just throw away the word "prescription", we may use something like written directive because we don't want to confuse people, we don't want to confuse pharmacists or physicians. So we mean by prescription that it's a written directive or order for medical use. Now medical use. Now medical use, you realize is defined in 10 CFR. It's the administration of byproduct material or radiation therefrom. So this is a written order for medical use for a specific patient, dated and signed by an authorized user or -- now here's the delegate -- a physician under the supervision of the authorized user is also acceptable here. And supervision is a term that's also defined in 10 CFR Part 35.

Basically that says that the authorized user trains this person, directs them and is always responsible for all of their activities. So if they make a mistake, it's the authorized user that's responsible.

Now the (a) through (d) are what we would like this written directive to contain. So for the diagnostic use, we would like -- the diagnostic use of radiopharmaceuticals naturally -- we would like it to contain the radioisotope, the dosage, the chemical form and the route of administration. For radiopharmaceutical

therapy, the isotope, the dosage, physical form, chemical form and route. For teletherapy, we would like it to contain the total dose, like 3000, number of fractions, 20 days, and the treatment site -- what's your target. And (d) for brachytherapy, the total dose. And in parentheses we say equivalent or treatment time, number of sources, combined activity. The radioisotope and treatment site.

So the real intent of this is just whatever you intend to do, whatever the authorized user intends to do, write it down.

MR. CLARK: The words "specific patient" still bothers me. Is that each individual patient -- we have to have a prescription for that patient or can we use a standardized form? The specific is kind of --

MR. TELFORD: Let me clarify, we're talking therapy, this is therapy now, strictly therapy. We're not talking about diagnostic studies. So for your therapy procedures, if you have a standard form, the patient's name is on the form.

MR. CLARK: Yes.

MR. TELFORD: The authorized user signs it or initials it and if it contains this information, it's good enough. That meets our definition.

We're really not trying to invent anything new. In fact, we'll probably need some hints from you of how to

change this, and one thing you might say is throw away that word, call it a written order, a written directive or a written referral or something.

MR. BOLLING: John, the next logical thing would be that in his program he'll describe where that record can be found. You know, one of the items in your QA program will say information regarding the prescription can be found -- you may have a log book or a file that you keep it in.

MR. TELFORD: Yeah, your road map to us might say we don't really write what you might call a prescription for each patient, but rather we have this standardized form and it contains all this information.

MR. BARNETT: In some hospitals we're involved in, we implant Iodine 125 seeds, and that implantation is a surgical procedure and the decision on the number of seeds to use are made at the surgical site, at that point in time. This says a written prescription prior to therapy.

MR. TELFORD: Right.

MR. BARNETT: I don't understand how that applies in that case.

MR. TELFORD: I think I understand what you're saying. Brachytherapy is difficulty. You have to go into surgery to find out what you really are going to do.

MR. BARNETT: This is a permanent implant.

MR. TELFORD: Permanent implant. In the

regulatory guide -- we'll talk about that this afternoon, and to give you some more detail of what we have in mind.

I can answer your question now to say that the physician, the authorizer user physician would probably have in mind an approximate number of seeds, certainly the treatment site and certainly the isotope. So if it's permanent then total dose is not so applicable, because then you say it's this number of seeds forever, which is slightly different.

But then in the regulatory guide, we'll discover that the physician has the opportunity to modify this prescription after surgery because oftentimes, even if it's not a permanent implant, I'm told that you think you're going to put in 15 seeds but there's only room for 12, so you modify the prescription after the fact.

I think the utility of this is the fact that after the implant is done, then you're basically watching the clock and the mistake that can be made by leaving them in too long. So if you've written that down, you have a better opportunity to pull them out at the right time.

Is there a question over here?

MS. ROY: I have one. In a case like that, could they write a prescription saying "up to" so many seeds and that would cover it, prior to the surgery?

MR. TELFORD: Or approximately.

MS. ROY: And then after surgery, they could modify at that point -- just put up to so many.

MR. TELFORD: Comment?

MR. LANDERS: I'd just say the implication there is that it may be okay to under-dose but not over-dose.

MR. TELFORD: I didn't mean to imply that.

MR. BARNETT: But even more so, you'd have the problem that there would always be a misadministration if you didn't get the right number of seeds.

MR. LANDERS: Yes, absolutely. We'll order eight extra seeds just in case.

MR. TELFORD: I didn't mean to imply that over-dose is worse than under-dose because if it's an under-dose and it didn't do the job you'd have to go back, so it's more wear and tear on the patient. As far as the misadministration goes, that's defined in the reporting requirements, which we want to hand out to you today so that you have a copy of that. Since it's not part of the pilot program it doesn't affect anybody in the pilot program. But we do want you to dig through those and bring your suggestions to the next workshop. We want to know how to better improve those. For instance, in brachytherapy, it might be you have to report if the administered dose is 20 percent different than the prescribed dose.

MR. LANDERS: The latest prescribed dose.

MR. TELFORD: The after-surgery prescribed dose.

MR. LEE: That was one of those cases where one or two or three addendums might have to be put into a letter during su gery. If you do Iodine 131, you may not use as many seeds as you initially thought you were going to use and you may lose some seeds. There's a lot of variables that go into that. The documentation is going to have to go into the patient's chart to ensure that (a) you were here, (b) you were here, (c) you were and you know, keep everything together.

MR. TELFORD: Yes, so it's sort of the prescription of record after surgery, that's the one that you're going to watch the clock with.

But the 20 percent, don't take that as golden, because that's what I want to hear your comments about at the next workshop.

DR. TSE: The intention of having a prescription is essentially to transmit correctly the information from the authorized user physician to whoever handled the source or the prescription, check on the curies and so on, as to what type of sources. It is not an intention to say when you write this thing down, you have to follow it. It's the physician, based on his judgment at the time, could modify the prescription. So if he estimates it to be ten seeds and it turns out he uses only five, that's fine. You can change

your prescription to say that's the number of seeds I can put in, that's the best of my judgment at the time I did that because you make a judgment at the time we implant. So it's not limited that you automatically become misadministration if you modify your original prescription.

MR. TELFORD: We'll go over those details in the afternoon when we talk about the guide. The guide is here, by the way, it begins on the third page and we'll go through that thoroughly. We would like to hear comments on the guide today if you have them.

Now the third item, the third objective really applies to diagnostic procedures. What it attempts to say is that for diagnostic procedures, we're trying to incorporate the way we understand that most business is done, especially for out-patient. You get a referral. We're using the diagnostic referral in tandem with the clinical procedures manual. So let me say about three, that two is what you do for therapy; three, this is what you do for diagnostics. Now we give the option here of using the prescription for diagnostic cases because believe it or not, in some states I'm told they do use a prescription for everything, even if it's a diagnostic procedure. So we put that option in there. Three is basically about diagnostic procedures, except the iodine. If it's I-125, I-131, greater than 30 microcuries, go back to number two. If it's

less than that, stay with the referral.

Like if you get a patient in for a thyroid scan, ten microcuries, bingo, that's number three, so you have a referral and a procedures manual. Since we're using those terms, we attempted to define them. That's on page two. By referral, the third item listed on page two, means a written request dated and signed by a physician, not necessarily an authorized user physician, just a physician. Oftentimes a non-nuclear physician, I'm told.

This is the ideal case now, you get a written referral before you do the diagnostic procedure. At this point, somebody is supposed to jump up and say no, I can't do that. So who wants to be first.

(Laughter.)

MR. TELFORD: That doesn't happen with you, does it?

MS. ROY: When they call over for the testing, we have -- the secretary usually calls it over, or the nurse, that Dr. Smith wants a thallium stress test. Okay, get all the information and fill out a prescription slip and the patient brings it with them.

MR. TELFORD: Oh, they bring it with them.

MS. ROY: Yeah.

MR. CLARK: Some of them do.

MS. ROY: Okay, now if we don't get prescriptions,

we can call that referring physician up at the time when they show up at the door without a prescription slip and say is it ordered, read it off the chart to me. And that covers it, because that way I know that that patient was ordered that test, it's written in his chart over there.

MR. TELFORD: Great. How about your case?

MR. CLARK: Well if they call initially and say, like for an out-patient, say we're sending this guy over for whatever. But that initial contact on the phone would not suffice for his -- I mean some of them show up with a prescription, some of them don't and we don't necessarily call them back and say hey, check the orders and see if this was really ordered. Because she has usually just come from the physician and says he wants this done. But we're not calling them back and saying check the orders and see did he really want this.

MR. TELFORD: That's some percentage of all the cases you have.

MR. CLARK: Sure.

MR. TELFORD: Is it a majority or a small percentage?

MR. CLARK: Some physicians send one every time and some of them never send one. They just have a form that says you have an appointment at 10:00 Tuesday for a bone scan.

MS. ROY: Wouldn't that suffice? I mean if they've got something that was written from their doctor's office, has the doctor's address and phone and name on it, and that says bone scan, 10:00 Tuesday the 10th -- isn't that enough to say that patient does need that, if it has the patient's name across the top?

MR. TELFORD: If the written referral was originated in your department, but you got the information over the phone?

MR. CLARK: They call us, we put it on our schedule book and then we have no more contact with that referring physician until he gets a report from us.

MR. TELFORD: Okay.

MR. CLARK: We had a case last week where a lady's daughter let her slip fly out the window as they were driving over there. Of course we didn't have anything then. But we don't call them back and say, you know, can you verify --

MR. TELFORD: You would have to call in that case.

MR. CLARK: She didn't -- she showed up and she didn't know what she was for, she got the time and that was all.

MR. TELFORD: Well this states the idea case that you have a written referral signed by the physician. What I want to say to each of you is that whatever you're doing,

how ever you're handling your extenuating circumstances, missing referrals or in some cases of some physicians never sending them, just say in your program what you do, you accept the information over the phone and you originate the written referral in your department, whatever you do, because of the diversity of licensees, we will be able to see a widespread array of practices, so we want to learn from those. So if it works for you we want to find that out. If it doesn't work for you -- well if it doesn't work for a lot of people, we'll find that out, at least the mistakes, and we may want to be a little more insistent. On the other hand, if it works for a lot of people, maybe we don't need to be so insistent. That's where your input is so important.

MR. LANDERS: The part that bothered me throughout all of this is the dated and signed by authorized user. That seems to be a stumbling block all the way along.

MR. TELFORD: Well we sid authorized users --

MR. LANDERS: Dated and signed by.

MR. TELFORD: Well dated --

MR. LANDERS: Taking an oral order over the phone and writing it down doesn't accomplish that, so is that a violation?

MR. TELFORD: Well let's not even use the term violation.

(Laughter.)

MR. TELFORD: This is one giant experiment. You said authorized user physician, now that's a prescription, that's for therapy. So we're making the distinction of who signs. For the prescription, that is the written directive for therapy, that's the authorized user that signs. For diagnostics, it's a physician signs.

MR. LANDERS: So what I just said was diagnostic referral instead of prescription.

MR. TELFORD: For diagnostic cases, you start with a diagnostic referral unless you want to use the prescription.

MR. LANDERS: Still dated and signed.

MR. TELFORD: Yes, sir. That's the ideal case. Like I said, I'm going to be the only one here that will claim this is any good. But don't take it as golden and please don't assume this is always going to be the case. This is our trial balloon, this is what we're wanting to test.

So if you ask me what's the best way to do it, this is my answer. Please give me a written referral dated and signed by somebody. It's dated and signed by a physician, therefore I know that somebody said yeah, I really wanted to give a liver scan to this patient. If I'm the technologist, I'm going to say I may know what to do

because I'm going to jump in and explain the current procedures manual, because you use the referral and the manual together. So this is the second item according to the procedures manual.

Now this is just a collection of written procedures that tells the technologist what to do, so that when a patient appears in the department and has a referral and it says liver scan, that's what it says, the technologist goes to the clinical procedures manual and says liver scan, here's what I do.

But if the patient shows up with liver scan, use ten millicuries of I-131, the technologist doesn't set off any alarms yet, they go to the clinical procedures manual and it says liver scan, here's what I do, there's no iodine here. Stop, find out what's wrong. That's what our reg guide says, stop and ask questions, figure out what's wrong.

So we see a sort of funny kind of verbiage here, we're using referring and the clinical procedures manual in tandem. We would like the authorized user to approve of the clinical procedures manual. See, we would like the authorized user physician to be in control two ways.

The first way is number two, where you have a prescription for therapy. This prescription is signed by the authorized user, so the authorized user physician is deciding what to do and is having a written order.

And number three, the way that the authorized user is in control is even though the patient comes in to the department with a referral, the referral should match with the clinical procedures manual. The authorized user has approved of it, so therefore, the authorized user knows what's going to happen to the patient, exactly what procedure and how to do it. So we're trying to minimize mistakes. Any other questions on two or three?

MR. GARRISON: I just have one comment. I know of a pathologist group that does nuclear medicine and I don't know if the College of American Pathologists has a similar type rule already, I think they do, but this group will not do a patient unless they have a prescription, a written prescription from the patient's doctor.

I know of one story where the patient came in and did not have it, so it was their procedure to call the doctor and verify it verbally. The doctor's office was closed, the patient sat around, they finally found out the doctor's office was closed. The patient went home furious and the doctor -- this patient had been coming there every year for a bone scan for five years. The physician was furious. That's one problem I can see right away.

MR. TELFORD: Well keep in mind that's a diagnostic procedure. The objective here is to have a referral for that, not a prescription. And secondly, let me

say that the idea case is a written referral but if that doesn't happen in your hospital for all your patients, then you just put down in your QA program the conditions under which you would allow something other than a written referral and go on with your business.

MR. GARRISON: I see.

MR. TELFORD: So we're not -- we want to avoid problems. We want to minimize mistakes, but minimize impact to the hospital.

Would anybody object to about a ten minute break? Let's go off the record.

(A short recess was taken.)

MR. TELFORD: Let's continue talking about the objectives.

Just to recap, number two is for therapy, number three is for diagnostic procedures. Refer to your handout for those words, it's not exactly on the screen, but you know, when you give talks you don't want to put everything down. That way, if you put everything down they won't have any reason to look at you, they just read the screen and go on, right?

Number four says that ensure that whatever you're using, if it's a prescription or if it's a referral and the manual, it's understood by the responsible individuals and that is, the people who are going to carry out the work.

Your program should say what you've done with these people as far as training or testing, how you quiz them to make sure that they understand what they're going to do -- what they are to do. That's the intent of number four, just to make sure everybody involved knows what they're supposed to do.

Number five is -- this objective says that we would like to make sure that any medical use, any and all medical use, is in accordance with either the prescription or the referral and the manual because if your real case is the administered dose is exactly what's prescribed, then everybody is happy.

Number six -- oh, number question?

MR. LANDERS: I've got a question on number five.

MR. TELFORD: Yes.

MR. LANDERS: Does that apply to therapy procedures?

MR. TELFORD: Yes, sir.

MR. LANDERS: Does the word "manual" apply there also?

MR. TELFORD: Not to therapy. Prescription applies to therapy.

MR. LANDERS: Okay.

MR. TELFORD: Try to develop a mindset for today that therapy goes with prescription -- or prescription

rather goes with therapy. Referral and manual goes with diagnostic procedures. Just a great dichotomy.

MR. LANDERS: But there's a clinical procedures manual.

MR. TELFORD: Yes, sir, the clinical procedures manual is the collection of all the diagnostic procedures.

MR. LANDERS: Doesn't refer to therapy?

MR. TELFORD: Not per se, because in the case of teletherapy there may be a lot of calculations to do, a lot of pre-treatment planning, designing and building blocks, use of wedges or alignment, on and on. We don't envision that in the procedure manual. We invented, if you will, this arrangement for diagnostic procedure, the use of referral in the manual because we're allowing referrals to come in under the direction of a physician, not a nuclear physician. So we wanted the authorized user physician to be in control. That person is in control of the procedures manual, so that if the requested procedure in the referral matches with the manual, everybody knows what to do.

So number five just -- for therapy you could read it that any medical use should be in accordance with the prescription.

MR. LANDERS: Who is -- in the case of therapy, who is to judge whether that is in accordance with the prescription, the prescriber or the technologist?

MR. TELFORD: Either I think, because if you have a prescription and it's for therapy, in the case of telethorapy if it's a whole dose of 5000 over 25 days and that's 200 per day, as you're administering those fractions, you record what was actually administered, the 200. So the technologist or the authorized user could look at this chart and say yes, sir, we were shooting for -- we were supposed to give 200 but we gave 250 or we were supposed to give 200 but we gave 205 or we gave 180. Anybody can see that it's followed.

MR. LANDERS: Okay, so the intent here is to ensure that the prescription is being followed, not that the prescription is correct.

MR. TELFORD: Oh, you bet, we don't want to get into the practice of medicine. We want the authorized user to be in control, we want the authorized user to say what should be done. That's the intent of number one, it says the authorized user has gone through a reasoning process and says this should be done for this patient. We never, ever want to second-guess the authorized user. We want that person to be absolutely in control.

Yes?

MR. BARNETT: We'd like to recommend a changing in the wording so it clarifies that radiation oncology and teletherapy procedures do not require the clinical

procedures manual. There's some degree of ambiguity in that.

MR. TELFORD: Okay, I like your suggestion. For therapy, please read number five to say ensure that any medical use is in accordance with prescription. That'll cover therapy. Maybe we should break this up into two sections. We should have 5(a) and 5(b). Like I said, I'm going to be the only guy in the room that says this is any good.

(Laughter.)

MR. BARNETT: In my reading, I thought there was a clinical procedures manual required for teletherapy. I've been in it a long time and I have never been able to develop one. It's just such a broad subject.

MR. TELFORD: You're exactly correct.

We had a hand over here.

(No response.)

MR. TELFORD: Okay, number six, the idea of number six is to make sure we get the right patient. We see a lot of cases of there's a waiting room full of people and the technologist asks for Mr Smith and Mr. Smith appears and gets administered the dose and it turns out to be the wrong Mr. Smith. You know this problem quite well. There are various procedures that you probably use of -- if it's an in-patient, you probably have an I.D. bracelet. You

probably say to the person "what is your name and what are you here for." Maybe you say "what is your birth date, what is your social security number" or maybe you use Polaroid pictures -- whatever you do, please keep doing it. I just have to write down that objective to say I want everybody to identify the patient because if the world could do that, a lot of mistakes would not be made. If you ask me how do I prevent these errors, that's one of the things I would say you should do.

Questions on that one?

(No response.)

MR. TELFORD: Okay, number seven say s that we're to identify the unintended deviations. That's the difference between the -- the unintended deviation, that is the mistake --the difference between the administered dose and the prescribed dose or in the case of a diagnostic procedure, say the patient was supposed to get ten microcuries of I-131 and they got 12 or 11, doesn't matter -- just identify it and evaluate it. Now number seven feeds into the manual audit, so this is commonly done in teletherapy where the daily dose is recorded. You know what the daily prescribed dose is so you can go right down there through all 25 treatments.

The purpose of number seven is to identify these unintended deviations. I mean if you know that you intended

to give 180 that day rather than 200, that's -- and you give 180, that's an intended deviation, that's acceptable, you don't have to identify and evaluate those. It's just those little slip ups.

Now some might be little slip ups, some might be big slip ups, but at the end of the year, with the audit then you can put all these on the table and evaluate them and you can say well we didn't have any big mistakes last year, thank goodness, but we had a bunch of little ones. Now is that telling us something? Does that mean that these were all little, just as a matter of chance or this is good enough. There's an opportunity at the end of the year to have a finding that your program is still sufficient. This is the feedback loop that goes on year after year, so that you can determine -- you know, assuming this becomes final, something like this becomes final, that's the whole purpose of number seven, to identify these little deviations. I'm sure some of you already do.

Any questions there?

(No response.)

MR. TELFORD: Now number eight. Here we address specifically brachytherapy and teletherapy and we say is in accordance with the prescription. Now you might say gee, you can -- what was that, number five -- I can take treatment or therapy out of number five and I can put it in

number eight and just say all nuclear medicine therapy, all teletherapy, all brachytherapy must be in accordance with prescription. So that's the intention of number eight.

But number eight goes a little farther than that because it says treatment planning. So especially for teletherapy, there's a lot of planning that goes on.

Any questions on that?

MR. FRYMAN: Would you define specifically what you mean by treatment planning?

MR. TELFORD: Treatment planning -- I think you've got me there, we don't have a -- we don't define that term, but roughly that's defined as how you're going to deliver 200 rads to a given treatment volume and exactly that, and usually involves the calculation of isotope curves and whether or not -- how you're going to use -- whether and how you're going to use blocks or wedges and how you're going to ensure alignment, et cetera. We're not here to tell you how to do your business, it's just that we say the very obvious actually of saying please let your treatment planning be in accordance with the prescription.

MR. LANDERS: There could be a little terminology problem there because the insurance codes consider treatment planning a physician process. It sounds more like you're talking about ancillary personnel here.

MR. TELFORD: Well we don't necessarily intend to

imply that anybody in particular do the treatment planning. We're actually trying to be silent on that. We put the authorized user as responsible for the prescription and logically that person would want to ensure that the treatment planning was in accordance with the prescription. How you get that done or who does the calculations, we want to be silent on.

MR. LANDERS: That's not the question here. Some treatment planning codes, CBT-4 for example, include ordering CAT scans, analyzing blood tests, things of this sort, which is purely a physician process. And I don't know whether you're intending to include that in this or to separate it from what physicists refer to as the treatment planning process.

MR. TELFORD: Yeah.

MR. LANDERS: It's two definitely distinctive things.

MR. TELFORD: Well I like your suggestion, that's a good question, we'll work on that. We don't mean to imply that, we mean to say that the -- if it's a physicist that's doing the treatment planning, that we don't mean to upset that.

Any other comments?

MR. BERK: We could use the words "dose planning" rather than "treatment planning".

MR. TELFORD: Would be better.

MR. BERK: Dose planning.

MR. LEE: Dose treatment planning or isotope plans.

MR. LANDERS: What is your intent here, is your intent to cover the physician's part of it, where he decides what tests are needed?

MR. TELFORD: No.

MR. LANDERS: Whether simulation is needed.

MR. TELFORD: That's his or her prerogative, this is what they decide should be done. We want, whatever the authorizer user physician says to do, that's what we want to follow. We don't to interfere with his or her judgment or choice.

Yes?

DR. TSE: I think it is the physics portion, because when we get into the regulatory guide this afternoon, we will talk about arithmetic errors, calculations and so on. Therefore, it is not the intent to include the physician's portion, whether he needs a CAT scan or not, it doesn't mean that. Perhaps the words can be modified to indicate -- if you have any suggestions.

MR. BARNETT: In the second part, y'all use the words "computer generated dose calculations". We feel like that would be less ambiguous than "treatment planning".

MR. LANDERS: I don't know what all you intend to include in that, you may include block making in that, contouring, I don't know, but I think you should, for terminology reasons, make sure it's not covering that thing that insurance pays for as a physician's service.

MR. TELFORD: Okay. Well let's say we're done with the objectives and if anybody in the room wants to make any comments or suggestions, let's give them an opportunity to say anything on the objectives.

(No response.)

MR. TELFORD: No takers. Okay, what I really want to find out is if I've explained these sufficiently well that you could say you understand the intent of these, regardless of the obvious flaws in the words. What I'm striving for is for you to understand the intent of these eight objectives, so that you can modify your program to meet these objectives.

If you understand those sufficiently well that you could do that, then I'm happy. So let me ask for a show of hands. Does everybody understand them to that extent?

Don't feel bad, it's like the person that asks the questions, everybody is going to benefit, you know. You may think you're the only one with that question, but once you ask it, then everybody learns from that.

LT. COMDR. PULCRANO: I notice you only mention I-

125 and I-131.

MR. TELFORD: Yes.

LT. COMDR. PULCRANO: Are those the only ones that you're particularly concerned with under these guidelines here?

MR. TELFORD: Well we don't have any jurisdiction.

LT. COMDR. PULCRANO: Okay.

DR. TSE: Your question is whether other isotopes are included?

LT. COMDR. PULCRANO: Yeah, I was just wondering about other isotopes.

DR. TSE: The main reason we put a little bit of emphasis on iodine 125 and iodine 131 is because for those isotopes you have a big, large differential in terms of activity. You could have ten microcuries, ten millicuries, hundred millicuries and the reports -- misadministration reports that we receive, sometimes they have mixed milli and microcuries or the technologies determine sometimes maybe this patient needs five millicuries, actually only microcuries. And those are very serious events.

The others, like iodine 123 which is not really diagnostic but the dose is also much smaller, and 99 MSR, all these are much smaller dose and not very easily have a factor of 1000, 10,000 parts and therefore we just put special emphasis on the iodine 125 and iodine 131.

MR. TELFORD: Yes?

MS. ROY: From what I can find out on reading this, you are still including all isotopes, it's just that the emphasis is on I-125 and I-131, but all the isotopes are covered.

DR. TSE: Right. Not all the isotopes, NRC is regulating the byproduct material.

MS. ROY: Right, technetium, thallium.

MR. TELFORD: All the other radiopharmaceuticals that are used for diagnostic studies that the NRC regulates or has authority over we include under number three. That's where we capture all those. P-32, isn't that used in therapy, so that would be in number two. Does that help?

(No response.)

MR. CLARK: I've got one more question on item number seven. Any unintended deviation --

MR. TELFORD: right.

MR. CLARK: Say a person was in for a study, 300 microcuries. If in your dose calculation it comes up to 280-290, should we document that? That's a deviation, but it's diagnostic quantities.

MR. TELFORD: Before you give it, if you documented the fact that you thought you had 300 but you really only have 290, if you documented 290 before it's administered, then you don't have an unintended deviation.

MR. CLARK: Well we log it, calculated dose, actual assay dose, we log that.

MR. TELFORD: That's great.

MR. KLINE: I just wanted to back up on that number eight issue regarding the definition of treatment planning, teletherapy treatment planning. It somewhat appears to me a little bit vague and it might be a little more narrowly defined definition or might need some clarification. I know the regulatory guide does address computer generated, which leads you to believe treatment planning would be computer generated dose calculations, but also that interpretation could be looked at as broad and topical covering the entire treatment process which might involve a prescription for the use of different modifying devices, wedges, blocks, the method of administering the dose, rotational therapy, this and that. So I think maybe your suggestion of a definition, which really more precisely defines that terminology because I know to a physicist treatment plan versus treatment planning process versus treatment regime or dose -- you know, they're all different, they all vary too. So that's a good suggestion and maybe that will help clear up that area.

MR. FRYMAN: Speaking of number seven when you speak of prescription deviation, are you speaking of the total prescription, daily fractionation?

MR. TELFORD: Unintended deviations?

MR. FRYMAN: Yes.

MR. TELFORD: That would be either.

MR. BARNETT: Actually it's both.

MR. TELFORD: Yeah, both, that's a better word, "both", it applies to nuclear medicine procedures as well as teletherapy or brachytherapy.

More questions or comments on the eight objectives? Yes?

MS. ROY: I don't like the way it's stated in number four for responsible individuals. Aren't all states -- don't they have licensed technologists?

MR. TELFORD: No.

MS. ROY: No.

MR. TELFORD: No.

MS. ROY: Okay. I guess that answers that.

MR. TELFORD: It would be nice, wouldn't it?

MS. ROY: Yeah.

MR. TELFORD: Anybody else?

(No response.)

MR. TELFORD: Well let me summarize the pilot program for you. We're in the pre-test workshop. By May 14 -- we'll talk about the schedule a little more this afternoon after we talk about the regulatory guide but just for now let's assume that we can start on May 14, that's a

60-day trial period from May 14 to July 13. During this trial period, you're going to have your quality assurance program -- you're convinced that it meets these eight objectives and that's what you tell us, it meets the objectives, here's a copy. And we'll evaluate it and confess to you what we think in a very no-fault kind of way.

During the trial period there are just three or four records that you need to make sure you've got; namely the prescriptions, the referrals, keep your manual, and the procedures manual and the administered dose or dosage, just record that. That may be part of your records now, wherever you keep those, that's fine.

Question?

MR. BARNETT: No.

MR. TELFORD: Okay. I may have said something I didn't intend to say -- you know, sometimes you're talking and all of a sudden there's a sound all around you and you say "did I say that". I just want to remind you about the records so that you don't have to do anything differently than you're doing today, so that if your site is chosen for one of the visits, then we would come and say may we see some prescriptions, may we see some referrals. Just be able to point them to us or pull them out of central records or whatever. We don't want you to do anything special, don't think we need extra copies, none of that. Just make sure

that your system retains those basic things.

Yes?

MS. RHODES: During this pilot program, you're going to do a 100 percent review of these things, is that correct?

MR. TELFORD: Of the programs.

MS. RHODES: Yes, if these things we've talked about.

MR. TELFORD: Well two things -- maybe I should let you get out your whole question before I attempt to answer it.

MS. RHODES: Well as you know, I'm a quality assurance person and when you do quality assurance studies, sometimes you decide you'll look at 20 percent of a certain kind of patient or 50 percent. I think I'm hearing 100 percent here.

MR. TELFORD: Well that's the idea.

MS. RHODES: Okay.

MR. TELFORD: But I don't want to claim that because we've got program review or evaluation and site evaluation. For the program evaluation, we'll go through the whole thing and we'll be asking ourselves the question of do we think this meets the proposed objectives, and if not, let's ask some questions about why somebody else does, maybe we can learn from that. But I think you're referring

to the site evaluation. Now if we go to a broad scope licensee and they're doing everything and you've got a very large department, we only have one day, I guarantee you it'll be on a percentage basis, it will be on an audit basis.

MS RHODES: Right. Well actually I was taking about both. What we want to do at our hospital is use this for our ongoing quality assurance program in the departments.

MR. TELFORD: Right. Some departments will do a monthly audit and they will -- in fact, when we talked to the American College of Radiology, talking about therapy, if you're a member of the ACR, which you probably are, you've seen their model QA program and that's what it suggests, they have a chart check and they have about 18 items that you go through periodically and discover what these little unintended deviations are. In this proposed rule, we just have an annual audit, as you know, but for our site evaluation, if it's a private nuclear medicine department and it's not very large, maybe we can do something close to 100 percent.

MS. RHODES: Okay.

MR. TELFORD: And we might be able to do it in half a day.

MS. RHODES: Uh-huh.

MR. TELFORD: But if it's a large place, we all know it's got to be an audit.

MS. RHODES: Okay, but for the pilot program, for our own use, not the site review, we can decide what percentage we're going to look at.

MR. TELFORD: There's no requirement for you to do that.

MS. RHODES: But we --

MR. TELFORD: If you want to do that monthly, great, I'd love it.

MS. RHODES: Okay.

MR. TELFORD: Yes?

MR. BARNETT: Maybe I misunderstood the letter, but the letter said, I thought, that you changed the new -- you wrote a new quality assurance program for your center during the pilot period, that covered the guidelines set forth in the back here. And these two things don't meet that criterion because there are several other documents that are needed, according to the guidelines you've got in the back.

MR. TELFORD: I think you're referring to the regulatory guide.

MR. BARNETT: Yes.

MR. TELFORD: Well if you do that, we'll give you a big A. But that's not really what we're asking for.

MR. BARNETT: Well the letter said you changed your QA -- it requested that you change your QA program to meet the new guidelines. Is that not --

MR. TELFORD: Could I differ with one or two of your words?

MR. BARNETT: Okay.

MR. TELFORD: I think what the letter was supposed to say was that please modify your current quality assurance program, if required, to meet the eight objectives, or to meet the proposed 35.35. Now that's right here on the first page. It simply means if you say to us your quality assurance program meets these eight objectives, all is well and good. The regulatory guide, beginning on page three, is for your assistance. If you want to use this or use these procedures --

MR. BARNETT: The guides from page three on are far more restrictive than what we just talked about.

MR. TELFORD: Okay, let me say again, the guide is only at your option, you don't have to use it at all. If you like it, please use it, we'll be appreciative to learn if it's any good or not. But it's for your information only. It's in no sense a requirement, it's not even a request at this point in time. The only request is that your QA program meet these eight objectives -- no more.

MR. LANDERS: Can you just guarantee that the

guide will meet those objectives?

MR. TELFORD: Oh, well sure. I mean the way the NRC does business is we publish a rule and the licensee sends back to us -- especially in a performance based rule. These are the what things to do -- and they would say back to us, okay, guys, come on, tell us how you think we're going to do this. So we have to give them some how-to guidance, but in this case for this pilot program and even if this becomes a final rule, this will be a guide that you can use at the licensee's option.

Now everybody knows that if the rule became final, that each program would contain some minimum sufficient number of procedures, but when I talked about we're going to confess to you the criteria we use to evaluate programs and what we think? Well what you will learn is how we use the guide to evaluate those programs, but let me say again, I'll be very happy if anybody uses the guide, because we'd like to find out if it's any good, but it's not the request. The request is to have your quality assurance program meet these eight objectives.

See, this is a giant test. We're just saying to you, here are the what things to do and you tell us how. The test is how well does that work because that's why I'm calling it a performance based rule. We definitely don't tell you anything close to how to do it but if you want

advice or guidance, that's in the guide, which we will talk about this afternoon.

MR. BARNETT: The only thing about that is you've said two different things. First, you said the only thing that would be required -- let's take teletherapy as a sample -- you said the only thing that we would be required a documentation to agree with one through eight would be to have a prescription and the dose that was administered.

MR. TELFORD: I didn't intend to say that at all. Let me say two things -- I'm sorry, are you through?

MR. BARNETT: Yes.

MR. TELFORD: I didn't mean to step in before you were through, sorry. All we want is for your quality assurance program to encompass and satisfy these eight objectives. Now during the trial program, 60 day trial program -- prior to that, you will have turned in a copy of your QA program, which we will want to evaluate. That's it, that's it for paper if you turned in a copy of your QA program. During the trial period, we want everybody to keep records of prescriptions, referrals, go to the procedures manual for administered dose or dosage, so that if we come to your site we will be sure to be able to find those things. We'll be able to say may we see some of your prescriptions, may we check out your patients as they go through your process. The principal question we'll be

asking ourselves is is this hospital implementing the quality assurance program that we evaluated. We evaluated the paper program -- we evaluate your program on paper, then when we get to the site, we'll be asking ourselves are they really doing what they say they're doing. So that my request for you to keep those records is to assist us in that. But we don't mean to go any further than that.

MS. RHODES: In essence you'll be looking at records that already have been looked at.

MR. TELFORD: Yes.

MS RHODES: Okay.

MR. TELFORD: Records. We may observe procedures, we may observe what you do with patients, how you do business.

MS. RHODES: When we send the written plan in one month, will you make suggestions about how we could improve it, or are we just going to --

MR. TELFORD: We will give you what we call an evaluation of your plan.

MS. RHODES: Okay, good.

MR. TELFORD: Which will be its strong points, its weak points and where we think it needs work.

MS. RHODES: And that will be before we implement the plant.

MR. TELFORD: No.

MS. RHODES: No.

MR. TELFORD: You could think of this evaluation as sort of a mock licensing. If it were real, we would give you -- you would send in your plan and say this is my application for the program, if this were real.

MS. RHODES: So we'll just send in a plan and fly by the seat of our pants until the end of the program.

MR. TELFORD: You'll send in your plans and you will use your good judgment and your experience to carry out the program.

(Laughter.)

MS. RHODES: Okay.

MR. TELFORD: It's not -- we don't want to evaluate your program before you do it. We want to come around afterwards and learn how you do it so that we can know how to write a better rule.

MS. RHODES: I understand.

MR. TELFORD: We want to do a program evaluation and a site evaluation in a very no-fault manner. This is for free. We won't even use the words "deficiency" or "violations" for gosh sakes.

MS. RHODES: They're recommendations.

MR. TELFORD: Well we won't even say that. I think when we get through the afternoon and have talked about the guide, it will hopefully be very clear that this

is just guidance, information that you can use as you desire.

This lady here.

MS. ROBERTS: If these two copies of our QA program that you wanted us to bring meet all these requirements, do we just continue doing -- going by our QA program and keeping records?

MR. TELFORD: Yes. What you're really telling me is that you already have a quality assurance program and it already meets these eight objectives, and furthermore, you're doing it now. Okay, then May 14 won't mean anything to you. For everybody else that will have to modify their program, then I'm requesting that they implement the modified program on May 14. We have to give this lady a star.

Ed.

MR. KAPLAN: I just wanted to mention that whatever you do send in, give us a road map that says this part of my program meets this objective, so we'll know when we go through and evaluate, where it is in your plan you're attempting to meet each of the eight objectives.

MR. TELFORD: Yes. By road map we mean like a one page outline that says we don't want to ask you to do any more work than is absolutely necessary. We don't want to ask you to write your QA program in any given format or in

any given way. You write it however you want to do it, in fact it can be copies of existing stuff. But if you have copies of this and this and this -- if your outline says objective one is met by this section over here, objective two is met by this other section over there, that'll just make our work a little easier and we won't have to search through it and say gee, I wonder where objective three is met, for goodness sakes. If your outline says go look at this section, that helps us a lot.

Yes?

MS. ROY: In my case where all I do is thalliums, I'll just put objective two not applicable.

MR. TELFORD: No therapy, yes.

Okay, more questions, comments?

(No response.)

MR. TELFORD: Why don't we do the next item on the agenda and then we'll break for lunch, if nobody objects.

Next we have Lloyd Bolling to clear up any potential misunderstandings about your current state requirements.

MR. BOLLING: Regarding those of you who are licensees in agreement states, if during the pilot program you have any misadministrations, you have any leaky sources or contaminated sources, equipment failure, a machine falls on a patient or you have any other thing that might be a

reportable incident or a requirement that you committed to in your licensing process or that is part of the regulations, you will have to continue to report those things as you would normally.

We've had no questions this morning about NARM material or electronic produced radiation. It is expected, although the NRC does not control these two materials, that when the rule becomes final and the agreement states will adopt these because of the compatibility clause in their agreements, it is expected that these requirements will spill over into the accelerator produced materials area and the LINAC area. Although, you know, the NRC has no jurisdiction in telling the states to do this, but it is our hope that there will be some benefit gained through the byproduct experience that you would want to adopt these measures in your other two areas.

Are there any questions regarding any part of the pilot program and how it relates to agreement states and agreement state regulations?

Yes?

MR. HILL: Would you expect that I-123 would be added to objective two?

MR. BOLLING: In an agreement state, yes.

DR. TSE: I think it should be in objective three, not two, therapy.

MR. BOLLING: You're right, diagnostic, yes.

Any other questions?

MR. TELFORD: If that's a state requirement currently then what we mean to say is if you have a state requirement, don't get yourself in trouble with the state. Keep doing what your license says so that if you have a requirement that's in addition to these objectives, please keep doing them. If you have a license requirement that's in conflict with these objectives, do what the license says. We hope there are none of those, but if you have them, just put it in your QA program and tell us you're going to do that.

MR. BOLLING: And obviously if you have any doubts or questions, you can call your state radiation control office. We've been over this with them. They have copies of the proposed rule, we are in the process of receiving comments by the April 12 deadline. So we've gotten I believe about ten comments so far in the 29 agreement states. So we will be analyzing their comments along with your comments as well.

Any other questions?

(No response.)

MR. BOLLING: Thank you.

MR. TELFORD: Let's go off the record for a moment.

(Discussion off the record.)

MR. TELFORD: The next item that we would like to cover on the agenda is actually not on the agenda, but it's a discussion of the evaluation forms. What I was mentioning this morning is that we really want your evaluation of not only what you think about these eight objectives and how to modify them, but we'll provide you with hopefully a very handy, dandy evaluation form to give us a grade on each of the eight objectives and each part of the regulatory guide that you may have used. I'll introduce Kevin Nelson from Brookhaven and he's going to talk about a draft version of that evaluation form which we would send to you whenever the actual 60 day trial begins so that you can look at it and say okay, this is what I want to record.

Kevin.

MR. NELSON: Thanks, John.

As John mentioned, we're from -- I'm from Brookhaven National Laboratory and we're assisting the NRC in the development and implementation of this pilot program and we're really looking at you to provide us two types of information; one is the QA program, which we would want to have you submit to us by I guess May 7 and we'll talk a little bit more about the schedule this afternoon. These QA programs will be evaluated and presented, the information gathered from those evaluations, presented at the second

workshop. The other type of information that we request is from this evaluation form. This evaluation form is used to measure your response to the QA objectives or specific points in the reg guide, and this gives you another chance to comment on specific objectives, and it's very important whether you're a large medical use institution or you have smaller use situation, that you comment. This is the only way that we can have an effective rule that will work for us.

This evaluation would be completed by you and sent to Brookhaven by July 31. We suggest that you bring a copy of this evaluation form with you, however, at the second workshop so we can discuss it at that time.

The NRC gives you two options for a QA program, you can use your existing institution's QA program and any modifications you may make, or you can use the reg guide. To measure the effectiveness of either the existing QA program that you're going to be using or the reg guide, we need a method to evaluate specific objectives or points in the reg guide.

The way that we're going to look at this is by looking at -- if we follow down here, benefit, economic impact, personnel availability, impact on medical care, covered under existing requirements, acceptability. And we're going to rate these, or actually you're going to rate

these from one to five, one being that it's a very good rule, it's not costly, personnel are always available, and five being it's a bad rule, it's extremely costly, very difficult to get people to help

We're going to have you rate either the reg guide itself if you don't have an existing QA rule, or the objectives, the eight objectives, one to five, for each of these topics. Now I should mention that this evaluation form is in a draft form right now. There are going to be some modifications. For instance, what you don't see up here is a slot for the eight objectives with the various topics. But what we hope you will do is again we try to keep this very simple to minimize the time that it takes for you to fill this out, but we want your suggestions and comments on either the objectives or the reg guide.

If we go along the top here, this would follow each of the points in the reg guide, if you wanted to comment on those. If you found that a specific objective or point was difficult for you to meet, you would rate that probably either a four or five. At that point, we're asking you to give us your comments on a page very similar to this. Again, these would be for the items that you have difficulty in meeting, as far as either the objectives or the reg guide itself. And again, and I can't stress this enough, this is the only way that we can really make a better QA rule, is

that if you take the time to explain the problem or mention maybe an alternative to what you do in your existing QA program. We don't expect that when we get these back, that they're all going to be filled out with ones or twos, just as we don't expect that we're going to get them back and they're all going to be fours and fives.

But again, on the ones that you do have some difficulty with, please put your comments down on this page. To help you with that, we will be providing you some guidance as to what we want you -- or how we want you to respond in some of these topic areas that we have along the side here. For instance, if you had a problem with one of these objectives or specific reg guide points, as far as the economic impact, it was extremely costly to you, we want you, for instance, to try to estimate the kind of additional costs that would be required. If you didn't have the people to help with this specific objective, we'd want you to indicate the types of people that you would need, how many people you would need.

Again, this information will be sent along with the revised evaluation form and we hope that will be in the early part of November.

Okay, any questions on the evaluation form itself or what's needed in filling it out? Yes?

MR. KAPLAN: Just to reiterate that if you're

inclined to put a lot of fours and fives, you're obligated to give us your comments.

(Laughter.)

MR. NELSON: And we can't stress enough that, you know, you do put your comments down because that is one of our best ways in making a better QA rule.

VOICE: This is going to come when, November?

MR. NELSON: No, this is -- this should be early May that you received the revised evaluation form, and we would like that completed by -- once you've finished the pilot program.

MS. ROY: I know that this is just a draft of it, but you've got "covered under existing requirements" and one is not covered and five is fully covered? To me that seems backward. I mean if it's covered under existing requirements, then that should be fully covered and one should be --

MR. NELSON: That's a good point. As I mentioned, there is some modification that we will make with this evaluation form and your suggestions plus several others are being considered now. Hopefully, it'll be better understood when we send it out.

And if you do have any questions on it, please give either the NRC or Brookhaven a call and we'll be more than happy to explain what we mean in the ratings.

MR. BAHADUR: Kevin, I just wanted to verify, you mentioned that by May 7 all the volunteers would have sent the QA programs to you.

MR. NELSON: Correct.

MR. BAHADUR: What are you going to do after you receive all these programs?

MR. NELSON: Okay, again, there's two types of information that we're gathering in this pilot program; one is the QA program which some of you have brought today, that lists the procedures that you follow in your institution for QA. The other type of information is this evaluation form that evaluates the impact you feel on the specific objectives or the reg guide itself. Once we receive the QA programs, we will evaluate those as to the -- how we feel they comply with the objectives, and that is a process that is going to take I think a fair amount of time. It may or may not, depending on your scope of operations. You may have a QA program that's one or two pages and you may only do a few new med procedures and that's it. Otherwise, you may have an institution that does everything and we would I guess anticipate that evaluation of those may take a little bit longer period of time.

MR. LANDERS: Do you want us filling these forms out with the input from the users, or do you want the users filling these out?

MR. NELSON: Well I guess we would anticipate that the people that are impacted the most by this would be filling the forms out. If it's the approved user that does the majority of the QA, I would anticipate they would be -- we would suggest that they would be the one to fill these out.

MR. LANDERS: Particularly in therapy, I'm not sure I'm qualified to grade the impact on medical care here.

MR. NELSON: You're talking about a situation where you have a number of these, you have nuclear medicine, you have brachytherapy and teletherapy, you may specialize in only nuclear medicine or teletherapy. In that case, I guess we would ask that you get input from these other areas if you don't feel qualified to evaluate the.

MR. LANDERS: Even in my own area, I don't feel qualified necessarily to judge the impact on medical care.

MR. NELSON: That's I guess one area that we're going to modify a little bit as far as what we really mean by that. As it stands right now, it isn't worded very well and I assume that, as with any QA program, there's always going to be some positive impact with minimization of impact on medical care.

You know, if you need assistance in evaluating the objectives, you don't feel qualified, by all means seek assistance from people that you feel would be more

qualified.

Any more questions?

(No response.)

MR. NELSON: Thank you.

MR. TELFORD: Let's go off the record for just a minute.

(Discussion off the record.)

MR. TELFORD: We'll going to break now for lunch and return at 12:45.

(Whereupon, a luncheon recess was taken at 11:32 a.m., the meeting to continue at 12:45 p.m., the same day.)

AFTERNOON SESSION

MR. TELFORD: This afternoon we will talk about the guide and Dr. Anthony Tse will lead you through the guide and then I'll come back and talk about the schedule and the summary of the workshop today and then you'll have a chance for individual remarks.

DR. TSE: Thank you, John.

This morning, we were talking about general objectives and this afternoon, we will talk about some specific items we are proposing as a guidance -- a very important word, guidance, not a requirement. The licensee may use this guidance to develop their QA programs or they can use some other guidance like ACR, GCH or what ever other guidance you have to develop a QA program. But the way we envision is that as long as you are meeting the objectives we discussed this morning -- if that becomes a primary focus.

I think you all have this document, the Reg Guide, we sent it to you some time ago, so you've probably had a chance to read it through. I'm not going to go into detail of each requirement but I'm going to walk through the general areas and then if anybody has any specific comments, suggestions or anything, please raise their hand.

Okay, the first page of the Guide is essentially to state that this is a guidance, very clearly states that

this is a guidance and we are asking for public comments. So we will receive some public comments from whoever is interested in this guidance and also, specifically, we will receive your comments as public comments so we can modify our guide to be a better document.

The second page, we said this is essentially a rough guide and we describe a little bit about the problems, the errors introduced, what size of estimate of the number of administrations and a little bit about what kind of problems we're facing. If anybody has any comments, questions or suggestions on each of these pages as I go through, please let me know and we'll stop and discuss your comments. If there are no comments, we'll go to the next page.

The next page, page three, page three generally said this quality assurance -- a sort of basic quality assurance program can be separated into human errors, or we may want to use the word simple human errors. Based on our misadministration reports, many errors are made because somebody multiplied wrong or read a number wrong or as John said this morning, Mr. Smith -- there happens to be two Mr. Smiths in that particular room, and those are simple human errors.

There are many other QA requirements currently already in Part 35 and these are more related to

instrumentation, machines and so forth. But they -- those are additional QA requirements. The basic QA program is only designed to prevent "human errors". Generally, that's the case.

Now under regulatory position, we have reiterated that this is a guidance. You do not have to use this but if you propose other things, NRC just wants to take a look and make sure they meet the objectives.

Any questions or comments so far?

(No response.)

DR. TSE: Then we go to a little bit specific item, page four. Number one talks about responsibilities, authority and audit. It's stated here that the licensee should have some -- should, it uses the word should -- have some kind of written policy to state who is responsible for what. I guess, probably, whoever has a QA program probably already has those statements. You need to know who is responsible for what.

The second item is about the audit. And it said -- as John said, it is stated here perhaps an interval of four months, and many people may want to use different time periods. There should be somebody who audits the program, is somebody which is not doing the work. If I'm auditing myself, if I make error, I will continue to make error, I will not discover it. So somebody should do this.

Yes?

MR. BARNETT: I have a question.

DR. TSE: Yes.

MR. BARNETT: The way our licenses are currently set up, is that person is usually the radiation safety officer of the program and it's supposed to be reviewed on an annual basis, the radiation safety program; is that an analogous statement or is -- do you have to have someone outside the organization to do your audit?

DR. TSE: No, you do not have to have somebody from outside your organization. There's no independent organization or independent person; however, the person who audits the program -- based on your management determination, should be knowledgeable in the procedures. If they don't know anything about the procedures, they may not be able to effectively make sure these procedures are correct or flaws in those procedures.

MR. BARNETT: Okay. Is the RSO an adequate person to review the program?

DR. TSE: That's why it specifically says here your management will have to decide because RSO has many different qualifications. But the essential thing is that he should be able to discover something wrong. If he couldn't, then there's -- you know, it will not fit the purpose of audit. But your management is the one to decide

who is qualified and who is not qualified.

Any other questions?

(No response.)

DR. TSE: Okay. Now, this Guide is structured in the way that the first portion, meaning item number two is applicable to all -- to all, meaning diagnostic therapy, teletherapy, brachytherapy, et cetera, all of those departments; so, therefore, it is essentially a general kind of a statement.

Now 2.1 on page four essentially says that those things have to be legible. These are very moderate kind of statements. Somebody writes a word, microcurie, millicurie, squiggle N or U, you couldn't tell whether it's milli or micro and that should be written in a more recognized manner. I think QA expertise probably says that is an important area so that people do not to make a mistake that way.

Second, 2.2 is to say that if you have a doubt, if for some reason the physician wrote something which is difficult to understand anyway, but I guess the health care workers may understand, if you are not sure, you should ask for clarification.

Does anybody have any comments or suggestions on this?

(No response.)

DR. TSE: Now, we will go to the next page. The next paragraph says that if there is a discrepancy -- like this morning, John said that if there's -- referral says lung cancer -- not lung cancer, lung scan take iodine 131, how many millicuries and it's different from your manual, clinical manual, then you should not do it. You know there is something wrong and you've got to check.

And, of course, the last item in the General is that you want to make sure what you're doing is correct.

Please?

MR. LANDERS: I have a question on 2.3.

DR. TSE: Yes.

MR. LANDERS: From whom should guidance be sought?

DR. TSE: I guess that you will have to -- if it's a physician, some physicians, related physician's discrepancy, you need to check with your physician. If it's a dosimetrist who wrote 1.2 milli and the 1 is like 7, you should go to the dosimetrist to seek clarification. Generally, we do not say who, but there are some things your organization can tell your people whom you should ask. If it's related to radiation safety, you may want to ask the RSO.

Any other questions or comments on this one?

(No response.)

DR. TSE: Now, we continue on --

MR. TELFORD: Page five?

DR. TSE: Page five -- no, wait a minute. We have not got that far yet. We are just at 2.3 Now, we are going -- still on page five, we go to Item Number 3.

The items in Item Number 3 are specifically tailored to radiopharmaceutical therapy and also for diagnostic procedures involving more than 30 microcuries of iodine 125 and iodine 131. Only applicable to those situations.

The first one for those cases which authorized user physician under the supervision of authorized user -- when I say authorized user physician, it includes all of these physicians. They have to review the case, they have to write a prescription and any referral will not -- the suggestion is that any referral, you should not go by that which is objective in two. You need physician to check first.

Any problems with those? Any questions?

(No response.)

DR. TSE: Now, we go down to number 3, Item 3.3, If any changes -- somebody say that this patient should be ten millicuries iodine 131 -- well, maybe that's not enough, should be 20 millicuries. The physician -- the authorized physician could make such a change. But if a technologist sees 15 microcuries iodine 131 and the technologist says,

oh, this patient, I know, may need five millicuries, he cannot make such a change. The change has to come from the authorized physician.

MR. LANDERS: Excuse me.

DR. TSE: Yes.

MR. LANDERS: Is it sufficient to get an oral order for change and have it signed and dated later?

DR. TSE: Well in here, we recommend that you make a change before administering the radiopharmaceutical. The concern is that sometimes oral we make a mistake of how many millicuries and so on. If you feel that interferes with your practice, then you might be able to make your program to say I'm going to do it another way. Whatever the way of doing it, you need to make sure that the oral -- whatever, prescription is a correct one, somehow. There is other ways you can do it other than this. So make that kind of suggestion in your QA program and do it that way. Maybe we will discover some more ways to do -- to assure that than this way, then we can add it in. We will have several alternatives, one, two and three.

Okay, the next item, 3.4 is the identity of the patient again -- for those therapist who are fortunate to have the right patient, right dose and so forth.

Number 3.5 just says that after you finish somebody should write down -- a qualified person should

write down the dose given to the patient and whether they are the same or not the same as what was prescribed. Now, it's not the same, of course, you have to correct it.

Anybody have a question on this one?

MR. TELFORD: In the interest of asking questions that some other group may have brought up, let me ask you a question here. Is it necessary to write down the agreement or lack thereof? Let's say that we have written down the prescribed dose and the administered dose, is that enough?

DR. TSE: Let me ask you a question. Do you have a problem with your writing agreement or not agreement? Anybody have a problem, say you write a prescribed dose, you write an administered dose, then here it says you've got to report agreement or not agreement; yes, they are the same, no, they are not the same. Do you follow?

MR. GARRISON: I don't. I have a hard time -- I can't -- it's hard for me to draw up 20 millicuries exactly. I don't know what you -- I don't know what I'm trying to say. I mean --

DR. TSE: Oh, I understand -- I think I understand what you say. Let's say your physician's prescription will be 20 millicuries, now you draw 19 or 21, now the administration says this is an unintended deviation. I don't think we really meant that. In some of the manuals, the clinical manual, you may have a range, you may have a --

have a -- okay, you understand?

MR. GARRISON: (Nodding head affirmatively.)

LT. COMDR. PULCRANO: Question.

DR. TSE: Okay. Let me finish with his question first.

LT. COMDR. PULCRANO: Okay.

DR. TSE: Are you related to his question?

LT. COMDR. PULCRANO: In a way.

DR. TSE: Okay, fine. Go ahead.

LT. COMDR. PULCRANO: It refers to -- sometimes physicians will write prescriptions -- they will say three to five millicuries. Okay, that's the prescription. Now, if the tech draws up four, he's within that range, does he still have to make a statement? Is that what you're saying? You still want him to make a statement?

DR. TSE: No, no, that's the question I'm asking you. If it's within prescription, three to five, four is right in the middle --

LT. COMDR: PULCRANO: Yeah, that's in accordance with the prescription.

DR. TSE: Right.

LT. COMDR. PULCRANO: Okay.

DR. TSE: But my question is this -- all right, maybe I just want to state what other group said. The other group said that if you have a column that says prescribed

dose, if you have another column that says administered dose, one is 20 millicuries prescribed and administered 19, it's obvious they either close or not close, why do I need to have another column here to say agree or not agree. So, we said that's fine. Maybe we should change this. It may not be necessary to say agree or not that you need to look at to see whether it is close enough or is it an intended deviation. If it is, you may want to follow the objective.

LT. COMDR. PULCRANO: Rewrite the prescription, right.

DR. TSE: Yes -- no, you cannot rewrite a prescription.

LT. COMDR. PULCRANO: We'll make a change in the prescription. I mean if those --

DR. TSE: I don't think so because if the prescription -- you can change a prescription --

LT. COMDR. PULCRANO: Before it's administered.

DR. TSE: Right. But after it's administered, if it's a -- let's say it's supposed to be ten millicuries and you somehow got 20 millicuries instead, then in that case, then you have misadministration. But before that, you can change the prescription, after that --

LT. COMDR. PULCRANO: I realize after, you can't.

DR. TSE: Brachytherapy is slightly different and we'll talk about that later.

Yes?

MR. GARRISON: So diagnostic doses, if it's not going to have dose on the prescription, but our list of -- you're going to have a range, let's say 15 to 25 millicuries, that's what you're looking for, right?

DR. TSE: Well, I just want to -- we use a specific term with specific meaning in here. It may not be corresponding to general use, but in this particular document, the prescription is specifically -- it is specifically tailored to the authorized user's prescription, written directives. You should include like radioisotopes and so on, curies and so on. But what you're talking about is a referral. A referral will only say like how many -- let's say a bone scan. Then your manual will say how do you do it. Those are the -- the manuals are the words to go by.

Any other questions or comments?

(No response.)

DR. TSE: If not, let's go to the next page. Now, this one goes to brachytherapy. I know we have a lot of comments on this one. 4.1 is the same, that the physician, meaning the authorized user physician should review the case, the patient's case and, of course, authorized physician should make the prescription.

Any questions so far?

(No response.)

Yes?

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(No response.)

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Any questions so far?

(No response.)

DR. TSE: I think generally they do that.

Now 4.3 is somebody should make sure that the sources that are going to be used by the physician is the source he prescribed. It is not so easy to do that. That's why we give apprentices, we give you some suggestions on how you do it. You know, different people do it different ways. But essentially, somebody has to check into whether those sources are the ones the physician needs, either in terms of radioisotopes or in terms of activity.

Now, anybody have a question on this one?

Yes?

MR. BERK: Verifying source strength; do you want the verification to include a measurement or that the number written is what it should be?

DR. TSE: Well, there is other requirements in terms of --

MR. BERK: I mean like when you order, say gold seeds from a company and they come in and they have four millicuries per seed, you don't want them to measure it to verify that it is four millicuries, just take that number?

DR. TSE: Okay. That's a -- I think is a separate question here -- from here. When the doctor says I want certain millicuries for something, you go to your vault, and to open the thing and then take certain sources and those sources you should have sealed so you will be sure that

these are the sources. Sometimes it's difficult when you want to take a look, so you may have a color scheme, but sometimes color scheme will not work right. So it's not so easy; however, we should try to verify those sources are the ones the physician ordered.

Okay, now we go to the next one. The next one is a change in prescription.

MR. LANDERS: Did you skip 4.2?

DR. TSE: Oh, 4.1 and 4.2, I put together.

MR. LANDERS: I got a little difference there and it relates back to something we've been discussing earlier. Are we asking the physicians to write down some generic prescription here which can be changed at the time of implant or afterwards?

DR. TSE: Right.

MR. LANDERS: But just to have something written down?

DR. TSE: Well, the physician have to written down something to convey his desire to dosimetrist or technologist or whoever, so that his wish will be fulfilled and not misunderstood by other people. So that's the prescription.

At the time he examines patient, he wants to do something and he writes that down and he can change it later before implant. Also, after implant if there's difficulty

for him to put -- on the computer, you can always have precise location, X,Y,Z, but that's not the case when you're trying to operate on somebody and implant the source, you may not go to the X,Y,Z position shown in the computer. So after you load the sources, if that turns out to be not exactly the point the computer planned, you can update it, that it's different from the other.

MR. LANDERS: I don't mean to beg the question here, but would that be an unintentional deviation?

DR. TSE: Well it could be, that's why I said exception. However, what you want this physician to do, he operate the patient, have in operating room, he try to put something in and it happens we cannot go to exactly -- maybe whatever the problem is -- cannot go to exact X-1, Y-1, Z-1 location, what you want him to do.

MR. LANDERS: In fact, sometimes you can't even do it.

DR. TSE: Okay, that's right. Therefore, those are -- it's a difficulty associated with those kind of operations. Now in nuclear medicine, it's very easy, you put in the dose calibrator and you know what they are, so you should not really easily make mistake. But these are the mistakes you're not making -- they have to put the source in wherever -- maybe they even do not know the size of the tumor before they operate. After the operation, the

prescription has to be written before the operation and you do not permit him to change it, you've got problem -- maybe every time.

MR. BARNETT: Maybe rephrasing the question a little bit, when does the physician's intention become a prescription? It's obviously not when we ordered the sources or even maybe when you get to the patient, but when does it become a prescription?

DR. TSE: I think it says here before administering the byproduct. Be[illegible] you put into the patient. Some people may do it at different times, but according to this -- you may do it differently.

MR. BARNETT: He must have made a decision on how many seeds before --

DR. TSE: No, just the decision is how many I think I need, maximum.

MR. LANDERS: Perhaps we could say --

MR. BARNETT: I'm not sure that's administering after loaded sources. Maybe we could distinguish between live implants and after loaded implants.

MS. RHODES: Well I'm wondering if at the point of surgery, the surgeon may go into an abdomen believing that he has a bad gallbladder but when he gets in there, he finds a big adenocarcinoma, so he changes his course of action, and it's in the operative record and it's really no

different. He intended one thing, but when he got in there, it didn't work out.

DR. TSE: That's right. That's essentially -- in this brachytherapy item, this is what is permitted. So we don't want to let the physician when he's doing this particular implant operation, think hey, am I going to get a misadministration. No, you do the best you can under those circumstances.

MS. RHODES: When you write your plan, you could put that in as an exception.

DR. TSE: Okay, John.

MR. TELFORD: Question under 4.2, I think you're focusing on the word prescription as before-the-fact kind of act. Maybe it would help you if we described that as sort of a plan rather than a -- see, we think of that as an approximate kind of prescription where the physician knows --

MR. BARNETT: Yeah, but you can't -- then that negates the definition of the misadministration. If you have a nebulous plan then you can always meet it.

MR. TELFORD: Let's skip forward through 4.2, 4.3 and 4.4. In 4.2, the intention is to say let's write down approximately what we're going to do. In 4.3, we check the seeds before we put them in. In 4.4, it says now lets write down exactly what we did because now if it's a temporary

implant the clock starts. So we know exactly how many seeds we put in, their location and now we can go calculate how long to leave them in. So it's 4.4 that's sort of the final. Is that wrong?

DR. TSE: No, it's not wrong. But final is 4.6, after implant, you can write down changes to reflect the actual loading. We realize actual loading may not be exactly the same as your planned loading. So 4.6 is the final prescription. Now that's only limited to this brachytherapy because we realize this has those kinds of problems. With radiopharmaceutical therapy you cannot say after injection, then I update change. That's not really good. But before, you can. If your technologist said that -- for example, the physician says hundred millicuries or whatever and technologist says I only have 30 millicurie or maybe 25 or 22, 22 is just on the order of ten percent, let's say 23 you're exceeding ten percent. If you intentionally did that, it would be misadministration. But before the fact, the technologist can go to the physician and say do you want me to wait or do you think it's okay. If the physician say it's okay, he change the prescription, sign it, go ahead. So the judgment of the physician is very important, the authorized user physician. However, it cannot be done -- after it's done, then that's obviously wrong.

Okay, any additional points on this? Yes?

MR. KLINE: In nuclear medicine, often you'll see in the diagnostic and also therapeutic prescriptions, there'll be a range given. In oncology, maybe in regards to your question over here, the final prescription versus -- the prescription before application of the sources versus the revised prescription after you put the sources in, would it possibly be a consideration to use a range of sources based on the particular application? For example, on a prostate where you're using iodine 125 seeds, the physician does not know if all the seeds are going to be able to be applied, you don't know where the tumor is, you don't know exactly how many seeds you need, the anatomical areas might be obstructing the use of a device to insert the seeds. These sort of things might be what you're referring to where you can be entirely off base from an optimal 20 seeds, you might not have any seeds or you might end up using 40 seeds.

DR. TSE: Right.

MR. KLINE: Would it be possible that the prescription could be more precise in their case where they would be given a range, zero to 20 seeds, to be used for this application?

DR. TSE: I think so because you can say -- you can use zero to 20 seeds or you can use 20 seeds or you can use 40 seeds just because of the maximum. Then later, after

you look at it and see the doctor said only I needed ten seeds, then you put down change to ten seeds, either before or after the implant. But if somebody make error, say that I want ten seeds of certain strength, let's say ten millicurie, whatever, and somebody -- the doctor meant one millicurie. Doctor cannot tell, he's just going to implant it and your plan is ten millicurie, actually load one millicurie, you may have a problem there, QA wise. But that's -- we understand this specific situation of the brachytherapy, that's why we make those specific suggestions.

Please?

MR. FURR: I understand the need for a written prescription beforehand if a technologist is called and the orders are confused. In the case where the physician is actually doing the implant, I-125 implant or even a cesium implant, he is following his own intention and I don't understand the value of writing a prescription for him.

DR. TSE: Okay. For example -- let me give you an example. If he tells the physicist or technologist, give me 25 millicuries, people may be involved with something else and take out a ten millicurie and you would not be able to tell if you don't use color or something. And so those are the things that -- the prescription, not to limit the physician, he has to do what he originally intended, but to

let other people know what he intends to give, what he wants. That's the purpose.

MR. LANDERS: I don't have any problem with after-loading. When they go into the OR and they put in after-loading devices, the administration hasn't occurred yet, we've got all the time in the world to do everything before the actual implantation. The live implants are the problem. Maybe we should distinguish between the two.

DR. TSE: Let me ask you why is that a problem? Can you describe the problem?

MR. LANDERS: I just envision problems writing down let's order -- let us implant anywhere between zero and 140 seeds in this case, all of them to be within a range of .34 to .38 millicuries. And then coming back afterwards and saying what we actually did. What's the reason for doing that in the first place? The .34 to .36 I understand, the per seed.

DR. TSE: But there are different ways of doing things. Some people may do one way, some people may say I want to give a certain dose to certain --

MR. LANDERS: Oh, yeah, we've got it all planned out ahead of time, sure.

DR. TSE: Now would you want to know, as a physicist, what the physician wanted in the first place?

MR. LANDERS: We'd never order anything without

him saying that.

DR. TSE: That's the purpose for that, is to let the physician tell you what he's thinking about. You can plan it and get back to him, he may want to modify it and say oh, that's no good, let's change another way. So it's to minimize the misunderstanding between the physician and the staff.

MR. KLINE: I think the detail you're bringing up here is being done anyway. The only difference here is --

MR. LANDERS: Right, it's being done, we're just now going to have to come back and change it afterwards to actually record a change.

DR. TSE: Do you record them anyway?

MR. LANDERS: We don't record a change, we just record the new situation, the real situation.

MR. KLINE: But this requires now a written documentation, that's the main difference we see here. Now that is often done in your dosimetry logs anyway, your brachytherapy dosimetry is, by recording the number of sources inventoried in and out, so you're keeping a record but it's not really a prescription, it's a physical inventory. So this is a documentation requirement that's not a big impact, the only difference is in regard to using a range and modifying the exact number later. And you're probably doing that already in your department. I would

think you would have to, to account for the sources and also to account to the physician in the chart what the dose is.

MR. LANDERS: Well we certainly do pre-implant dosimetry and the physician picks a line and says let's do this or that line and we order accordingly. Then we do post-implant dosimetry and if the two bear a relation to each other, that's great; if they don't we take what happens.

DR. TSE: That's true.

MR. LANDERS: If it's an after-loading case there's no problem at all.

MR. KLINE: But isn't the final dose administered documented in the patient's chart in the oncology department?

MR. BARNETT: Yeah, we don't have any problem about defining it.

MR. LANDERS: No problem there.

MR. BARNETT: It's the pre-information.

MR. LANDERS: Yeah.

MR. BARNETT: The other problem you run into is this is not like a -- if you do a number of these, you don't order seeds for an individual patient. You may have mixed activities from -- suppose you ordered 40 seeds for a patient, you only use 20. On the next patient you will use those 20 which were not individually ordered for that

patient, or you might use those 20 and an additional ten. So your inventory was not based on an individual patient, it's not like a pre-dose.

DR. TSE: Maybe I use the word "order" and you were thinking I mean purchase. When I say order, we mean the physician would like say how many curies, how many seeds you would use, that's what I mean.

Now let me emphasize, this is just a guidance and if you have a better way and you have no problems, please state it because we might be able to improve on these things, if you can let us know.

MR. TELFORD: Tony, you may be telling us in 4.2 that we're over-specifying what we need to specify here and what needs to be written down.

MR. BARNETT: Well I think all we're saying is that permanent implants cause special problems. I don't think any of us have any problem with after-loading devices in any of these things.

MR. TELFORD: At the next workshop, if you have a way to split this up so that you could say let's do this for permanent implants and let's do something else for temporary implants, that'd be very helpful because we see what you're talking about. It could be that we're over-specifying in certain cases.

MR. BARNETT: Yeah, I don't think anybody -- in

terms of after-loading -- that any of this is a problem. It's just in the permanent implants.

MR. TELFORD: Okay, maybe you can give us a suggestion for permanent implants at the next workshop so that we can make this a lot more workable.

DR. TSE: Yeah, in fact they can write it to us.

MR. TELFORD: Let me say this, the QA program and the guide are completely different. There's two objectives. You're going to say in your QA program how you do it in your facility, but just for the guide's sake and to help everybody else, if you had a suggestion the next time on how to fix the guide, just independent, in and of itself, that would be useful. But don't think of the guide as being locked in concrete.

DR. TSE: Let me continue now to 4.5 -- we already talked about 4.4 which is that changes are permitted.

4.5, does anybody have a question about 4.5?

MR. LANDERS: Yes.

DR. TSE: Okay, please.

MR LANDERS: Sometimes -- it sounds to me like we are requiring the physician to have radiographs made for calculational purposes. In some cases it's not necessary, in some cases it's counter-productive -- not counter-productive but you get zero information out of it, and I'm thinking now of an eye plaque where the gold shield

completely hides what you're trying to see. I realize this is a suggestion but --

DR. TSE: But other than eye plaques, what do you think?

MR. LANDERS: Well for a single o-void?

DR. TSE: For the temporary.

MR. LANDERS: No, no, no, I think it's fine in almost all cases, just there are a few cases in which it is not useful at all.

DR. TSE: But do you find any problem?

MR. BARNETT: I guess another one is -- I don't guess we really -- I haven't gotten into this, but I got a high dose rate after loading, kind of totally negates all of that.

DR. TSE: Right.

MR. BARNETT: Because you can't make radiographs with sources in after-loading. You can't do that at all.

DR. TSE: I know, that's a problem. I think somebody in the other workshop mentioned that in some cases they make radiographs during the atomic sources.

MR. BARNETT: After implanting, is bad -- yeah.

DR. TSE: This is the kind of thing they suggested and we're going to change, modify those. Any other questions about 4.5?

(No response.)

DR. TSE: And then 4.6, we already talked a little bit, after implantation, modify your prescription to reflect the actual loading conditions. Anybody have a question on that?

(No response.)

DR. TSE: And then 4.7 is essentially the same thing as before, you have to -- a qualified person have to record the dose.

MR. LANDERS: Again, a moot point, but just to make sure we're talking the same terms in dose here, if we implant a tumor with a permanent implant and it shrinks, the dose in terms of rads may not be a real well known number. As long as we're talking about administered dose like milligram hours or millicurie hours or something of that sort --

DR. TSE: That may be the place we should modify this to include the other qualification number, which in the prescription, definition prescription, we already did that, just the addition of another way. We probably should do this the same way. Thank you.

Any other questions?

(No response.)

DR. TSE: Okay, then we go to next page, page seven. Page seven, 4.8 is a calculation verification for checking and we say that we -- here we say that you should

have a person who did not do the calculation to check the calculation. And there are two ways to check it, one is by checking your manual calculation and 4.8.2, check your computer generated calculation and then the 4.8.3 is a combination.

Now anybody have a questions?

MR. LANDERS: I don't have a problem with 4.8.1, .2 and .3 but with 4.8. I can see circumstances when this can be onerous. We have done needle implants before and made a calculation about as fast as we could and found out that pretty soon we had to pull the needles out. Who's going to check the calculation? Is it okay to check it after the implant is over?

DR. TSE: If it's 4.9, which is down below on the page, in case of emergent situations, you could. But you're talking about a high density kind of brachytherapy, right?

MR. LANDERS: Well no, I thinking of where needles have converged and created a high dose region.

DR. TSE: How long are those?

MR. LANDERS: And we end up with a 24-hour needle implant, which implies that I've got to get the calculation done within the first 12 hours and someone else has to have checked my calculation within that same time frame.

DR. TSE: That's according to this.

MR. LANDERS: Right.

DR. TSE: Now do you have a problem with that? What do you normally do, do you have an implant first before you calculate or you calculate first before you implant.

MR. LANDERS: Well we do a pre-implant calculation, but with needles that sometimes bears no relationship to what happens. The geometry can get away from you in cases like that. I just see this as being -- sometimes being a little onerous. In particular if two competent people are not available, you're going to end up with someone who is not qualified checking someone who is qualified.

DR. TSE: Other people made that same suggestion too. Some small facility maybe only has one person. The suggestion is that perhaps one person can check up on himself with two separate calculations or with computer -- with hand calculations so there's ways you can achieve the purpose without having a second independent check. If you have a problem like that, your quality assurance can do -- for the pilot program, you can do what would be the best way you think to check it. But make a comment like say this will require additional --

MR. LANDERS: Yeah, some of us that doesn't affect.

DR. TSE: Doesn't what?

MR. LANDERS: It does not affect because we've got

plenty of people available, but I know some facilities that this is going to create a little hardship on.

DR. TSE: Right, and that's precisely the reason -- originally, something like this was in the 1987 proposed regulation, that proposed regulation had those specific items in it, the regulation itself. If it become final regulation, people have to do that or come to NRC for exemption, but if it was put in the guide, people -- if they have a problem, then they can use alternative way of doing it. This is not cast in concrete, even if this becomes final.

MR. LANDERS: Would this also be considered to be covered by the emergent situations where you're going to give a massive single dose, for example?

DR. TSE: If that's an emergent situation, then you do not have to do it.

MR. LANDERS: Well it may not be an emergency, but there's only going to be one treatment, so it would certainly require two people to make the calculations ahead of time.

DR. TSE: Well if it's only one treatment, you could either -- your facility could either make a check first or if you cannot meet the 50 percent criteria maybe you want to say in my situation if I do not have a check, I have to check afterwards. So you decide what you think is

the best way to handle for those situations and this is our suggestion. We may modify these suggestions if we find out later that these things should be modified. For now, this would be a suggestion that you do the best you can or whatever you think is the best for your facility.

MR. BARNETT: And again, I think the other situation -- we don't do all of this, but I understand at a high dose rate remote after-loader, you know, the whole treatment may be ten minutes. It's going to be hard to get all these things in at 50 percent and everything else.

DR. TSE: Same situation.

MR. BARNETT: Well the understanding is the rules have got to be able to take those things into account, or the guidelines, because they becomes rules I guess, or something.

DR. TSE: Right. And that's why currently it's working this way. With your comments, if there's a problem, it may not be exactly this way. Maybe we'll say for example, you do whatever, maybe with your suggestion, perhaps we can modify those. But anyway, the question is some people make errors, how do you make sure that these errors are not propagated into a misadministration. That's the main thing.

MR. CLARK: This debate on item number 4, I'm not involved in radiation therapy, but I would like to take the

correct information back to those who are. I don't understand the debate over number 4.

DR. TSE: Number 4?

MR. CLARK: Yeah, under 4.8, number 4 down under 4.8.1.

MR. BRIGDON: Oh, 4.8.1.

MR. CLARK: That was the point you were just debating?

MR. BARNETT: No, no, it was 4.8, the 50 percent. If the whole treatment only lasts like ten minutes to do all of the calculations, at the 50 percent point, it's kind of hard to do.

MR. CLARK: Okay, I see, I didn't understand. I want to get the correct information back.

DR. TSE: Sure, please ask. Whatever you want to know or you have a question, any question, please ask because we are involving three different separate disciplines; like diagnostic, radiopharmaceutical therapy, rad therapy.

Okay, 4.9 toward the end of the page is just that in emergent situations you need to do something different, the purpose of this is not to interfere with the emergent situation. If the physician feels it's an important treatment, he should treat the patient first. If that's the case, go ahead.

Yes?

MR. TELFORD: In the last line, it says "will be performed within two working days of the treatment."

DR. TSE: Right, you would go ahead and do it first and then check later.

MR. TELFORD: You mean policing the treatment or end of the treatment or when? Did anybody ask that?

DR. TSE: I think everybody understand that.

MR. TELFORD: Oh.

DR. TSE: It's at the end of the treatment. Some people in other workshop had this question. Middle of treatment, before, after. We said the conclusion.

Okay, now we're finished with brachytherapy, the next page will be teletherapy.

In teletherapy, it's similar to brachytherapy for some items; 5.1, that authorized user shall review the case, which is for all therapy, that's the same thing.

Item number two, the authorized user should write a prescription. Now here is the words "treatment plan" If you read the third line, I wonder if anybody have a problem with the words "treatment plan" here. Is it understandable what we mean, or not? If not, please let us know. Perhaps we can use different terms for the future.

MR. LANDERS: That's clear to me. However, I question what do you mean by treatment modality. Are you

meaning the beam?

DR. TSE: No, like cobalt-60 versus accelerator. Somebody use -- the physician says use accelerator and --

MR. LANDERS: So you're talking about the specific beam of use in this thing.

DR. TSE: Because if it's accelerator, then the patient should not be given cobalt-60, that's a different mode.

THE REPORTER: Excuse me, I can't hear you, Doctor, would you repeat that last one?

DR. TSE: I said that's a different mode the physician would like to have.

MR. LANDERS: So if he makes a prescription that we will treat this patient on the cobalt unit until the patient is discharged from the hospital, at which time we will transfer them to this 6MD unit, that's okay.

DR. TSE: Excuse me.

MR. LANDERS: If the physician makes a prescription that we will treat this patient on the teletherapy unit until discharged from the hospital, at which time we'll transfer them to a 6MD accelerator, it's okay?

DR. TSE: It's okay if the physical prescribes it. But the question here is that somebody -- physician may prescribe for accelerator unit, somebody make error to bring

this patient into the cobalt-60 unit, which is contrary with what the physician requests. That's why we need to put down is this for cobalt-60 or for accelerator.

Any other question on this 5.2?

(No response.)

DR. TSE: So the word "treatment plan" here may be a little bit clearer because the longer sentence included other words in here that in the other -- the objective perhaps we might want to think about we could use another word.

Now 5.3, for the teletherapy patient, the physician, authorized user physician may also change the prescription. It's not necessary that the first prescription has to carry all the way through because unusual circumstances, maybe the patient has a reaction or something, so the physician says no, I want to skip a day or something, which of course he can do.

MR. LANDERS: And frequently those changes are made by phone. Is there a problem with having the change written in the chart, signed and dated at a later time?

DR. TSE: If you feel that it's necessary. Remember all these are just suggestions. If your hospital has certain problems with the physician some way or other and he wants to make the change, you can. But the problem is on the phone, the person who receives on the phone will

write down exactly what the physicians says. That's the question.

Yes.

MR. KAPLAN: One thing that came up, at least at the first workshop, was the recording of something in the patient's chart or in another appropriate record. I wonder if anybody here has a problem with that, another appropriate record.

(No response.)

DR. TSE: Do you always write it in the patient's chart or you could have different pieces of paper which may not be in the patient's chart?

MR. LEE: They're probably in the same areas, but for simplicity -- for ease I mean. If you've got two or three treatments and you say let's decrease a dose or skip a day, then they don't know that. For simplicity, I think it'd probably be best in one place, is just my opinion.

DR. TSE: In some hospitals they do that, but is it possible at other hospitals they don't put this sheet of paper in the patient's chart -- that's certainly possible, which in here, as long as you record it somewhere --

MR. LANDERS: Yeah, what do you mean by chart there, do you mean the hospital's chart or --

DR. TSE: The patient's chart.

MR. LANDERS: -- radiation oncology chart. The

hospital's chart is irrelevant for the radiation oncology department sometimes.

MS. RHODES: Are we talking about in-patient?

MR. LANDERS: Either, it doesn't matter. We have a separate radiation oncology chart.

MS. RHODES: Okay, for in-patients, when a patient goes down, their hospital record goes with them, their in-patient record and everything is recorded in there. The physician will write a physician's progress note and then there's a separate sheet for radiation therapy that they record dose and what they did.

MR. LANDERS: And that goes in the hospital chart?

MS. RHODES: Yes, it does.

MR. LANDERS: I don't feel that's necessary as long as the radiation oncology department maintains their records.

DR. TSE: Well that's why we have "or", so you can do it either way, as long as there's some kind of record.

I guess most departments would have those records.

Then under 5.4, after the dose fraction, somebody should write down the administered dose. And here again, it's the same discussion we had earlier.

MR. BARNETT: Is it? I think this is a different point.

MR. LANDERS: Yeah. Is it enough to say that if

you don't indicate disagreement, that it was agreement?

DR. TSE: I think --

MR. LANDERS: Is it sufficient to just say treatment and not indicate agreement?

DR. TSE: I think that the workshop -- participants in other workshops essentially said we don't need an extra column to say agree or disagree. If you write out the prescribed dose and administered dose, you automatically see it. If it's different, you've got to do something.

MR. LANDERS: Well we could have a disagree column, sure.

DR. TSE: Maybe you don't even need any, but if you detect a significant difference, you need to take some action to alert somebody to the problem. If it's within the tolerance level, then you say that's good enough.

So we may or may not need it the way we suggested to have those columns, but actually, according to the participants in other workshops, we may not need such a column, and if you agree we don't need such a column, don't put such a column in, you're wasting your time to say yes or no, which is so obvious. But if you like it, do it.

Please.

LT. COMDR. PULCRANO: Another thing that came up concerning the technician writing in the chart the dose

delivered and everything, it says here "signed". Okay? We have our charts set up so that the technician will initial in a little bitty square. If you're going to say we want a signature, we've got to redesign the whole form.

DR. TSE: I don't think so.

LT. COMDR. PULCRANO: Are initials okay?

DR. TSE: The intention is that -- this is of course a guide, anything you want to do or not to do is okay. But the intention is that somebody can trace who did that in case there's a problem. If you have initial and you know who this person is, then no problem.

LT. COMDR. PULCRANO: Okay, thank you.

DR. TSE: Yes?

MR. BARNETT: On this lack of agreement, is that say primarily a machine malfunction? What are some of the things that you're looking for there? Because anything that deviates from a prescribed dose or say if they made a calculation error and it was picked up the next day, how is that handled? Is that an agreement or disagreement?

DR. TSE: This particular item is right at this time when you finish, record what dose was given, or sometimes it could be the time. Some people say 1.5 -- but when he records this, he will look at what was supposed to be given. If he made an error or something is not right, for example, he thought it was 1.8 and it turns out later to

be 1.3 but he gives a 1.8 to start. This would be disagreement.

MR. BARNETT: But they would record the 1.8, right, not the 1.3 or something?

DR. TSE: If both items are error, he could not find it. But one item is correct, the other item is in error, he would find it. If he finds it, he would let somebody know about this disagreement. What we say here is it doesn't say disagreement, but it's essential to meet the other objectives, an intended deviation should be reviewed and evaluated. If you find something is wrong in what you supposed to give versus what you give, then you should evaluate to see whether that's within the tolerance, outside the tolerance, whatever.

MR. BARNETT: Maybe my question is the difference between say the number of -- well teletherapy units, the amount of time you put in versus dose. I mean I would think the intent -- and the assumption here is a qualified person is the technologist, I assume. I think the general intent is that they're going to agree that they're trying to set the proper time to deliver the proper dose.

DR. TSE: Right.

MR. BARNETT: Okay. And I was just kind of curious, even though they didn't deliver the proper dose, they would -- at the time they delivered it, they would be

in agreement that they would be delivering it, even though there was an error there, because I don't think they would intentionally deliver a treatment that had a lack of agreement with the prescription --ma be that's what I was trying to say.

DR. TSE: Okay, that's true. If this technologist believed he read 1.8 and he saw 1.8 and he recorded 1.8 and then he took a look, still 1.8 -- then he does not discover anything, everything agree.

MR. BARNETT: Right.

DR. TSE: But if he thinks he saw 1.8, he set the machine 1.8, he finished and come back to write down 1.8 and he said oh, this is 1.3, I misread it, then he discovers the disagreement.

MR. BARNETT: Okay.

MR. LANDERS: Now is this something that, as far as you're concerned, if a correction is made for on the spot, the disagreement disappears?

DR. TSE: No, he will have to check with his supervisor, whoever.

MR. LANDERS: Well I mean, you intended to deliver 1.8, you deliver 1.5, so then you go ahead and deliver .3 more.

DR. TSE: I think you probably should let the supervisor know too much and if it's too much perhaps the

next time they can --

MR. LANDERS: I'm thinking of an under.

DR. TSE: If it's under, the physician may say you do a little bit more, maybe say do it next time.

MR. LANDERS: No, I'm talking about in the same session, the session is still under the machine, the tech set the timer for 1.5, it should have been 1.8 --

DR. TSE: Oh.

MR. LANDERS: It cuts off, he sees I gave 1.5, dials in another .3 and delivers it.

DR. TSE: I think that's what your hospital procedures --

MR. LANDERS: Okay, that's up to us.

DR. TSE: Yeah, how we do it I'm not quite sure exactly. Each hospital may have a different procedure, but the point is that if you want to do something different, the technologist should not order a procedure unless he is told to, he should follow the physician's order and if something is wrong, he should report it.

Any other comments?

LT. COMDR. PULCRANO: You noted here in 5.4, you just said qualified person, can we take that to mean the same qualified people as you listed previously? Somewhere in here you said authorized user, physician under authorized user, technologist. Is that still the same?

DR. TSE: I think so.

LT. COMDR. PULCRANO: Okay.

DR. TSE: The qualified person is determined by you.

LT. COMDR. PULCRANO: By us, okay.

DR. TSE: 5.5 is a weekly check of the daily cumulative dose. Does anybody have a --

MR. LANDERS: Yeah, again the noisy corner over here. I have a problem with that, I don't have a problem at all with performing a weekly chart check, but when somebody tells me what I need to do is check the addition, my response is that a prescription should never say treat until the numbers add up to such and such. There should be a dose of 3000 rads in 15 fractions. Now you say okay, obviously that's 15 200's that are supposed to add up to 3000. My point is that I don't think we should make this so specific that we say we have to check the additions. We do it, but my goodness. Far more important than this is to check and make sure you didn't write down 17 treatments instead of 15, if you're using a horizontal chart.

DR. TSE: The intention here is that in the past some people added things wrong and not discovered it.

MR. LANDERS: But that implies that they're going by the sum of the column instead of the number of treatments, for example. The number of treatment is just as

good, if each treatment is the correct fraction, the number of treatments is more important than the total. What's the distinction there?

DR. TSE: But does somebody have different dose in different treatment? If some people --

MR. LANDERS: Sure, yeah, that's a deviation.

DR. TSE: Right, but you cannot add the number of treatments to get the sum of the dose.

MR. LANDERS: Correct.

DR. TSE: Okay, so if your facility each time is the same, then that will be essentially okay, just add the number of fractions times the dose per fraction -- it's the same thing, it's the same check. But the problem -- the intention is to check somebody added wrong, then you have a wrong total.

MR. LANDERS: Also another problem I have with that is that in many situations, I record given doses in charts instead of "a tumor dose" and they don't add up to the prescribed target dose.

DR. TSE: You mean the prescribed target dose is different from the recorded dose?

MR. LANDERS: What I'm saying is that in the chart sometimes I record not the target dose, but the given dose to each port, the dose at max to each port. When I total those up, the totals are not the target dose total. It

doesn't do me a whole lot of good to check those totals. It's more important that I need to check the target doses and they're not available to me to add up in that particular way. It's just a problem I have.

DR. TSE: Right, but do you have a correlation?

MR. LANDERS: Oh, yeah.

DR. TSE: Okay, if a qualified person for that weekly check, can he make a quick correlation are they close enough or not.

MR. LANDERS: Not always real quick, but he can make the calculation.

DR. TSE: Well the problem is that are you sure that the additions are right after that week, and if they're not right, better to discover at that time rather than at the end. At end it will be finished and depending whether it's ten percent or not ten percent, you may have a problem.

So if it's a different dose we're using, a qualified person should be able to convert the one to another, and to still check whether it's okay or not or have errors or no errors.

Any other questions?

(No response.)

DR. TSE: Then 5.6, 5.6 essentially is similar to the brachytherapy, checking for calculations, manual calculations, computer calculations or combination. But

this says 25 percent of the prescribed dose. Now in some cases may be okay, some may not be okay. What do you think about this particular element? Any questions, comments?

MR. LANDERS: Same comments we had before.

DR. TSE: The 25 percent.

MR. LANDERS: Sometimes we do only three fractions, sometimes two fractions, sometimes one fraction.

DR. TSE: Right, that's why some other people in other workshops suggested maybe three fractions and 25 percent. So again, if it's a target fraction and it's 25 percent, so perhaps in your facility if you have three fractions or one fraction, you may want to prescribe the check beforehand or you might have people to check afterwards. But you still need to be check to be sure if something is wrong.

Other than that, other questions?

MR. BERK: Do you think it is too restrictive to have in there before any dose is administered, it's checked? Because we do, we have two people check it before a patient is administered.

MR. LANDERS: I don't have a problem with that, but I know a lot of places that would. And I don't think we need to increase the cost of medicine that much, in some places, requiring the hiring of additional people. That's the concern that I have, it's an onerous problem for some

facilities.

DR. TSE: That's true, that's the reason we use a performance proposed rule and this can vary depending on different facilities, but the intention has to be somebody's got to check. But when you check it, depending how available personnel is. We don't want to have somebody -- you must hire another person to get independent check, may not be necessary, they can do something else.

Okay, any other comments?

(No response.)

DR. TSE: Then let's do 5.7. Now this, somebody said that we have different layers of check, check the check and so on. And almost like a nuclear reactor system here, triple redundancy. But in this particular 5.7, after you perform certain full calibration measurements -- not all -- you should have independent check of the output and the independent check, how you check is described on 5.7.2, essentially one way is to use another independent physicist with independent instrumentation, another is to use TLD.

Any questions, comments? Please.

MR. BARNETT: What if you have -- okay, is this an independent check, suppose you have two physicists within the same physics group, each of which has an independent dosimetry system. Is that independent enough or do you have to go outside that physics group to perform an independent

calibration?

DR. TSE: No, in this particular paragraph, it does not say you have to go outside. 5.7.1, but again the person check -- it's another person who did not do the original computation.

MR. BARNETT: Okay, now how about if the calibration of the two instruments is tied to a single NRC -- I mean accredited calibration?

DR. TSE: I think if it's accredited, it's probably okay.

MR. BARNETT: But one primary and one secondary system. Is that considered independent enough?

DR. TSE: What do you think? Is that independent or not?

MR. BERK: To me it is.

DR. TSE: If the calibration is based on the -- let's say I have instrument A and instrument B. If the calibration of this is based on that, then that's two tied together, they are not independent. But if they have a different calibration tied into a standard, then it would be independent.

MR. BARNETT: If the accredited center calibrated the primary dosimetry system and one physicist used your primary to calibrate that unit. Okay, and then your primary calibration system is used to cross calibrate your secondary

system, and then your other physicist used that, is that an independent check?

DR. TSE: Well I think that the problem is whether the second instrumentation is solely dependent on the first. If it's solely dependent, then if this is wrong, that's wrong too. But if you have the third source check against this but this is a cross check, then that's not a primary, the primary is this way, that would be independent. So I guess each facility, you're all knowledgeable, maybe you want to make a decision if they're direct tied in. Then if this system is wrong, then that automatically would be an error, and the same error and you would not find it.

MR. BARNETT: Yeah, but at the same time if you use it for more than one -- I mean that's true if you use one piece of equipment, but it's unlikely that you'd have several different loose calibrations.

MR. LANDERS: Just a general comment. I like this idea, I see some problems for some remotely located facilities who have trouble getting even one physicist to come by, so I foresee the solution to this is mail in calibrations and I wonder if the places that have that service available are ready to handle the volume of business that this may thrust upon them.

DR. TSE: If you'll look at the -- when do you need this independent check, it's not annual calibration.

MR. LANDERS: Correct.

DR. TSE: And the other kind of calibration measurement is not very frequent.

MR. LANDERS: Right.

DR. TSE: So it's not a big volume because maybe once five years or something. Annual calibration is not needed because you always will be able to check against the decay to be sure you're right.

I have spoken to --

MR. LANDERS: You're probably right, this is probably a small perturbation loss.

DR. TSE: Right. Okay, then let's go to next page -- oh, excuse me.

MR. KLINE: I'm sorry, I just wanted to bounce off, it was brought up a minute ago under item 1 of 5.7.2 where let's say you have two physicists in a facility, a full calibration is performed after a source change, those two physicists work together on initial calibration under a set of conditions, let's say a particular output that you're verifying. In order to satisfy having an independent physicist perform a function or perform the output check of the other physicist, do you see any problem where you've got two physicists working together and they come to the same conclusion and all of a sudden you take one of them and he does the same output check himself? Would there be any

conflict?

DR. TSE: Well I think under this item --

MR. KLINE: Well I know often to expedite things your physicists are going to work together after hours. You know, the clinic's closed down and you're working in the evening, so you double up. Is that considered somewhat of a conflict or not?

DR. TSE: Well I think that if the physicist is not involved with the full calibration -- he's not doing the full calibration measurements, we have to -- in my view, he could independently check on the other physicist. It doesn't mean that two physicists working in the same hospital have to have a conflict of interest there, they are independent professional persons. But if both of them involve fu l calibration measurement together, then both are working this full calibration measurement, if they check on themselves, they might have some errors which they may not be able to find.

MR. KLINE: Yes.

MR. BARNETT: So we're talking about a third physicist being involved.

MR. KLINE: No, we're talking about the TLD.

DR. TSE: Yes, the TLD is a possibility.

MR. KLINE: Yeah, it's very identical to the dosimetry system, if you have an error in one, you're going

to have an error in the other. If one physicist believes the chief physicist is correct, he's not going to question his method of performing the calculations. It could be a very similar sequence of a comedy of errors. Sot it is an impact if you don't use a TLD system. But I don't see how you can get around it.

DR. TSE: That's why we put the TLD.

MR. BERK: Question about TLD's, we have our own TLD service that we do ourselves routinely. We're not accredited. But we use it like to check when we do total bodies, we will put TLD's on the patient to verify dosage. We would use it routinely and we have a technologist who is trained and was sent to school on how to use TLD's and I've used it to crosc check calibration on a gamma unit, gammanite. Are you saying I can't do that, I have to sent them out? I can't use my own TLD system?

DR. TSE: I think the answer to that is that if your TLD system, you have a certain percent, plus or minus five percent, if you have a certain -- you can establish a certain percent error --

MR. BERK: We would have less than two percent error on the gammanite, between TLD's and ionization chamber done by two independently different people, two independent systems.

DR. TSE: If you are sure that -- actually

accredited may be misleading -- maybe we might change it, somebody in another workshop said what's accredited, maybe we could change it to accepted so when you write your program, you say my TLD is checked against certain things, I want to use that. But has to be relatively simple, if it's 20 percent, that might be a problem.

MR. BERK: Well within two percent.

DR. TSE: Any other comments?

(No response.)

DR. TSE: Then we'll go to page ten, 5.8. Under current regulation, full calibration measurements does not include the transmission factors for the beam modifying devices, so sometimes they have a wrong transmission factor. So here, we suggest that perhaps those should be measured. Anybody have any comments, suggestions? Do you normally measure them, transmission factors?

MR. LANDERS: When wedge trays get broken and the wedges are remounted, certainly we measure them.

DR. TSE: How about annually?

MR. LANDERS: If the edges of the trays are not worn off or chipped or anything and the wedge is receding in precisely the same way all the time -- I'm not sure I understand the reason for remeasuring that wedge factor.

DR. TSE: Annually.

MR. LANDERS: Certainly it makes sense to do it.

DR. TSE: The problem sometimes is it shifts a little bit or dropped or whatever, would that be changing the wedge factor?

MR. LANDERS: Oh, yeah, if you get a little corner of the wedge chipped and it doesn't replace properly, certainly that makes a difference.

DR. TSE: So this is the kind of suggestion you need, those kinds of things, perhaps you should do it -- perhaps.

Okay, 5.9 is essentially a similar kind of situation. If you conduct a measurement and it's a certain size, field size and it's not been measured before and now you want to use a size either smaller than the smallest you measured or bigger than the biggest you measured, should you measure -- I think some people suggest that should be done. And we indicated like 25 percent so it's unnecessary to stop working on this patient while you measure. Do you have any problem with the 25 percent?

(No response.

DR. TSE: Okay.

Now the next item, 5.10.

MR. LANDERS: I've got one there.

DR. TSE: Yeah, I knew you would. Let me -- whoever want to speak first, please. Now for other people, the idea is this, when you use a new program or your

machine, the sources has been changed, the original 5000 curies are too low, you put 10,000 curies in the source, this particular item says you should use your computer program, make a calculation, let's say 200 rads per minute and certain configuration, then you set up your machine and at the same configuration expose to a TLD and it should almost read roughly 200 rads per minute. If you don't read that way, you have a little problem, 300 or 100 you've got problem. That's essentially what this says. So let's hear some comments.

MR. LANDERS: Okay, from this corner, first of all, there are questions involving whether the manufacture should have time calculators built into their isotopes computers anyhow. That beside the question, there are certainly some computers that do not have absolute dose rates built into them and for those computers, this is completely out in left field. It doesn't matter what the calibration of the teletherapy unit is, if the computer works in given dose as opposed to minutes, it doesn't matter.

MR. BERK: What about open field in air, none of them have that.

MR. LANDERS: If a computer won't make a calculation at 45 degree angles that's the same, I'm not going to use it anyhow. I don't understand.

MR. BARNETT: What's the intent of number one, I didn't understand the intent.

DR. TSE: Okay, let's talk about the fundamental first. These are conditions under which -- do you have a problem with the theoretical purpose of this?

MR. LANDERS: Yes, I do. For a new computer, I've got no problem at all, for a new computer, new software that needs to be checked out. For an existing computer that does not work in minutes or time units for a teletherapy unit, it doesn't matter what source I have in my teletherapy unit, it doesn't matter what kind of radioisotope it is or what strength it is.

DR. TSE: Right you're working on relative --

MR. LANDERS: I'm working on relative outputs.

DR. TSE: What's in there is that you work on relative dose, go through your manual calculation to verify the dose because if it happened previously in the past -- happened in the past, somebody forgot to change it and it could cause problems. But your procedure may still have 5000 rads worth of decay in it, but you actually already changed -- let me stop there, sorry -- 5000 curies in it, but your source comes from new source. So when you go through this procedure, if for some reason your procedure does not have the new source strength in it, you will find it because it will not match. Now how to measure, that's a

separate part. The intent is to make sure your procedures include the computer code, include the manual calculation together, they should match the measurement. If it doesn't match, something else is not right and it should be checked. If they did that, they could avoid that misadministration.

MR. LANDERS: It's just scary to see something like this that might filter down to the states who will absorb it and apply it to everything.

DR. TSE: The details they already have.

MR. LANDERS: You don't think they'll take the regulatory position?

DR. TSE: No, no, I mean items 1, 2, 3, those are the details.

MR. LANDERS: Right.

DR. TSE: The intent is that you should cross check. Do you have a problem with the intent?

MR. LANDERS: Yes, for those computers that work on relative output, even the intent I question. If there's no absolute dose rate built into the computer, even the intent I question.

DR. TSE: Okay.

MR. LANDERS: But only for a new computer you justify, you verify, you make sure that it's calculating properly, but after that, the concept of dose rate should never enter into it.

DR. TSE: Let me ask you this then, how do you verify your procedure because you have computer calculation versus -- not versus -- and that sets up with a manual calculation to get either time or dose, is a correct way after you change it.

MR. LANDERS: That's in the manual calculation part, the computer doesn't have anything to do with it.

DR. TSE: But you need to go through that. Maybe then the question is if you use manual calculation you only verify by the manual calculation, maybe that's a solution.

MR. LANDERS: Yeah, fine. As long as -- I'm just worried about the future, I don't want this to come down to say that I have to go in there and do a lot of exercises on my computer that are totally irrelevant. And if they don't include the absolute dose rate, then they are irrelevant.

DR. TSE: So the comment is that if the computer involves the actual dose calculations, use the computer.

MR. LANDERS: Oh, yeah.

DR. TSE: If the computer use relative calculations and the source is input under manual calculations, then you just use manual calculation.

MR. LANDERS: Right, because the computer then tells me what given dose to give and I go manually and use the dose rate to calculate the given dose.

DR. TSE: Okay. Now in principle, you think you

should check, right?

MR. LANDERS: Oh, yeah.

DR. TSE: Now let's talk about items 1, 2 3 of -- now let me first qualify, I'm not a medical physicist, I'm an engineer. People made the suggestion to us there are other ways to write this. What do you think, these are appropriate, are not appropriate, you would do it differently, much simpler but achieve the same goal or what?

MR. LANDERS: For number one, I would just do it at two different angles.

MR. BARNETT: Well I think even the question for number one is what are the two things you're comparing. I certainly know what the measurement is in number one, but what is it you're going to compare from the computer? In order to make a comparison, you have to have two things. I think we all clearly know how to measure open field in air at eight angles to get an isocenter, we don't have any problem about that. What is it that we're comparing it with from the computer though? Because the computer doesn't calculate -- that's what you were talking about -- it doesn't calculate dose rate in air.

DR. TSE: Maybe if you have a suggestion, perhaps you can make the suggestions to us.

MR. BARNETT: Yeah, a physical size panel, fixed diameter, a 20 centimeter diameter cylinder or you know -- I

have no problem with those things but right there there's no two things that are compatibly comparable.

DR. TSE: So maybe when you consider these -- by the way these are just suggestions, let me repeat those remarks -- when you -- if you think in principle this is the way we should do and you know how best way to do it, please let us know. You may not even do these things because the period is very short, two months, and those things are not generally not -- you do like every five years or so. However, it's still true if you know what's the best way to do, let us know, so we can modify or put as alternative, we can do this way or that way if you have good suggestions. So please let us know.

Okay, 5.11 --

Yes.

MR. BARNETT: I think all of these -- in (2), there's no specified position, again there's no way to correlate what you're measuring and what the computer gives you. I mean, you know, to take a 45 degree wedge and angle it 45 degree with the surface of the phantom, depending on where you put your ionization chamber, you have a whole myriad of things you can measure and the same is true of a mantle, a mantle can go anything from 40 by 40 to 20 by 20, and the configurations here -- you know, if you're going to do these -- I believe I'd like to not get this specific but

if you're going to get specific measurements, then it's got to be more specific than this because there's just too much ambiguity in the points of measurement and then I thought the biggest thing that was left out was the criteria for agreement. Suppose you got a 50 percent or 100 percent discrepancy, is that acceptable, because there was no criteria on here as terms of -- you know, are you looking for a two percent discrepancy as being okay? Or a 50 percent or a 100 percent discrepancy. There's none s' whatsoever.

DR. TSE: We purposely did not say that because it might be depending on your instrumentation of how much wa in error, measurements, calculations, so whatever you feel comfortable with.

MR. BARNETT: Well that's not stated in here.

DR. TSE: Right. Also, I think you're right, if you think -- you know the intent of this paragraph and you think you can -- there's an easier way, a better way or whatever, alternative way, you could either write it in your QA program, you may not use it for this pilot program but it would certainly provide us some additional information we could use or we could consider.

MR. BARNETT: I'll tell you another -- just in terms of intent, actually you picked about three of the hardest things the computer could do and forgot the easiest

things, whereas if you're missing the simple stuff, you know, you set the hardest configurations to check, set no tolerance for acceptable and yet a ten by ten field at a nominal SSD, you didn't ask if the computer could do that at all, a very simple calculation.

DR. TSE: Could you make a suggestion? That's very important to make suggestions to us, then we can look at those suggestions and perhaps we can include those.

Yes.

MR. LANDERS: Is it true that the final version will contain a regulatory position that will filter down to the agreement states, not that they have to use the regulatory position, but it will be sent to them?

MR. BOLLING: Oh, sure the guide would be sent.

DR. TSE: In any case, those are the public documents, anybody can receive a copy and of course our colleagues in the states would like to see those too.

Ed.

MR. KLINE: Just a comment on this 5.10 before we leave it. Certain larger departments maybe the size of the University of Virginia or whatever, will have a number of different treatment planning systems, some being developed, software being developed, some manufacturers will want to see the clinical applications. Therefore you might have two different operating systems and if you measure under the

same conditions, the data will show different values. These sort of things happen under these particular types of tight situations. You see all sorts of things that are different with different software packages. But I think you might want to stress that the intent, as you have, is that this is open for complete revision and the obvious things that you mentioned, the ten by ten deals, these sort of things. These are hard conditions for computers, you're going to see the greatest error amongst computers or measured versus calculated with these particular circumstances possibly in this example. But that doesn't preclude that some sort of calculation needs to be done to verify the software. I think that's the intent.

MR. LANDERS: Absolute.

MR. BARNETT: Yeah, I agree with that. The other thing is that I think we kind of lost in here is actually there's two levels of computer -- dose calculating computers that are available. One is the ones that just do time and monitor unit calculations and the others is the ones that we call treatment planning computers that include greater -- I think maybe the original intent -- somewhere in here we got lost, I think we went from one type of calculating computer to another without making any kind of distinction between the two.

DR. TSE: Maybe we should have two different --

MR. BARNETT: Yes, because I think the first -- the previous guidelines were more directed toward the first type, for instance you have manual dose calculations and then you have computer generated dose calculations like in 5.6. Those could be just the desk top type, you know, what we call monitor unit time calculation packages versus a full blown treatment plan system.

DR. TSE: But item three though in that section is the relative calculation and the manual calculation.

MR. BARNETT: Yeah, I mean I think they both -- I'm just saying that it applies to all of them.

DR. TSE: Right.

So I would re-emphasize if you know a simpler way to do it, let us know, but the intent is clear. How do we achieve this check, is depending on experienced people or practiced people like you are.

Yes?

MR. BERK: The other problem is for stereotactic radiosurgery, 5.10 does not apply at all. It's impossible to do those three -- we might suggest that it can't be done.

DR. TSE: It's not intended to --

MR BERK: The treatment system for stereotactic linear surgery should be exempt from 1, 2 and 3. There may be some other tests.

DR. TSE: Well would you think you -- if you're

going to write a QA program are those things you could say?

Any other comments?

(No response.)

DR. TSE: Okay, 5.11 is just the exemption. And again, this also has two working days after treatment. Now teletherapy treatment is not the whole treatment --

Okay, any other general questions? It's about 3:00, maybe I should stop. Any other general questions about the guide?

(No response.)

DR. TSE: Thank you.

MR. TELFORD: We can go off the record now.

(A short recess was taken.)

MR. TELFORD: We're back on the record. There are three items that we want to cover this afternoon before we conclude. The first is we'd like to give you a copy of the Federal Register notice that was published in the Federal Register on January 16. The reason I want to give you this copy is that is contains the reporting requirements. Please note that the reporting requirements do not apply to the pilot program. But I would like very much to hear your suggestions for how to modify these reporting requirements for the next workshop. That would give me a lot of valuable input for how to modify those for the final rule. So we can count on that being discussed at the next workshop.

The second item is the schedule of future activities. I talked a little bit about the schedule this morning, but I want to go back over it one more time. The handout that has the eight proposed 35.35 objectives, look at the last page of that which should be a schedule. There's one item on here -- I mean there's one item that's not on here and that is that we would like -- if you don't have your QA program with you today, we would ask you to please send it in on or before May 7.

MR. LANDERS: Who do we send it to?

MR. TELFORD: To Ed Kaplan at Brookhaven, the gentleman from which you got your decision letter. Now the reason we need it by May 7 is that if your facility is chosen for a site visit, our QA team needs to go through your program very thoroughly before they arrive on site, so they know what to expect. So we sincerely need it on or before May 7.

Now May 14 is the start of the 60 day trial. Does anybody have a problem with May 14? Can everybody start? Is everybody with me here? Can you all start on May 14? All right, everybody says yes. It will end on July 13. Okay, July 13, that's the end of the 60 day trial.

Then the next two weeks you will have to fill out the evaluation and write up what you think of the program, your suggestions, what you think of the proposed 35.35, the

guide, everything.

Then the post-test workshop will be in August. We'll have five more of those to do, except that it will be two days long to give everybody time to get in their input.

Now I have one more item on the agenda, which is concluding remarks, which is where you get to talk. Let me pause for a minute and check with my colleagues. Is there anything else we need to discuss before we go to that?

(No response.)

MR. TELFORD: Now, concluding remarks, everybody can have five, ten minutes or whatever you want within reason. Just say whatever you want to say, give us your impression so far of your expectation or how you think it's going or whatever you want to say.

So let's start over here.

MR. BARNETT: I have a couple of questions. Okay, we have a QA program, what do we do about discrepancies? I mean, are we supposed to keep track of how many -- and I'm also in an agreement state and we don't normally report misadministrations. So we've got this QA program and there's a discrepancy in a chart or something, do we just -- do we record those over this period of time or what do we do? Is there any recordkeeping in terms of the pilot program that we're supposed to do other than generate a QA program?

MR. TELFORD: Okay, I'll give you two answers. First records, yes. Keep a record of prescriptions, referrals and your procedures manual and the administered doses. So those are records.

The second part of the answer is I would think it would be a very good idea for you to audit your system, audit your program, so that when you come to the workshop or when you evaluate your own program, or the modified program according to the objectives, you could tell us how good it is, did it do you any good in terms of catching precursor kind of events or mistakes of any kind.

MR. BARNETT: So we have to document those one way or the other.

MR. TELFORD: But how you do that, that's up to you. Don't make it a big deal, just do it so that it's sufficient for your needs, so you can do your evaluation and you can tell us about it, because by your input, we learn from that.

Tony.

DR. TSE: In fact if you discover that this QA program is useful to identify certain problems, that would be very good to put in the evaluation sheet so that we would know the usefulness of the program.

MR. BARNETT: But you do not expect any kind of statistics in terms of the number of patients that went

through our centers, the number of charts reviewed, any information like that, you don't care to have any kind of information from us, statistics? How many misadministrations, how close -- nothing? I mean it's fine with me, I'm not looking for it, but I was amazed that, you know --

MR. TELFORD: Notice that we plan to go to 18 sites, so from our point of view, we will collect that kind of information when we go to those sites, but I think it would be very helpful to hear how well your program did. So while I don't really want to give out a list and request that everybody keep all that information, it certainly would be helpful to you.

MR. BARNETT: Even the number of charts reviewed or--

MR. TELFORD: I think you would need to keep a list of patients.

MR. BARNETT: Say how many people deviated from ten percent -- I mean, it's fine with me, I'm just surprised that you didn't want any kind of feedback other than generation of the QA program.

DR. TSE: I think we would like to have that information except we do not want to say everybody have to keep certain records by certain format and so on. Certain information that is useful, would be very useful to indicate

in the evaluation sheet and also you can bring in to the workshop so everybody will know what your experiences are. Then that will be very useful to us. So we did not specifically say everybody should keep those kinds of information because each one perhaps looks at things in a different way. And they may want to collect some information, either good or bad, to bring to the workshop or indicate in the evaluation form we're giving you, and we can properly consider the experience.

MR. BARNETT: And I guess the other thing is that includes physics measurements, so in terms of the measurements that we discussed under the ten or eleven, you don't plan for us to make or attempt to make over that period of time.

MR. TELFORD: Under 5.10?

MR. BARNETT: Yeah, whatever.

MR. TELFORD: That may be source change.

MR. BARNETT: Well I know, but I mean in terms of the pilot program, to see if these things --

MR. TELFORD: If any of you have a source change and if you use the guide, that would certainly be very useful feedback, if you can tell us what you did and how it worked. But certainly we don't expect you to go out and make a source change.

MR. BARNETT: No, but you can make the

measurements without making the source change.

MR. TELFORD: I like the full calibration.

MR. BARNETT: I don't know that you have to make a special, but an additional measurement. The measurements in Section 5.10 are new and they would not have normally been -- in my impression, would not have normally been made under full calibration anyway. And I just didn't know if you wanted an evaluation of those as well.

MR. TELFORD: Sure.

MR. BARNETT: If y'all don't ask for them, I'm not going to do it.

MR. TELFORD: We'll take it.

MR. LANDERS: It would seem like your -- you would benefit by us attempting to keep track of things that were prevented from happening as opposed to things that were found to have happened.

MR. TELFORD: Either kind of information would be very useful because if you --

MR. LANDERS: Even though when we prevent something from happening it's not recordable or reportable, you're really interested in that from this pilot?

MR. TELFORD: Yeah, one of the objectives that I had was to try and detect those things that are mistakes along the way, that don't become a misadministration but rather it's an intermediate step.

The reason we're trying to go to all this trouble of course, is so that we can have a final rule that will have a minimal impact on all of your facilities. So the more of this kind of evaluation you want to do, to tell us that the program that you developed and as modified detected mistakes, caught them, prevent misadministrations or what was efficient in detecting mistakes after the fact, that just shows that your program works and if you can show that your program works, then that's very useful information to us because that tells us what to do with the final rule. If your program is still sufficient but yet has minimal impact, then we should certainly use that as a guiding light.

Any other questions?

(No response.)

MR. TELFORD: Okay, let's go to concluding remarks. We'll start over here.

MR. LEE: I think everything went very well. I just kind of want to reiterate that the main thing you are looking for us to do specifically are these eight primary objectives. Anything else is gravy, you can use it for your advantage or whatever. Correct?

MR. TELFORD: That's right. I would like you to tell me that you have a quality assurance program that meets those eight objectives. Then the rest that's in the regulatory guide, if you want to use it, I'll be very happy

because I'd like some input on it.

MR. GIPSON: I don't think I have any specific questions. You touched on one question I had and also as far as if our institution was one of the institutions to be checked, what form -- I guess this should be used whether we expect it or not, but what form would be best to have this data in? In other words, Gary and I were talking, we meet a high percent of these, if not all of these eight, in different forms, without making a new manual like we were saying, having a road map type sketch or whatever drawn up, to where this requirement is met in our procedures manual. But say for the prescriptions for the -- I think you referred to it as a consult and referral -- what form would be best to have that in as far as if you came in to look? In other words, here's a listing of all referrals, which type of doctors, what exams, did it meet those specific indications for those exams or whatever, having a form that you want to keep it in and just having to pull X amount of charts and take out of those charts that particular information.

MR. TELFORD: It might be helpful if you had a list of those cases that you completed during the 60-day trial, but left your records in whatever form they currently are so that if we wanted to look at some sample of those, we could ask you to retrieve those records.

MR. GIPSON: That would certainly help keep down starting a new filing system or a new system for us.

MR. TELFORD: Yeah, I don't want you to do that.

MR. BERK: I'd like to offer my congratulations to whoever is responsible for having this workshop. I think it's extremely useful and sort of nice and pleasant to have a two-way dialogue between the user and the regulatory people to let us express our opinion. I'd like to thank whoever is responsible for it.

I'd like to say a couple of words also about the regulatory guide. As someone who has had many years experience as an RSO, I've always heard regulatory guides are not the law. However, when compliance inspectors come down, they sort of take it as the law. And unless you have a good justification for not doing something that is in that regulatory guide, you get cited for it, and it's very difficult to say that what you are doing is equivalent to or meets the objectives of the guide, and so again, I'd like to re-emphasize that the comments that were made about the regulatory guide really be taken seriously and not with the attitude that oh, they're just for your advice and you don't have to follow them, just go by the eight statements. Eventually -- from Virginia, the State of Virginia will get ahold of that regulatory guide and they'll just take it in total and say this is what you have to do for linear

accelerators, and I worry about that greatly and that's one of the main reasons I volunteered to come here. And I hope that there will be a second workshop, as you said, and we can go into more detail about the regulatory guide and hopefully offer more suggestions on how to improve upon it and so that it would not be an onerous burden to a big institution like the University of Virginia or smaller institutions.

LT. COMDR. PULCRANO: Coming from the military command and as most people know, the military is quite exorbitant when it comes to quality assurance programs, there was a lot of us that thought oh, my God, what are we going to have to do now. It's a good thing we came because I think we can breathe a little bit easier, I think we'll be okay. It was a good workshop.

MR. CANADA: I learned quite a bit coming here, especially when you brought out the intended meanings behind the eight objectives. I think it could have been a little helpful if we had had those, it might put us a little more at ease.

MR. WHITE: I found this to be very helpful and I'm appreciative of the examples given, it helped me to understand the guidance.

MS. GOODWIN: I found it very helpful also and I particularly enjoyed the different representatives here and

our input together. I think we can help each other as well as help, hopefully, with the guidelines and with the pilot program. I found it very enlightening in all ways.

MR. LANDERS: I'd like to say that despite my mouth, I like the overall intent of what we've seen. I particularly like the aspect of attempting to place some judgment back into the user's arena. I feel a lot better about the whole process now that I've attended the workshop. From that point of view, I think it was a success. I think it's been a good workshop and I hope that some of our comments and suggestions will be incorporated.

I wonder, as a question, specific question, should we include only new patients during this pilot study or should we include patients under treatment at the start of the pilot study?

MR. TELFORD: All of them.

MR. LANDERS: All of them, okay. And my last comment, which I'm sure many of you have heard many-fold before, is that I feel like the legal system is by far the best regulatory in medicine.

MR. FRYMAN: I enjoyed the cross section too because I don't get a chance to intermix with very many people from different entities. For instance, I don't even know where our nuclear medicine department is. I've made it a point not to learn where it is. Now I guess I'll know

where it is anyway, but I've enjoyed hearing the other concerns and how this is going to impact them and now me too. So it's been nice to have one-on-one with people who actually formulate some of these ideas.

MR. BARNETT: We appreciate being included in getting ahead of regulations and then the same thing, we'd like to point out that from our standpoint or my standpoint, again as an end user of the guide, regulatory guide, is that that's very important to us because that's -- the guide is used very specifically for what is expected of the sites that we're all involved in and that's why we feel very strongly if we can influence some of the things there, then I think we've done well and we appreciate being able to participate.

DR. TSE: I want to thank everyone to come here today and give us some suggestions. I want to especially assure everybody we are listening, we will change all rules and guides in accordance with the comments, reasonable public comments, and reasonable suggestions given to us. When you prepare your QA program, if you feel that certain things would meet the same objective, please put it in there so when we review the QA program, we know what you think. It's also opportunity to meet the intent, perhaps those things in the regulatory guide, the regulatory guide would not be exclusively one alternative, perhaps we can have

several. That way we can solve the problems we may have. We handed out the proposed regulation, there are important requirements on misadministration, modified misadministration requirements in there that we did not discuss today. Please review things and if you have any questions, you can call me. My phone number is on that document, and next time we'll get to discuss those.

Thank you for coming.

MR. BOLLING: I'd like to again thank everybody for coming. I think that any time the regulators get together with the license community in an atmosphere separate from an inspection action or licensing action, that we all seem to learn something.

My specific job and my main reason for being here is that I have to take some of the NRC regulations and reg guide and boil them down into language that's acceptable to all of the states, agreement and non-agreement states, into something called the suggested state regulations, and those regulations go out to all 50 states and basically what it means is that I am in interpreting NRC's regulations and directives and the states then will use it to regulate you people, so obviously I've got to get it right and they've got to get it right. We talk about it at training courses throughout the year and we meet -- state regulators meet at least twice a year and discuss it there too.

Again, I'd just like to say thank you for all the volunteers that have come out to help us and look forward to that second meeting.

MR. KLINE: I walked in in the middle of his comment here, I apologize. This particular rulemaking process is quite unique in the sense that -- I guess it's somewhat unprecedented -- where the licensees are pretty much determining the rules that they're going to play by. It means that you're developing your own rules for which you can run your department. It's a little bit unusual from the previous experiences you might have had where there are very prescriptive rules, you have to do it this way and whether or not you believe in it, it's in the regulation and therefore it must be fulfilled in order that you're not in trouble with the NRC. I think the mechanism that is now allowing you to write your particular needs specific to your particular environment is a great way to go. I think medically it's somewhat of a deviation from the way in the past things have been done and I think it's good, I think it's the best method to use. That philosophy is what I would think most people would want to get out of this document or these documents we've been discussing today. None of this is hard in concrete, it's broad topical areas open for any modification justified or review, and looking at it in that manner, it carries a lot of weight. So I

personally think it's a good mechanism where you can have an impact on some rulemaking applicable to your particular facility.

The other area I want to comment on, just touch on, I don't know if I necessarily want to make this any endorsement, but there are other agencies that hospitals are quite concerned with regarding quality assurance. You might want to look at your total picture. I imagine that there are certain hospitals that have quality assurance managers that are aware of the total quality picture, meaning certain guidelines, certain agencies, certain bodies that are generally accomplishing all quality -- you might want to look at the total picture where the NRC can maybe fit into this quality assurance program for the whole hospital and that way you might find that there are other reasons that you can use this rulemaking process in your own specific institution, not to make you feel like it's a rule process specifically only for this one agency. And that might be something you might want to consider when you start looking at your quality assurance program.

I thank everybody for coming and participating, it has been enjoyable.

MR. KAPLAN: Well I have a personal thanks, you've been very cooperative when I've called you and told you about this and listening to your pregnant pauses and saying

oh, my God, there's another program, should I participate. You've been very, very cooperative and very professional, especially recognizing the fact that you'll have an impact on rulemaking, more so than just a simple letter coming in.

So that's been very, very useful to me, to know that I can call you and you are cooperative. And I would like to just mention that one thing that would make our work much easier is this thing that we've talked about as a road map. If you could be very explicit in telling us -- using just the cover sheet, one page perhaps -- where to look in your QA programs to satisfy the objectives that were discussed here, it would make our evaluations of your programs much easier. Please don't forget that when you send us the QA programs on May 7th. So thank you for being here and I look forward to seeing you in mid-August.

MR. CLARK: Like so many other people have expressed already, I appreciate the opportunity to contribute to a project like this. The more simple that you can make a regulation, and understandable, the easier it is to comply with. Nobody wants to make an error, everybody wants to detect errors and make them correct. That is going to take a conscientious effort by the people doing it in any situation, and we are in a pretty serious profession and nobody wants to make a mistake. Just the more simple the regulation is, the easier it is for us to comply with.

MS. ROBERTS: I think it has been very interesting and informative and I agree with him, and it has also given me some insight on how I might could modify my program and I feel that it's been an honor to participate.

MS. RHODES: Well I've certainly learned a lot today. I don't think they should let me run the linear accelerator quite yet.

(Laughter.)

MS. RHODES: We have needed for some time to redo our quality assurance program in radiology -- I'm glad you brought that up -- and I think we can format this so it will take care of your needs, Joint Commission needs, state licensing needs, so I think it was a wonderful opportunity.

MS. ROY: Well I thank you for inviting a small out-patient facility to be involved in this law-making workshop. It has been an experience. There are certain things that of course will not affect our facility at all, but other ones that will and other ones that I was thinking about. There's more and more out-patient facilities opening up. The State of Florida is becoming populated by single cameras in doctors' offices. And even though a lot of these rules and regulations are made for hospital based programs, there are certain things that should be said and I will put them into my quality assurance program that I will send to you, for just out-patient facilities. For nuclear medicine

is where I'm thinking mostly because I don't know anything about therapy, the most I know about therapy is what I've heard here today.

The quality assurance programs that hospitals have and the guidelines that they have, out-patient facilities aren't under those guidelines and so many variations can be with them that I think they need to have other things. I know that more rules and regulations for anyone to follow, nobody wants them but ultimately it's for the patients' safety and their well-being and that's something that we seemed to pass over today, we were all thinking about complying with new regulations and looking at new annual inspections and more paperwork for us, but we weren't looking at the patient safety as the end result of all this extra paperwork and I think that we all need to look at that.

In our facility, we're very much aware of the patients themselves and we spend time with them and I know other facilities don't have the time to spend with them, maybe because of all the paperwork, it's a catch-22 situation, but I think that we ought to make sure that we keep that in mind.

The other thing is that the August meeting, I don't know about anyone else, but all vacations seems to end up in August and that may be a difficult time, I know for

myself to get here to a two day workshop. I don't know about anybody else, but I know most departments hit their vacations in August, so you might want to consider that.

That's about it.

MR. GARRISON: I've enjoyed it, I think that I feel really privileged to be part of it. This is the first time I've experienced anything other than inspections with the NRC and I just feel like I learned a lot and hopefully I can have some input into the final rule.

MR. TELFORD: Well I -- oh --

MR. BAHADUR: Can I say something?

MR. TELFORD: I guess so.

MR. BAHADUR: It has been so nice to be here, I've enjoyed the workshop and as Ed said earlier this could have been different if you hadn't cooperated and decided to come here. But other than that, there's one more factor which has made this workshop the way it is and that's the hours of planning that has gone behind it and the people who have done that are John Telford here, Tony Tse, Lloyd, and they were helped by the able contractor Kevin and Ed from the Brookhaven National Lab.

Let's give them a hand.

(Applause.)

MR. BAHADUR: This is probably the first time somebody came from Washington, D.C. that was really helpful.

(Laughter.)

MR. BAHADUR: So when you go back to your facilities and start in this pilot program and enforcement, just remember one things, those eight objectives that John talked about this morning is only part of the object. Keep your eyes open to see how the rule is really affecting your day-to-day life. Is it making life easy or is it burdensome. Make notes of those so when we come back in August, we would like to hear about that.

Thank you.

MR. TELFORD: Kevin.

MR. NELSON: I'd just like to say a few things. First of all I thank you all for coming, I enjoyed listening to your comments and speaking of comments, again I want to really stress that we need your comments. We went through a lot of time and effort to select not only large institutions that maybe have a number of these different areas that are covered, but also smaller facilities. So please take some time and write down your comments on the evaluation form. If you don't like 5.10, here's another chance to have input. If you feel there's something that could be done better that you use in your institution, here's a chance to put that down.

Thank you.

MR. TELFORD: Anyone else?

MR. HILL: For all of you not from Georgia, I hope your stay has been a good one. We're glad y'all came. It is a precedent setting method or approach to rulemaking and I appreciate all your input, being a regulator in an agreement state, it's going to come back down and we're going to have to work out the same rule, the same set of licensing guidance. I think your input is quite valuable not only to the NRC but also to agreement states. Thank you.

MR. TELFORD: Anybody else?

(No response.)

MR. TELFORD: I thank you for your kind attention. I've enjoyed the workshop today and I look forward to the next one.

(Whereupon, the meeting was adjourned at 3:42 p.m.)

C E R T I F I C A T E

This is to certify that the attached proceedings before the U. S. Nuclear Regulatory Commission in the matter of:

Name: PILOT PROGRAM WORKSHOP

Docket Number:

Place: Atlanta, GA

Date: April 6, 1990

were held as herein appears, and that this is the original transcript thereof for the file of the United States Nuclear Regulatory Commission taken stenographically by me and, thereafter reduced to typewriting by me or under my direction, and that the transcript is a true and accurate record of the foregoing proceedings.

WILLIAM L. WARREN

Official Reporter

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