OFFICIAL TRANSCRIPT OF PROCEEDINGS

Agency: Nuclear Regulatory Commission

Title: Workshop on Pilot Program Objectives (Proposed 35.35)

Docket No.

LOCATION: Irving, Texas

DATE: Wednesday, April 18, 1990 PAGES: 1 - 217

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

- - - - - - - - - - - - - - - - - - x
:
WORKSHOP ON :
:
PILOT PROGRAM OBJECTIVES :
:
(PROPOSED 35.35) :
:
- - - - - - - - - - - - - - - - - - x

Conference Room 8
Holiday Inn
4440 West Airport Freeway
Irving, Texas

Wednesday,
April 18, 1990

The above-entitled workshop was convened, pursuant to notice, at 9:10 a.m.

PRESENT:

JOHN L. TELFORD, Chief
Rulemaking Section
Regulation Development Branch
U.S. Nuclear Regulatory Commission
Mail Stop: NL/S-129
Washington, D.C. 20555

ANTHONY TSE
Office of Nuclear Regulatory Research
U.S. Nuclear Regulatory Commission
Washington, D.C.

LLOYD BOLLING
State Agreements Program
U.S. Nuclear Regulatory Commission
Washington, D C.

JOSIE PICCONE
Senior Health Physicist
U.S. Nuclear Regulatory Commission, Region I
King of Prussia, Pennsylvania

JOSE A. LOPEZ
Radiation Control
Texas Department of Health
2561 Matlock
Arlington, Texas

DAVID DADARI
Northwest Texas Hospital
Amarillo, Texas

TAWFIQ K. HAIDER
Maury Regional Hospital
Columbia, Tennessee

PATRICIA WOOD
Union Medical Center
El Dorado, Arkansas

GERALD WHITE
Penrose Hospital
Colorado Springs, Colorado

SANTIAGO GOMEZ
University of Puerto Rico
Medical Sciences Campus
Puerto Rico

DAVID BELLEZZA
Baylor College of Medicine
Houston, Texas

MARK SHAFFER
VA Medical Center
Houston, Texas

EMERY J. JANICE
Memorial Medical Center
2606 Hospital Boulevard
Corpus Christi, Texas

BRANDY WALKER
Nuclear Medicine
VA Medical Center
Dallas, Texas

EDWARD KAPLAN
Brookhaven National Laboratory
Upton, New York

CHARLES W. LEE
St. John's Hospital
Salina, Kansas

ASHOK DESAI
Hermann Hospital
Houston, Texas

BRUCE HAMMOND
MASI Healthcare Services
Fort Worth, Texas

JON R. SHARP
Bureau of Radiation Control
Texas Health Department
Austin, Texas

CARRIE W. RUDOLF
Perkins Cancer Center
Baton Rouge, Louisiana

JOHN J. FELDMEIER
Cancer Therapy and Research Center
San Antonio, Texas

WAYNE A. WIATROWSKI
Cancer Therapy and Research Center
San Antonio, Texas

P R O C E E D I N G S

MR. TELFORD: Good morning. My name is John Telford. I'm from the Nuclear Regulatory Commission headquarters in Rockville, Maryland.

I have the responsibility for doing this rulemaking and I'll be talking to you this morning about the Pilot Program.

To get started, the first thing on your agenda is that we have an introduction. What we do is we let everybody introduce themselves and the other people in the room would like to know, as well as me, your name, your position, which hospital or clinic you're with or represent, the size of the hospital, how many beds, and if all of the various departments within your hospital are participating in the program, that is, brachytherapy, teletherapy nuclear medicine, or is it just some subset of that.

So I will start over here and let you introduce yourselves.

MR. LOPEZ: I'll make a deviation of what you said. I'm not with a hospital. I'm with the State of Texas, an agreement state.

MR. TELFORD: Okay, if you're a state regulator, just say so.

MR. LOPEZ: Jose Lopez is the name. I'm the inspector in this region, in the Dallas area region, about

50 counties.

MR. DADARI: He got off real easy. My name is David Dadari, Northwest Texas Hospital, Amarillo. I'm chief of nuclear medicine tech and I'm also radiation safety officer.

We are a 350-bed hospital. We are a county hospital. We take a lot of emergencies from 26 counties.

That's about it.

MR. HAIDER: I'm Tawfiq Haider, Columbia, Tennessee. I'm a medical physicist and I only represent brachytherapy and teletherapy, even though I tried to convince nuclear medicine. There's not enough people but they informed me that they do all of it that's already in here that I will share with them.

There's 450 beds, most of them empty probably, but 40 patients a day in radiation therapy.

MS. WOOD: My name is Pat Wood and I'm from El Dorado, Arkansas, Union Medical Center. It's a 300-bed hospital which recently merged with the other hospital in town. So it's now called Medical Center of South Arkansas.

It's pretty much nuclear medicine. The therapy is separate. It's an outpatient facility with SARTAG but we do some work with them.

MR. WHITE: My name is Jerry White. I'm from the Penrose Hospitals in Colorado Springs. We have three

hospitals, three Nuclear Medicine Departments.

We do radiation therapy but it's all with accelerators. We treat about 60 or 70 patients a day and we anticipate that all of the departments will be participating.

I'm one of the physicists there.

MR. GOMEZ: My name is Santiago Gomez from the University of Puerto Rico, Medical Science Campus.

I've been working there as a radiation safety officer for ten years but now I work as a physicist in Nuclear Medicine Department.

We have two licenses. They both are full licenses for the Medical Science Campus and they work in isotopes and research in animals in vitro and in nuclear medicine and radiotherapy in humans.

This is not the big thing but since we have the waste disposal license, we have several problems in the waste disposal, but in relation with the quality assurance program, we have a quality assurance program for our Nuclear Medicine Department but we do not have any waste disposal program for radiotherapy.

MR. BELLEZZA: My name is David Bellezza. I'm a medical physicist at Baylor College of Medicine in Houston.

I'm representing the Radiation Therapy Program that we have there which serves the Harris County Hospital

District.

MR. SHAFFER: My name is Mark Shaffer. I'm the radiation safety officer from the VA Medical Center, Houston, which is a 1200-bed hospital inclusive of nuclear medicine, teletherapy and brachytherapy.

MR. JANICE: Emery Janice, Memorial Medical Center, Corpus Christ, Texas, chief cook and bottlewasher, associate radiation safety officer.

We have about 400 beds in the hospital district and so far all sections are going to participate in the program.

MS. WALKER: My name is Brandy Walker. I'm from Dallas here, from the VA Medical Center. I think we have about 600 beds but I'm not sure.

I'm from the Nuclear Medicine Department. The Radiation Oncology Department is not participating but it wasn't clear to me that they were supposed to be, so I'll approach them when they get back.

DR. TSE: My name is Anthony Tse. I'm from the NRC in the Washington Office of Nuclear Regulatory Research. I'm the program manager of this project.

MR. BOLLING: My name is Lloyd Bolling. I'm from the NRC State Agreement Program and formerly from Mt. Sinai Hospital Medical Physics Department, New York City.

DR. PICCONE: My name is Josie Piccone. I'm a

senior health physicist with NRC in Region I.

MR. LEE: I'm Charles Lee. I'm at St. John's Hospital in Salina, Kansas. We're a 139-bed hospital.

We have nuclear medicine, which will participate; radiation therapy or our physicist is also in the program and he will take care of the radiation therapy area.

We also have an outreach program in nuclear medicine. So that will also be involved.

MR. HAMMOND: My name is Bruce Hammond. I'm executive director and radiation safety officer for MASI Healthcare Services in Fort Worth.

We provide nuclear medicine services on a mobile basis to 65 hospitals in Texas and we're part of a 2,000-bed hospital chain, not for profit; a religiously-affiliated group in Fort Worth.

Our Nuclear Medicine Departments will participate.

MR. SHARP: I'm Jon Sharp with the Texas Health Department, Radiation Control and the Medical and Academic Licensing Branch and we have one bed which we have made for ourselves and we have to lie in it.

[Laughter.]

MS. RUDOLF: My name is Carrie Rudolf. I'm medical physicist and radiation safety officer representing Perkins Cancer Center in Baton Rouge, Louisiana.

Perkins is a free-standing clinic. We treat about

130 patients a day with brachytherapy and external being therapy utilizing linear accelerators.

DR. FELDMEIER: I'm John Feldmeier. I'm a radiation oncologist from San Antonio Cancer Therapy and Research Center.

This is also a free-standing center. We treat about 140 patients per day, including teletherapy with cobalt machines as well as high-dose rate brachytherapy and some standard low-dose rate brachytherapy.

DR. WIATROWSKI: I'm Wayne Wiatrowski. I'm from the University of Texas Health Science Center, along with Dr. Feldmeier, representing the Cancer Therapy and Research Center. I'm a physicist there.

MR. TELFORD: Very good. Welcome, everyone, I'm glad you here.

I want to sort of go through the agenda now to get you acquainted with what we expect to do today.

We're going to talk about the pilot program, first of all to let you understand what it is in its entirety, what we want to do, what everybody's role happens to be.

Then I want to talk about some current misadministrations, to show you some of the problems that we're trying to fix.

Then I'm going to go into the review of the proposed rule, the 35.35. If you've seen the Federal

Register notice, you realize there are three sections to this proposed rulemaking.

There's 35.33, which is recordkeeping and reporting requirements for diagnostics; 35.34, which is recordkeeping and reporting requirements for therapy; and 35.35, which is just the proposed rule. That's really the subject today.

I'll tell you more about how we're going to get to the recordkeeping and reporting requirements at the next workshop.

So by the end of the day -- excuse me, let me go on with the agenda.

We'll talk about any special conditions that may apply due to state regulations. Then we will talk about the evaluation forms and then we'll talk about the Regulatory Guide and then we'll review the schedule of future activities.

By the end of the day I think you will know everything there is to know about this.

Let me note we have just been joined by another person. We've gone through introductions. We ask that you tell your name and your position, the hospital you're from, its size and whether all departments will participate, that is, teletherapy, brachytherapy and nuclear medicine will participate in the pilot program.

MR. DESAI: My name is Ashok Desai. I'm chief technologist at Hermann Hospital in Houston, Texas. We are a 900-bed trauma one hospital.

We don't have any brachytherapy. We don't have any radiation therapy.

So I'm here to represent nuclear medicine.

MR. TELFORD: I'm going to give you a little bit of an idea about the background of how we got to where we are today.

Back in the fall of '87 the Commission asked -- the Nuclear Regulatory Commission -- When I talk about the "Commission," I'm speaking of the five Commissioners that you can think of as our board of directors.

I'll be careful to distinguish between what the staff says as a staff proposal to the Commission and what the Commission has approved of.

Back in the fall of '87 the Commission requested two rules. One was a basic quality assurance rule and one was a comprehensive quality assurance rule.

The one that we are working on currently is the basic quality assurance rule.

You can tell by this chronology here that by June of '88 the staff provided a proposal to the Commission -- March of '88, the staff provided a proposed rule to the Commission.

The rule was in fact a prescriptive rule and the medical community through its various organizations let their views be known that it didn't particularly like this rule.

It was too prescriptive; you're telling us what to do and how to do it and that's not appropriate.

So the Commission then asked for options and what we gave the Commission back was a proposed rule for a performance-based rule, whereby this performance-based rule would say what should be done. Here are the goals. Here are the aims.

Each hospital or clinic can then decide how to do that.

We had various meetings. Then June of '89 -- that's why June sticks in my brain -- we provided the draft proposed rule that after long deliberation was finally published in the Federal Register in January of this year.

With this proposed rule, because it's performance-based, because we like to do it right, because we want to try it out, the Commission also asked for a pilot program, now that we have a proposed rule, to give it a trial period, make improvements to it and then decide if we want to go with the final rule.

In the pilot program what we said we wanted to do was to proportionally represent each NRC region, each

agreement state, of which there are 29, each class of licensee, that is, whether or not you do teletherapy, brachytherapy or nuclear medicine, and the type of facility, whether or not you're in an urban location or a rural location.

As you were introducing yourselves this morning, I was sitting here ticking off a little list in my head and I see, yep, we have some of each.

Most people here, I think, are agreement state licensees. As a matter of fact, there are just a few states in the NRC's Region IV that are NRC states. For instance, Oklahoma and Missouri are NRC states.

We went through an elaborate selection process and Ed Kaplan is the gentleman that joined us who didn't get a chance to introduce himself but he's from Brookhaven and I'm sure you've all talked to him on the phone.

He deserves all the credit for having gotten all of you here and made all those calls and gone through all that and for the fact that we do have this representation in the pilot program.

An overview of the pilot program would be each licensee has -- or volunteer, excuse me, has one month basically to modify their program; one month to implement; By that, I mean train any personnel who need to be trained; two months for the actual test; and then one month to

collect results.

I'll go through this more in detail and we're going to have two sets of workshops.

This is the handout. This is part of another handout. We've distributed that. This would be page one of the other handout.

What I attempted to do here was just write down some of the objectives that we want to accomplish with this pilot program.

First of all, the way we are playing the game is we give you the proposed rule, 35.35, and we'll go through it in a minute. But basically all it says is have a program. Here are the objectives that are desirable to be met and you tell us how to do it or how you are going to do it.

Therefore, we want to understand how you develop your program, what you put into it. We want to understand how you conduct it in your facility; that is, what unique changes you do in its implementation to short of tailor fit it to your hospital.

Then we want to determine if any of these objectives have the effect of preventing mistakes that might be intermediate step kind of mistakes, that if not detected or caught could lead to a misadministration.

Then we'd like to find out if these objectives, in

your opinion, are useful or effective in preventing mistakes in medical use; and if not, what sort of objectives would be useful.

Here's a little bit more of a detailed outline. The trouble that Ed went to and all that work happened in January and February.

It turns out that when he calls someone, then he finds out that, "Okay, we may be interested. I have to check with two other people."

He calls back and says, "Okay, I checked with those people. I have to check with three more people."

And three weeks later we got an answer, "Yes, we'll play," or, "No, we won't."

So that took a while. We closed off the invitation process in early March.

This next month that I was talking about in the previous slide, this is when the volunteers would review the proposed 35.35 that you received in the package from Ed.

You would determine that your program currently meets 35.35 or your would modify it so that it meets. That would be basically the month of April.

Now, we have two sets of workshops. The first set we're into and the first workshop was March 29 and that was in New York; April 4 was Chicago; April 6 was Atlanta; today we're April 18th in Dallas; and the 20th will be San

Francisco.

After this workshop you have basically a month to do any day-to-day procedure modification or training of technologists or any little last-minute changes that you need to do before the 60-day trial.

So I say all of this, if required, because it will be true to varying degrees for various hospitals.

Then the volunteers will then try out your new program for the 60-day period between May 14 and July 13. You will retain a few records, which we will talk about.

For 18 of the volunteers -- Let me tell you how many volunteers we set out to get, first of all.

We went to get 24 NRC volunteers and 48 agreement state volunteers. That's a total of 72 to represent basically 6,000 licensees across the country.

There are 2,000 (on that order) NRC licensees and 4,000 agreement state licensees.

So we were after 72 and I believe we came up with 22 NRC and 45 agreement state volunteers. So of the 67, 18.

We will make a random selection of the 67 and come up with the 18 and for these 18 we will do sort of an in-depth review.

We will have what we're calling our QA team. These are four people that will do the work that I'm going to describe, three of which are very experienced NRC

regional inspectors, and one of which is Dr. Anthony Tse, who has been in this since the fall of '87 and knows all of this stuff backwards and forward.

The other person that's here today that's on the quality assurance team is Dr. Josie Piccone.

So if I get in trouble today with what I say, then I have a regional inspector here to bail me out so you can correct me.

For the QA team, after we've chosen these 18 facilities, we will review the program in depth.

This is a paper review of the program and the principal question that the QA team will be asking is, does it meet the proposed 35.35.

Following that, the QA team will go to these 18 sites for an evaluation and the principal question they will be asking is: Is this hospital implementing the program that they say they are implementing?

As we go on today, you'll see that there will be a lot of opportunity for feedback and evaluation from all sides.

First of all, this program review and the site evaluation is a very no-fault kind of review. We're talking about a proposed rule here, so we won't even use any words like deficiencies or citations, for goodness sakes, you know. None of that; this is no fault.

I'll tell you a little later what everybody will get out of this but, in particular, what the 18 will get.

Then we'll have some post-test workshops following the 60-day trial period and these will be in August.

We'll have a whole lot to talk about, because the volunteers will have had the experience of trying out the program they can tell us about, which is each of you; what you think of the proposed rule; and your suggestions for how to fix it.

The QA team, in turn, will then confess to you the criteria that they used to evaluate the program, each of the 18; the results of those evaluations.

Thirdly, the criteria that they used for the site evaluations; and fourth, what the results are.

When they say this, it's going to be like these are the strong points, these are the weak points and these things need work, but it will be in a no-fault sort of way.

On the handout, I'm on the next page of the second handout.

What you can expect is that you can then get an insight into the criteria that at least the NRC would use to evaluate programs.

If there's a final rule, then this would be the licensing stage. This would be when you send in an -- well, not you, but if there are any NRC licensees here, when you

send it in to the NRC as an application, then these would be very much like the criteria that we would use to judge your application.

So this is an inside view and a step up on what's coming.

We also learn the results of the application of these criteria. You would then understand the criteria that would be used during a site visit.

For all regular rules we call this an inspection. For this, this is the site visit and we would learn the results from these site visits.

I assume that the agreement states do something very similar. I'm sure here in Texas they do a better job but I'm sure they have something similar for site visits, or they have inspections, too.

But you would learn, then, the results of that, so you're ahead there.

Then, sixth, we will, I guarantee you, listen very carefully to your evaluation of the proposed rulemaking.

We'll talk later today about what the evaluation form will probably look like, the kind of questions that we will be asking.

I think the impression you get after we go through those evaluation, or questionnaire, the impression you get is that we're turning this thing inside out and we're giving

you complete carte blanche to tell us how you would do it.

Then after your evaluation of what you think of it, then we would ask for your suggestions for what to change.

That will become very clear this afternoon.

Now, what do we expect of you? We would like you to modify your current program, or if you don't have one, develop one, that meets proposed 35.35.

All I will ask you to do is to say, "Here's a copy of my program. I think..." This is you talking. "I think that it meets the proposed 35.35." That's all I want you to tell me.

Then the pre-test workshop. You're here today.

You would provide any instructions or train any personnel as necessary, because it may not be necessary in your hospital, to prepare for the 60-day trial.

Try out your modified program for 60 days and then evaluate this proposed rule, which is 35.35, and provide suggestions for improvements.

Attend the post-test workshop, because that's when we will have the opportunity to discuss all these things and that's my opportunity to learn from you.

Let me back up. Let me refer to the agenda and say we've now covered the first topic. That's discussion of the pilot program.

So I hope now you have an overview of the pilot program and what's involved.

So let me stop for a few minutes and let you ask questions and comment.

Anybody have any questions about the pilot program?

MR. WHITE: The hospital end of this is basically trench, grunt worker hospital personnel but the inspection arm in the pilot program seems to be hand-picked, highly-qualified NRC inspectors.

Why did you decide to do that, rather than choose a sampling of agreement state inspectors and train them for the final evaluation?

MR. TELFORD: That's a good point. I didn't mention anything about the agreement states during the site visits.

For the 18 volunteers that will be selected for the program review and site evaluation, six of those will be from agreement states and twelve will be NRC.

So we're heavily weighted towards the NRC for the 18. However, for each of the six -- I can't say insist, but we will plead with that agreement state to accompany us on the program evaluation and the site evaluation, so that we have the experience and expertise from both groups.

Is that basically the point, we were kind of

ignoring the agreement states?

MR. WHITE: I guess my point is there are two very important components of this. One is what the hospital does and the other is the behavior of the inspecting agency.

I think they both need to be tested in a pilot program and I think you're only testing half of it.

I will be inspected by somebody who has been working on this as a career project for three years and a pilot program and should it become a final rule, in our state I'll be inspected by somebody who has quite different attitudes, qualifications, things like that.

I think that that would be an important thing for you to pilot, is the evaluation procedure.

MR. TELFORD: Oh, okay. You're from Colorado?

MR. WHITE: [Nods head.]

MR. TELFORD: So that's an agreement state. If your facility were chosen for the site visit, then a person from Colorado, ideally, would come with us, a state inspector.

So your point is, we should be looking at --

MR. WHITE: Let him inspect me and let these people ev. te both my performance and the inspector's performance.

MR. TELFORD. Our concept was to do it jointly but I think yours is an interesting modification of that.

Well, that might work if we could get the agreement for Colorado to do that. Sometimes the states say to us, "We'll go with you but we don't want to do that work."

What I have to do is say, if they don't want to do the work with us or even for us, we have to do it.

I basically agree with your idea.

Anybody else?

MR. BOLLING: I think it's important to note that in developing this whole procedure, we have spoken to agreement states in their annual meetings and we have also a conference meeting of all states, all 50 states, which incidentally is coming up next week.

We spoke to them last year at this time, so they are well aware of it.

We had even a meeting of the conference of radiation control program directors, which represents, again, all 50 states, back in March and we had four representatives come in from different parts of the country and we explained it to them at that time as well.

We anticipate that these kinds of ongoing meetings and training programs will filter down to the actual medical inspector in each state and we do have ongoing training for those inspectors as well.

MR. LOPEZ: The state inspector, I'm new to the

concept but the way I understand it is that what we're trying to do is to get 35.35 to be the best it can be.

MR. TELFORD: Yes.

MR. LOPEZ: Therefore, the inspection will eventually evolve to meet 35.35. I don't think we should be concerned about the way that the state or the NRC is going to be inspecting them, but the focus of the whole program should be what 35.35 is going to be; that is, that it's adequate.

MR. TELFORD: Right.

MR. LOPEZ: Eventually the states, since they are required to have compatibility with NRC, will modify their regulations to meet whatever 35.35 will be.

MR. TELFORD: I guess there's something I didn't say. Since we have 67 volunteers, we're going to review everybody's program.

We're going to go through a programming review for everybody's program and you will get feedback from that. But we can't go to everybody's site. We don't have time.

One of the criterion that we used to pick the 18 was how many sites can we go to during a 60-day period while people are trying out their program.

If you start scheduling all these site visits all across the country, we sort of cut back. We cut back to 18. So that's one of the reasons that it's 18.

We're looking at the group of 18 as sort of a sample of the 67, because if we can get a good impression of the program review and then what we learn from the site reviews, we want to extend that, of course, to the group of 67, 67 sites.

There are various aspects of this but you are really right. The desirable end product is to have the proposed 35.35 to be the best it could be.

Anybody else?

MR. SHARP: I think Gerald White has touched on an important point, the performance of the people that are going to be in the field looking at these things.

I think there's been a little reluctance to commit agreement state effort to training workshops and even getting heavily involved in the comments until we had a little clearer picture of what 35.35 was going to look like.

To that extent, I think Jose is right. The focus of this part of the program is weighted toward developing what can be done and what can best be done by the individual licensees.

Also, we need to include a third phase in this; that is, a state evaluation of these programs, essentially how the licensing section reviews these things on paper before the inspector gets out there to review the implementation of whatever has been down on paper.

Both those things will have to be addressed as the states try to become compatible with whatever rule is developed.

To some extent it will fall on the states to carry out that by themselves. To some extent it will be encouraged by the prospect of review of the NRC in the routine reviews that they do for us, and I hope that they will work with us in whatever special training we'll need to implement it as rapidly as we can when we get to that stage.

MR. JANICE: But by the same token, aren't most of what's in 35.35 now, Jon, being taken care of already, such as the receipt, the disposal, the dosage?

MR. SHARP: Indirectly.

MR. JANICE: Identification?

MR. SHARP: Indirectly, many of those things are. Indirectly, but not with the idea that quality control is something that should be in and of itself addressed.

I think this is the first attempt to systematically look at that and I think it probably will fill in some gaps that we've got.

But I think you're right, too, three-fourths of it perhaps is there.

MR. JANICE: I know John is going to make sure that it's there when he comes around.

MR. TELFORD: I didn't mention but I take it

you've already assumed by now that if this rule becomes final, it will be a matter of compatibility for all agreement states.

When we started this effort for the pilot program, Lloyd Bolling's office sent a letter to all agreement states asking permission from each agreement state to let their licensees participate in the pilot program.

He said, "If you agree to this, send us a list of all your licensees according to the following format," and they did, all 29, to their credit.

So let's see. We had a meeting with four representatives from agreement states and two of the gentlemen have two hats in that they're members of the Medical Committee that's from the all agreement states organization.

Lloyd's office also sent a letter to every agreement state saying, "If you would like to discuss this proposed rule or the pilot program, just let us know. We'll come to you."

We're doing our best to work with the agreement states. As we go on and people find out more of what it's about, I'm sure that they will sort of jump in.

I want to switch to the next topic on the agenda and talk about some recent misadministrations.

When we started this, we looked at the

misadministrations from 1980 to 1988, with the question in mind of what are the problems that are occurring; what can we do about these things? That is, how could we structure requirements or list objectives that, if followed, would prevent these things from happening.

I wanted to go through, I think I've got 10 or 11, misadministrations to give you the insight of what's happening around the country, of what we're shooting at, what we're trying to fix.

It turns out that the first one is from Texas and all I want to say about it is it happened in May of '88 and it was a switch from 30 microcuries to 30 millicuries.

It happened in the West Houston Medical Center and Jon Sharp has volunteered to discuss it with us.

MR. SHARP: It's pretty well summed up here. The orders were verbal. The technician, in looking at the field notes, was obviously confused about millicuries and microcuries.

It was the substitute technician not fully familiar with the procedures.

She did have enough concern for the high count rate that she got when she scanned the dose with the pinhole collimator and the gamma camera to question the authorized physician about it, but because of the way of checking the dose he said, "Well, those things are relative. Don't worry

about the count rate," which is, I suppose, roughly accurate for that way of verifying that you've got the dose there.

It does point out the weakness of not using a dose calibrator in this case.

It was about 12 hours before she finally had her misgivings bother her enough. In the process of ordering some other doses with the pharmacy, the pharmacist and she eventually arrived at the discovery simultaneously, that the previous order for 30 millicuries actually should have been a diagnostic dose.

Compounding the situation was the fact that this hospital was customarily ordering doses of 10 microcuries of Iodine-131 for diagnosis, followed by 30 millicuries of technetium.

This had been changed recently and unofficially to 30 microcuries of iodine and 30 millicuries of technetium and she was used to ordering diagnostic doses and dealing with millicuries.

So the mistake was not completely out of the blue, let's say.

The patient's thyroid was affected, as you might expect.

They have instituted procedures that are remarkably like 35.35 on their own. They are having written therapy orders and descriptions and they have standardized

and posted their list of procedures so that everybody is aware and deviations from it need to be individually authorized.

MR. TELFORD: Thank you.

MR. WHITE: Can I ask you, as you go through the misadministrations, you might highlight how the new regulations would have prevented it.

MR. SHARP: In this case, they adopted essentially some of the precepts of 35.35 for iodine therapy.

MR. WHITE: But this was a diagnostic study.

MR. SHARP: It was supposed to be a diagnostic study.

MR. WHITE: But what would help us, I think, is if these procedures had been in effect, what would that technologist have done differently?

MR. SHARP: They have made an arrangement with the pharmacy so that therapy doses cannot be delivered without written or verbal authorization by the authorized user.

So in their arrangement with the pharmacy, they have gone an extra step. It would have blocked the delivery of a therapy dose.

MS. WOOD: Isn't it mandatory to recheck a dose before you give it to a patient?

MR. SHARP: If you mean by that, do we require --

MS. WOOD: Dose calibrator?

MR. SHARP: -- a dose calibrator on site at licensees in Texas, the answer is no.

MS. WOOD: No?

MR. SHARP: No.

MS. WOOD: I'm more familiar with California and they do, so I didn't understand.

MR. SHARP: In our terminology we call it double-ended calibration and we don't require it for the expense.

MR. JANICE: Our pharmacy has gone one step further, Jon.

In the past, as in most pharmacies I think, anyone who picks up the phone says, "Hello, here's the order for tomorrow," and starts writing.

Now our local pharmacist says, "Uh-uh." The registered pharmacist has to take the order and call back the order to the tech that's ordered it.

MR. GOMEZ: And do they perform the radiations from the writing?

MR. JANICE: Pardon?

MR. GOMEZ: Do they perform the radiations from the writing?

MR. SHARP: Of course, outside of the scannings, I don't quite know what procedures in detail they had set up with the pinhole collimator and their gamma camera.

Obviously, whoever originally set that procedure up had some count rates in mind as trip levels.

This technician, being a substitute, apparently was not well acquainted with that procedure and obviously using a gamma camera where you only get counts per minute is not a way for an inexperienced technician to be able to unambiguously say, "Oh, this is the wrong dose."

A dose calibrator where you can see it, where it essentially says what the dose is and you don't have to convert it is obviously a little more foolproof.

DR. WIATROWSKI: I have a question. What were the qualifications of the substitute technologist? I can't imagine an NMRT not knowing that a 30-millicurie dose was therapeutic.

I mean, I just can't imagine that.

MR. SHARP: The technologist in this case was a registered technologist, x-ray I believe.

DR. WIATROWSKI: Yes, but not nuclear medicine.

MR. SHARP: No.

DR. WIATROWSKI: So perhaps the more fundamental issue, rather than regulating minutiae might be to ensure proper qualifications of the technologists and personnel who are -- because an NMRT-registered technologist would clearly know that a 30-millicurie dose is uncalled for in a diagnostic procedure.

MR. SHARP: Speaking for a minute with a different hat on, for many of the licensees in Texas who have nuclear medicine on a marginal basis -- I mean marginal financial basis, hiring an RT is even out of the question.

Hiring a nuclear med tech is not possible for numbers and probably not possible from financing.

We can probably get some input on that from Bruce Hammond, who serves rural hospitals.

MR. HAMMOND: I agree with you, Jon. In a nice world it's great to have all registered nuclear med techs, but the simple fact of the matter is, there are not warm bodies out there that are properly trained.

So you end up with some kind of cross-training of personnel.

I go back to the same question, though. 35.35 is kind of the Band-Aid on the problem on this thing.

We're after the fact treating what happened to this patient, when in fact if the hospital would have been required to have a $2,000 dose calibrator as opposed to a $30,000 technologist, this wouldn't have happened.

Instead of coming in with a quality assurance program that for most of us mimics what we're already required by Joint Commission or Medicare or somebody else, let's make some basic minimum standards for what it takes to qualify for a Nuclear Medicine Department.

Instead of saying you have to have a camera and a warm body that knows stop, start and reset, in nuclear medicine you've got to have a dose calibrator, survey meter and things that work.

This patient wouldn't have this problem if simple precautions would have been taken, whether you had the janitor do it that you trained in nuclear medicine.

MR. SHARP: Well, in this hospital's defense, this was a substitute situation. Their normal technician most likely would not have had the problem.

MR. TELFORD: Let me take Jon off the hot seat here.

This is one agreement state. To give you another agreement state, this is Maryland. This happened over a 13-month period, '87 to '88.

This was in Cumberland, Maryland, in the Sacred Heart Hospital. It's a teletherapy misadministration.

They had a source change. The cause of the problem was they changed the source but in one of their computer programs they didn't put in a new number for the new source string.

So they used that program and they overdosed 33 patients.

The actions taken to prevent recurrence was they implemented an overcheck procedure. Part of that was to get

qualified personnel and the other part was to make sure things are done correctly.

There is another agreement state. This happened March 27 of '89. Most of these are very recent dates. I'd like you to note that.

This was Indiana University School of Medicine in Indianapolis. This is the teletherapy.

The patient was to be administered a certain number of treatments, a certain number of fractions of 300 rads each, I believe, and they were to 9 sites on his left hip and groin but they should have been administered to the right hip and groin.

So wrong treatment site.

What was the cause? Miscommunication among the technologists; speculate as to others.

The patient got 2700 extra rads to the wrong location.

The action taken to prevent recurrence was, the licensee has instituted new procedures to verify treatment site.

There are various things in 35.35 that require written... 35.35 basically says, first of all, write down, tell me what you're going to do, first. Write it down.

Then, ideally, have somebody check it. Make sure people know what they're doing.

Then write down what you did.

MR. WHITE: Indiana School of Medicine doesn't have written prescriptions for radiation therapy?

MR. TELFORD: Well, like treatment site tattoos. I don't want to give these guys a hard time but here are the facts.

This is an NRC state. July 24, '89. Worcester City Hospital, Massachusetts.

This is another teletherapy, was to get a dose to the lumbar spine instead of the prescribed treatment for his right lung.

So what was the cause? The technologist failed to confirm the patient's identity with the available photograph; that is, didn't use it.

The technologist failed to recognize the absence of existing tattoos, which would have told him that either he's got the wrong patient or he's got the wrong site.

The patient received an unintended 250 rads to the spine.

The actions taken: The licensee has now instituted new procedures, which require that each patient's identity be verified by photograph and in questionable cases the physician will verify prior to treatment.

This is another NRC state. Geisinger Medical Center, Danville, PA, February of this year. Teletherapy.

In this case there were a specific number of fractions to be given and they just kept giving them, kept going.

The technologist misunderstood or didn't remember the number of fractions to be given. The technologist didn't keep a record, saying, "Okay, I've given that one," checkmark, or, "I've given that one. It was 200 rads," or whatever it was supposed to be.

So the patient received 4200 rads and should have gotten 3,000 and this was to the spine.

The actions taken: The licensee has now instituted procedures that require clear marking of the patient's chart when a treatment is completed and the staff has been instructed to review all prescriptions prior to treatment.

This is an NRC state. Josie, if I get some of these wrong, you can tell me, because this is your territory.

This is brachytherapy. I don't want it to seem that I'm picking on any one thing but what I'm trying to do is to give you the same view that I can see from looking around the country.

January of '89, Yale-New Haven Hospital, New Haven, Connecticut.

The nature of the misadministration was the

technologist entered a decay factor of 267 instead of a factor of 128 and this is an after-loading device, high dose rate, for you that understand brachytherapy better than I do.

The problem was the technologist simply misread a number. There was no recheck procedure to detect that.

The patient then received a thousand rads instead of 500, for that fraction.

The action taken was the licensee established new procedures to prevent recurrence by instituting an overcheck.

This is an agreement state.

MR. BOLLING: No, it hasn't.

MR. TELFORD: Uh-oh, I've been corrected.

This is Missouri, not an agreement state. You're right.

I just said that this morning, right? Missouri is not an agreement state. I gave that as an example. Thank you.

January of '89, St. Luke's Hospital, Kansas City, Missouri. This was a Cesium-137 case with source strength supposed to be of 25 and 20 and they loaded 25 and 5 milligrams reading equivalent.

The cause of the problem was that one storage drawer contained sources of two different strengths.

The patient was 56 percent under-dosed.

The action taken to prevent recurrence is now the sources have been arranged so that each drawer contains sources of one strength only.

Boston, Mass., agreement state.

VOICES: No.

MR. TELFORD: No. I was just checking to see if you were listening.

Okay. March of '87, New England Medical Center Hospital.

The patient received the wrong radiopharmaceutical and the wrong dose. The patient was to receive one millicurie of I-123; instead got 5 millicuries of I-131.

The cause was the technologist misunderstood the wording in the notes made by the referring physician in the patient's chart.

For the sake of 35.35, let me point out this says "referring physician."

The patient received approximately 5,000 rads to the thyroid as a probable consequence.

The action taken was: Procedures have now been implemented to verify each diagnostic study requested.

MR. JANICE: No disrespect to anyone's handwriting, but there's a large difference between written and legible orders, you know.

MR. TELFORD: Yes.

This is May of 1989. Abbott-Northwest Hospital, Minneapolis, Minnesota. This is an NRC state, right?

MR. BOLLING: Right.

MR. TELFORD: All right. Nuclear medicine procedure, the patient received a 3 millicurie dose of I-131 instead of 300 microcuries of -123.

The technologist misunderstood the referring physician's request of what radiopharmaceutical to use and the dosage.

The patient probably got 3,000 rads to the thyroid.

The action taken was the licensee has instituted a procedure that no I-131 radiopharmaceutical will be administered to a patient without prior approval by the nuclear medicine physician.

For the sake of 35.35, we want to put the nuclear physician in charge.

Okay. October 18th of '89, Mayo Foundation, Rochester, Minnesota.

Dose of I-131 administered to patient was ten times too much.

The referring physician -- note, "referring physician" -- ordered a scan using one millicurie of I-131 instead of a hundred microcuries by checking the incorrect

box in the diagnostic approval form, and there was no overcheck at that time.

The patient got approximately a thousand rads to the thyroid.

The action taken is the hospital has now revised its procedure for use of iodine and to have the nuclear medicine physician review and approve the request and to write the prescribed dosage on a referral form and check it and make sure it's right.

November 1st, '89, Desert Good Samaritan Hospital in Arizona. This may be the one that's in Mesa rather than in Phoenix, actually.

The patient received the wrong dose. The patient got a hundred millicuries instead of a hundred microcuries of -131.

Causes, probably too many to list, but let me give you a few. The radiopharmaceutical order was ordered by phone, a verbal order.

The dose was not measured in the dose calibrator. There was miscommunication between two technologists.

No doubt the patient's thyroid was ablated, probably a dose of a hundred thousand rads to the thyroid.

Action taken: The state, first of all, the State of Arizona suspended all -131 use at this hospital until the licensee could show how future misadministrations could be

prevented.

At a time later they said, "You can now use up to 100 microcuries without prior approval from the state."

Let's see, I have one more.

This is November 30th of last year. Kuakini Medical Center, Honolulu. This is an NRC state.

The wrong patient received a therapeutic dose of nine millicuries of I-131.

The technologist called Patient B. Patient A responded and took the I-131 dose.

The patient, however, was supposed to get 20 millicuries of technetium for a bone scan.

Probable consequence, 9,000 rads to the thyroid.

Action taken: Procedures have been implemented to require that a single technologist be responsible for correctly identifying patients and handle all aspects of I-131 therapy.

Also, the technologist, the physician and the patient are now required to sign the therapy worksheet prior to treatment.

I wanted to give you a quick snapshot of what we see. I've got several slides here that I could go back through.

I think these appear in the Federal Register but what we did was summarize the misadministrations from '80 to

'88 and we sort of catalogued all the things that went wrong.

I propose not to go through that because you've just seen several sort of case histories, quick snapshots of the misadministrations.

I have no doubt that everybody here would say, "No, I don't like these happening. I don't particularly like it when people get over-dosed like this or even under-dosed."

What the proposed 35.35 would like to do is figure out a way that we could solve this problem once -- maybe not solve it. Let's say attempt to solve it once.

Let's strive for excellence. Let's strive for zero imperfections but let's be realistic.

What's been happening is that NRC has 2,000 licensees and it appears to me that we've been solving this problem one at a time.

Hospital A has a problem. Okay, what procedure are you going to do to fix it?

Hospital B has a problem. Okay, what procedure are you going to do to fix it?

The agreement states have 4,000 licensees. So wouldn't it be nice if we could figure out one set of procedures that might be useful to everybody to prevent these problems from happening.

We have a proposed rule. I'll probably be the only person in this room that will say it's any good for anything. That's fine.

What I want to do is have a pilot program. I want to test it and then I want to hear from all the participants on how to make it better.

It won't hurt my feelings a bit if you tell me, "Oh, this is no good."

All I want you to do is tell me what to do better and I'm confident we can do that because we have so much experience and such a wide representation from all the participants in all the entire pilot program.

Let's briefly do some questions and answers and then maybe take a break.

Anybody have any questions or comments? Yes.

DR. FELDMEIER: I have a question about the implementation of the program.

You indicated that there would be a period of amnesty for the participants, that in the process of implementing the program NRC, either with a site visit or by review of submitted documents, reviews the QA programs and finds deficiencies and there aren't going to be any fines levied or anything like that.

Is there any kind of guarantee from the states that are not NRC states? Are the state boards going to

offer the same kind of amnesty.

MR. JANICE: I see John is keeping a very sober face.

MR. TELFORD: Yes, Lloyd.

MR. BOLLING: I'm going to get into this a little bit after lunch but this is not a rule.

What you're doing is you're proposing to meet some requirements that we've ginned up and any commitments that you've made in writing to your state agencies, you are expected to keep those commitments.

If there are any discrepancies between the two, we would expect you to get to the state immediately and tell them, "I've agreed in my last renewal or in my initial license application to keep books in a certain way," and during this pilot program most likely you'll be keeping something a little extra and not something less.

But if there appears to be a contradiction, we'd expect you to get to the state agency and work it out with them.

DR. FELDMEIER: So the basic answer is, there probably will not be any amnesty extended by the state governing boards?

MR. BOLLING: No.

MR. TELFORD: What Lloyd, I think, is saying is that if you have a current license condition, if -- we're

sort of getting into Lloyd's talk, the subject of his session, but basically we would like you to -- We can't say otherwise.

We want you to keep following your license conditions. If the license condition is in conflict with anything in proposed 35.35, you still have to follow your license condition; or if it's in addition to, then you still have to follow your license condition.

From our point of view, we'll work around that. Maybe what you're really asking is if the state joins us for the site visit, are you worried about the state inspector then discovering things and citing you for it?

DR. FELDMEIER: Basically that's what it boils down to. I don't think anyone would realistically expect the state to suspend their governing regulations in any way, shape or form but since by participating in this program, you're volunteering for a much closer scrutiny, potentially, if it's a fine point or matter of interpretation or anything like that, I think some sort of understanding with the state that if it's a nebulous activity and especially if it's in conjunction with this voluntary program, that there might be an inclination to be a little bit more liberal in interpretation. Not a substantive sort of thing.

MR. BOLLING: Let me say, we had a training course at the University Medical Center in Oklahoma a couple of

years ago and part of the course -- this was a course, by the way, for agreement state inspectors, brand-new inspectors.

As part of the course we had a tour through different medical facilities and in going through there we saw a couple of technicians drinking in a hot lab.

These are things that just cannot be overlooked. I mean, it doesn't matter if it's part of a pilot program or not. That's a clear violation of regulations and standard practices.

Obviously, if the state inspectors or if we see something like that, we're going to tell you about it.

We may not have the authority to give you a fine or something like that but certainly you're in violation of state regulations with something as clear as that.

Something that's borderline or maybe a sign has fallen off a door or something, I've never been too excited about things like that.

I think that we can talk about it and get a new sign up. I don't see that as being a big problem.

DR. FELDMEIER: Would the plan be, when the site visits occur and the NRC site visitor comes, to bring a representative from the state board's committee?

MR. BOLLING: Yes. We designed this program so that it had as little impact on the states as possible,

because of dollars and personnel implications to the states.

John and Tony and some of the rest of us don't do licensing and inspecting on a day-to-day basis.

Our job is writing regulations and explaining them and implementing them and so forth, but the state people don't have that luxury.

They are hired to do inspections and to do licensing and there's very little time for them to do the research and the regulating.

So we designed the program so that they can be involved if in fact they have the time, but we didn't want the program to fail or have problems because a state could not get involved.

It is our intention, though, to have a state inspector at each site visit.

MR. TELFORD: We will request that.

MR. BOLLING: Yes.

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

MR. SHARP: Well, it would be very surprising if much was made of anything but the most significant violations by a state person.

The idea is to learn with the NRC about what makes a pilot program or what makes a viable QA program.

The practicality of it is that we're going to be another ear to bend and that may be more important when the

state's plan is implemented, that it is, quote, compatible.

I think, in fact, it's going to be advantageous to the volunteering licensee to have the state person there.

MR. TELFORD: We'll only have one day at each site and we will be highly focused on your program, your proposed QA program.

We will not be there for any other purpose. We'll be completely focused on that.

There will be a lot of things that they could look at just within that little program. So they will not be looking at anything else, unless, like Lloyd says, they're walking down the hall and they stumble over something.

If that occurs, then it will be referred to the regional office, if it's an NRC licensee.

Any other questions or comments? Lloyd.

MR. BOLLING: Just one other thing before we break.

I think that the eight points, the objectives of the QA program, should really be viewed as icing on the cake.

We believe that most of you are doing a very good job and misadministration rates indicate that, but we feel that every once in a while they do occur.

They do have serious consequences to an individual patient.

Some of you hospitals involved in the therapy area have been involved with the Centers for Radiological Health in the past, which were funded by FDA, I believe, and some of you have continued to keep your books in a way that we believe lends itself to easy adoption on some of these objectives of the QA program.

So we feel that you're probably doing this already. Perhaps you have information scattered in different areas and maybe they need to be Xeroxed and tied together in one notebook or something and have a comprehensive sit-down session with your technicians and say, "Now we have this discrete QA program designed to reduce errors," and that will be part of their training, their in-hospital training.

MR. TELFORD: Anybody object to taking a ten-minute break?

[Recess taken.]

MR. TELFORD: Okay. What we'll do for the rest of the morning, I'd like to discuss the proposed 35.35.

What I'd like to do is explain to you our intentions for each of these parts of the proposed 35.35 so that you understand them sufficiently well that you can then make your own judgment as to whether or not your program meets 35.35 before the start of the 60-day trial.

The first paragraph of 35.35 basically says we'd

like you to have a written quality assurance program. Put it all in writing.

If this were a final rule, it would say have it all in one manual, but that's not essential for you. It's not necessary.

The real purpose of 35.35 is to, quote, provide high confidence that mistakes in medical use will be prevented.

That's our aim that we want to keep in mind.

The key is that even if it becomes a final regulation, each licensee would develop their own QA program, because this is intended to be a performance-based rule.

It's not intended to be a prescriptive rule.

The eight objectives that I'm going to talk about in a minute are just that. They're things that we think are good things to

As far as the pilot program goes, those are the eight that we want to work towards and those are the eight that we will modify when we get done.

Just so you understand that there is a feedback loop built into proposed 35.35, it would require an annual audit.

In some places there are monthly audits, where the licensee audits their own program. In other places, there

are quarterly audits.

This one just asks for an audit at the end of the year and a management evaluation of that audit and a determination that the program is effective and to make prompt modifications.

If they discover a problem that needs fixing, they should make prompt modifications to prevent recurrence.

So this is in the spirit of being performance based. You, first of all, get to set up your own program to meet your needs at your institution.

Next you get to audit it to fix it each year, if it needs fixing.

So all you really need to focus on now is we want to construct a quality assurance program. We want to meet these eight objectives.

The first one says that, "We want to ensure that the medical use is indicated for the patient's medical condition."

I first need to say that we do not want to get into the practice of medicine. We want to stay out of that.

We would like the nuclear physician, what we call the authorized user, to be in charge and to decide what should happen to this patient, whether it's diagnostic study or a therapy study.

So the intention here is just so that there is a

thought process that goes on, that someone is convinced, we hope the authorized user is convinced, that this study should be done.

The second one, this is a recommendation if you will, that for all therapy cases, that prior to medical use we have a prescription.

We have a definition of this word, which I'll go into in just a minute, but it's defined to be a written directive.

So if you don't like that word, we'll focus on what it means or what we say it means.

We have a prescription for any teletherapy procedure, any brachytherapy procedure, any radio-pharmaceutical therapy procedure or any radio-pharmaceutical procedure, whether or not its first intention was to be diagnostic therapy, but if it involves more than 30 microcuries of I-125 or I-131, we have a prescription.

So the intention here is for all therapy procedures, first of all, write down what you're going to do.

In your handout it's got a definition of prescription. It's on the next -- you may have to flip two pages to your handout now.

Basically it says it's a written directive. It's dated and signed by an authorized user.

It's not signed by the referring physician but, rather, it's signed by the nuclear physician.

For various types of therapy it recommends the content, the minimum content of that written directive.

The intent here is if there is something to be done to this patient, let's write it down before we start.

Objective 3 is all about diagnostic procedures. Though it says "prior to medical use," we think it's a good idea to have a diagnostic referral.

I said "or prescription" in parentheses, because you always have that option.

We'd like you to have a diagnostic referral for any diagnostic procedure and we note that even if it's a diagnostic procedure, if it involves more than 30 microcuries of I-125 or I-131, you have to go back to (2) and have a prescription.

In (3), the way that we're trying to arrange this is we're trying to incorporate business as you probably do it.

For a patient that's going to get a diagnostic procedure, we envision you having a referral. This comes from a non-nuclear physician, typically, so that the referral is a written directive dated and signed by a physician (that's on your definition page), but it's not an authorized user physician necessarily.

The way we envision that this works is the Nuclear Medicine Department, let's say, has a clinical procedures manual.

A patient comes through the department with a referral. It says "thyroid scan, liver scan."

In the clinical procedures manual, it's defined what the technologist is to do so that the referral and the clinical procedures manual work together in tandem.

The way that we are intending to keep the authorized user physician in charge is to have that person approve of the clinical procedures manual.

So even if we have a patient that comes from someplace else, from a physician that you've never worked with before, and the patient appears with a referral and it says, "Liver scan with 3 millicuries of I-131."

The technologist picks up the referral, goes to the manual and says, "Oh, the manual says something different here. Maybe I shouldn't do that."

So we're attempting to keep the authorized user physician in charge by having that manual direct the technologist as to what's to be done.

Yes.

MR. JANICE: Are you saying that the referring physician is automatically going to have to know how much is used for a liver scan or how much is used for a bone scan?

MR. TELFORD: No, not necessarily. Just that we hope that one of the functions of the clinical procedures manual is to prevent the wrong radiopharmaceutical or the wrong procedure from being used, maybe the wrong route.

The referral can just say -- Let's look at the definition on the referral.

Why don't you read it for me.

MR. JANICE: "Diagnostic referral means a written request dated and signed by a physician before a diagnostic medical use that includes the patient's name, diagnostic clinical procedure, and clinical indication."

MR. TELFORD: Okay, that's it.

MR. WHITE: I'm not sure if it's time for this question or not but in our hospital we don't practice that way.

Referrals for nuclear medicine procedures, diagnostic studies, come in one of two ways.

A physician in his office will ask his nurse or functionary to call the hospital scheduling office, who will then enter the physician's order into a computer and that appears on a computer in the Nuclear Medicine Department.

The other option for inpatients is that a physician will request a similar study and he will either type it in using his code number or the nurse on the floor will type it in using his name as the authorizing physician.

Does that sort of thing count? I mean, in our hospital nuclear medicine would grind to a halt if we had to get a referring physician, whose office is five miles away, to write a dated and -- How do you envision that happening in real life?

MR. TELFORD: Okay. For the pilot program, what I would like you to do is to say in your quality assurance program how you meet the intent of number (3).

The intent of number (3) is to have a written directive given to the technologists, or at least some clear instructions to the technologists, so they know exactly what to do, what's expected.

So if in your hospital you don't use written referrals, just say what you do.

You may say that, "99 percent of the time we use written referrals but under extenuating circumstances, here's what we do."

So for each of you, that's all I ask, is just you to say in your quality assurance program what you do to make sure that the clear instructions get delivered to the technologist, because I don't want anybody's practice to come grinding to a halt.

Any other questions on this? Yes.

DR. FELDMEIER: I'm kind of ignorant so forgive me. I'm a radiation oncologist, not a nuclear medicine

person.

It seems to me to be totally inappropriate for a referring physician to send a patient with a specific request of an isotope and an activity, that that's within the realm of a nuclear medicine physician licensee to determine that.

I mean, in my mind as a clinician, that's akin to a general practitioner sending a patient in need of gallbladder surgery with instructions to cut on the dotted line.

I think that's totally inappropriate and if that's done, I think that's something that the NRC and the states' regulatory commissions and governing boards should -- That's something that should be done away with.

I mean, as a radiation oncologist, I don't have patients sent to me and say, "Give 600 rads here," although I've heard that in the past that's happened.

People will come with drawings and notes stapled to their lapel, you know, "Treat here, give her 25 rads."

But I think that the NRC and the corresponding state boards should see to it that only appropriately licensed and trained practitioners should prescribe isotopes and doses.

MR. TELFORD: We agree. We agree and that's what we're trying to do is to make sure the authorized user

physician is in charge, both of prescriptions and of the diagnostic --

DR. FELDMEIER: Is that a fairly common practice?

MR. TELFORD: Well, I gave five or six talks last year and people would tell me horror stories.

The authorized users would never question the fact that these things happen. They would just say, "But I want to be the guy in charge."

I could always say, "Yes, I agree with you."

So I won't comment on its frequency of occurrence. Strange things happen sometimes.

Okay. We're up to (4). In (4) we're saying prior to medical use we would like to ensure that either the referral and the manual (they're working in tandem) or the prescription is understood by the responsible individuals.

That is, all those folks that need to be communicated with need to be told what's to be done, that they understand what they're supposed to do.

I don't mean that every time but you may work with some folks and you find out that this person needs a little more training or you need to quiz them or something.

Yes, Tony.

DR. TSE: I want to alert the participants if you have any questions or comments on each of these objectives, if you feel it's difficult for you to do these, that you

should raise now.

For example, the one question over the Objectives (2) and (3) which says, "Iodine-131, Iodine-125, 30 microcuries or above, you need a prescription," the definition of prescription is to say you must have your authorized user, meaning the user physician to write a prescription to indicate certain things.

Do you have a problem, do you have a concern with those kinds of -- the proposed regulation?

If you do, please raise it.

MR. JANICE: No, because I feel that now, anyone that comes for something requiring that much is going to be consulted from the referring physician to the nuclear medicine physician, who in turn is going to talk to us.

So I think that more or less that's already in the mill somewhere that that's documented.

MR. TELFORD: Give him the punch line.

DR. TSE: If there's some nuclear medicine technologist here, you know there's many cases involving hippuran, which is more than 30 microcuries.

Now, would you have a problem doing these things for hippuran cases? That's the punch line.

VOICES: Oh, yes.

MR. DADARI: Definitely we do have a problem with it. We already have a policy to require prescriptions for

any amount of Iodine-131 which involves 100 microcuries.

We require a prescription from the nuclear medicine physician but we do not keep that prescription in our department.

We pass it to our pharmacy. The pharmacy will not deliver the dose without that prescription.

But in the case of Iodine-131 hippuran, it might come up doing the night. You want to do a radiogram and we don't have access to a prescription.

We do have access to a physician by phone. We confirm it and the pharmacy will deliver it to us and we do not consider hippuran as hazardous as Iodine-131 alone.

That's why we never required that.

MR. JANICE: But in essence, with the definition of prescription, you have an out on exactly what you said, because it says "a written direction or order."

MR. DADARI: Well, I believe we have in our prescription or our license the chemical form of Iodine-131 requires Iodine-131 alone, not in different chemical properties.

MR. JANICE: So if this is what you're saying, if they pick up the phone and say, "Hello there, we want a hippuran study. This is Dr. Joe Blow saying go ahead and do it," as long as that's documented somewhere on the request saying that that patient could have that much?

DR. TSE: If you follow Objective (2), then you cannot do it that way. You have to have your nuclear physician to write the prescription to indicate 300 microcurie of Iodine-131, because these words do not distinguish between the sodium iodide chemical form of hippuran.

I wanted you to think about those and make a suggestion if you don't think you...

MR. TELFORD: This is very similar to the question on diagnostic referrals.

I'm claiming that the ideal case is to have all diagnostic referrals written, signed by a physician.

My answer was for the pilot program, if you don't do that, just say in your quality assurance program what you do, how you handle the cases of when you don't have written diagnostic referrals.

MR. JANICE: I suppose we get back more basic. How did you come up with the magic number, 30 microcuries, because you're also talking --

MR. TELFORD: Let me answer that question in a minute but I think there's something that needs to be said here, because these folks are over here wondering about, "Oh, what am I going to do with hippuran?"

It's a similar answer, you see. For your quality assurance program you would say that, first of all, in your

hospital this is a hundred, not thirty.

MR. JANICE: Exactly.

MR. TELFORD: You do that. Here you would say if it involves hippuran, it can be a verbal order and you would give the conditions under which you would accept that verbal order.

Just say whatever it is you do but say it in your quality assurance program.

Now back to the question of why did we come up with 30.

Well, we noticed a lot of cases of the micro to milli switch.

MR. JANICE: That could be done with ten. It could be done with one. It could be done with twenty.

MR. TELFORD: Yes.

MR. SHARP: But it starts to get serious at 30 millicuries.

MR. TELFORD: just happens to be that if you switch at 30, that's 30,000 rads to the thyroid.

In part, it's arbitrary. We tried to use some rationale.

DR. TSE: John, the reason to come up with this 30 microcuries started in '87. In 1987 we proposed a proposal regulation.

That proposal regulation included all levels of

Iodine and public comment suggested that there should be a cutoff and should be limited to only above certain microcuries.

It was suggested 100 microcuries, 30, 50, and so on.

The Society of Nuclear Medicine and other organizations suggested 30 microcuries because they believe most are done acceptable within the 30 microcurie level.

That's why we suggested this but the main reason we would stress is if this is adopted, the technologist would know as long as I see 30 microcurie or more of Iodine-131 or Iodine 125, I cannot go ahead unless I check with my supervisor or my physician.

That's the reason.

MS. WOOD: It doesn't work that way. They are not always available to check with.

If you have a written order for hippuran, for hippuran renal study, isn't that an order that needs to...

MR. TELFORD: Yes, but as this gentleman pointed out, it's a different chemical form.

So all I'm saying is just document in your QA program what you do for the hippuran studies.

For the ideal case you have all therapies involving large doses of this, you have it written down. You have a directive from the authorized user physician.

While we would like to allow the vast majority of the diagnostic studies involving this to come in via a diagnostic referral, which doesn't require that it be written by the authorized user physician but, rather, the clinical procedures manual here would then say what's to be done and how to do it.

MR. SHARP: John.

MR. TELFORD: Yes.

MR. SHARP: What was the thinking of not adding something to the end of that, such as "as iodide."

MR. TELFORD: "As sodium iodide," or something?

MR. SHARP: Just didn't want to make it complicated?

MR. TELFORD: That's a good point. In fact, it was in one version.

By the way, I welcome all kinds of suggestions like that and at the next workshop we will take these things apart and put them back together again.

So don't feel bashful about making recommendations.

Yes.

MR. WHITE: I don't have a lot of experience in designing pilot programs. You're part of it but I'm going to venture an opinion anyway.

In our clinic, we do mostly non-iodine studies. I

bet 95 percent of our patients receive an isotope other than Iodine-131.

So in looking at how the final rule is going to affect us, I'm looking at some of the other steps, and the one that concerns me the most is this diagnostic referral.

I know what you said about the pilot program but in the actual execution of the regulations, this is really quite clear.

I'm thinking about now arguing with my state inspector about this. This says a written request dated and signed by a physician.

What they're going to ask me for is a piece of paper that the referring physician has touched, written on, signed and dated.

We have 300 referring physicians, all of whom are not at the hospital.

I don't understand how this is going to work and I think of the pilot program, this seems to me to be the biggest stumbling block.

MR. JANICE: If the patient is in the hospital, he's going to write the order on the chart. That is your prescription, your referral.

All you do, if necessary, just Xerox or copy that sheet and stick it in with your folder.

MR. WHITE: That is a cumbersome procedure to go

through.

MR. TELFORD: Let me see if I understand your point.

You're saying at various hospitals around the country people do things differently.

Some folks will use a written referral all the time. Some folks will use a written referral half the time. Some folks will never use a written referral.

Okay. We have 67 volunteers. To each of them I say, put into your quality assurance program what you actually do.

I say the ideal case is to have it written. You tell me under what conditions you were deviate, you would not use a written referral.

We're going to have 67 examples of different degrees of use of written referral and that's going to be a powerful piece of evidence as to whether or not other than written referrals will work.

MR. WHITE: I understand that.

MR. TELFORD: I view it as a very interesting aspect of this pilot program, that if indeed -- Let's say that through our site visits of these 18, we come in and we say, "Let us do a little paper trail audit here. Let's look at some studies that were done."

One of the things we'll ask for is for you to

record the dose given to these folks.

Let's say you've got a large number of diagnostic studies. We would come in and say, "Well, let's take a sample of these. We're only here for a day. Let's take a sample. Let's go back and see what was supposed to be done."

If it turns out that in these 18 cases this is a minor problem, very minor things occur here, then we can translate that to the total of 67 programs and see what the programs are telling us to do.

On the other hand, if we look at it and we say, "Gee, these folks are using verbal instructions, but that's 90 percent of the problem. Whoops. We better insist on written referrals."

On the other hand, if it's a minor problem, maybe we'd want to go back and say, "Maybe we don't need written referrals."

At the next workshop you will get to tell us your experience of trying to meet the intent of this objective, how you did it, what your experience was and what you think of that objective and, fourthly, how it ought to be changed.

I can understand your point of view. You're saying, "Well, what if this were a final rule and I had to face a state inspector all of a sudden based on this." Right, life would change for you.

But the pilot program is a giant experiment. We proposed something. We're going to try it. We're going to fix it before it ever sees the light of day in an enforceable regulation.

DR. WIATROWSKI: Can I make a comment?

MR. TELFORD: Yes.

DR. WIATROWSKI: On packages that you get for all the radiopharmaceuticals where the kits you get, those kits are legend items and have a statement that it requires the prescription of a physician.

That statement is issued by the Food and Drug Administration. It has nothing to do with the U.S. Nuclear Regulatory Commission.

So the interpretation at one of the facilities that I consult at was essentially that since it was a legend item, and legend items required prescriptions by physicians to be dispensed to patients, in fact that item needed a written prescription to be dispensed to the patient.

The second point is I think under JCAH Accreditation Manual, they refer to the referral of a patient for a radiologic or a nuclear medicine procedure as a consultation between the referring physician and the physician who is to interpret the scan and in that context require certain clinical information be provided to the physician who is to interpret the scan to improve the

likelihood of a correct diagnosis.

So I think there's some precedent involved for some sort of written documentation for the referral.

The most impressive of that is the fact that I think if you look on the packages where the pharmaceuticals come, they indicate they require prescription by a physician

MR. TELFORD: Let me see if I understand.

Your bottom line is there's a precedent for written directives?

DR. WIATROWSKI: Yes, I think so.

MR. HAMMOND: It's coincidental that we've been involved in a process in Texas for about four years now about provision of radiopharmaceuticals by a mobile scanning company to hospitals, where you have circuit-riding radiologists and you have referring physicians.

Texas Radiation Control regulations specifically state that unlike x-ray where any referring physician can order the administration of x-rays to a patient, that only a licensed nuclear medicine physician can order the administration of radioactive materials to a patient.

So it's a little bit different. Prescription-wise, we've been involved with the Texas Food and Drug folks, U.S. FDA, Texas State Board of Pharmacy and the Board of Medical Examiners and Board of Radiation Control for about four years on the issue.

Basically, where we've ended up is the written prescription can be a listing of the exams you're going to do and the amount, routine dose, with exceptions, you know, if it's a pediatric case or it's a possible pregnancy or whatever the exceptions are established by the medical director of the department.

Those are signed by that physician or the authorized user.

So you have a list of prescription dosages. It's not patient specific. That's my concern.

In this, the objectives state that you have to have a written prescription for teletherapy and brachytherapy, but if you look at the definition of a prescription, it includes patient-specific prescriptions for all diagnostic uses, which is going to be cumbersome.

I think Wayne's got a valid point that between what's required by existing regulation, at least in Texas, plus the Joint Commission requirements, you're going to have most of these bases covered.

The interpretation by the NRC is that you have to have patient-specific prescriptions and that changes it.

DR. WIATROWSKI: I think the issue is it's not radiation related. In fact, as a pharmaceutical, whether it's tagged or not, that is a legend item and is controlled by those regulations outside of the NRC that govern the

administration of pharmaceuticals to humans.

If in fact that product requires a prior written order of a physician before administration to a patient, then I don't think the NRC can supersede that requirement.

MR. HAMMOND: But the question is whether or not it meets written prescription.

MR. TELFORD: Let me see if I understand your point.

Let me distinguish between a prescription for therapy and a referral for a diagnostic study.

Are you saying that there are existing requirements to have a prescription for therapy studies but they are not patient specific?

MR. HAMMOND: No, I'm referring to diagnostic uses. There's a requirement. When you get all of the laws of the State of Texas together and the U.S. FDA standards together, Wayne is correct, there is existing requirement that you have a prescription for that particular patient, that there has to be a prescription for the diagnostic administration of a radiopharmaceutical.

MR. TELFORD: And this is a diagnostic study?

MR. HAMMOND: Yes.

MR. TELFORD: Does it name the patient?

MR. HAMMOND: No, the interpretation we've had at the state level and so far, hopefully, we'll get the FDA to

agree to it, is that like any other procedure, whether it's a contrast media in radiology, you can develop standardized protocols for operations and standardized criteria for the patients who meet a certain criteria.

You use this protocol and this prescription amount of the legend drug to administer this patient.

Basically, it goes back to Item (4) about the clinical procedures manual. All these things are laid out and they've got to be approved by the medical staff of the hospital, plus the medical director of the department who assumes responsibility for the administration.

So you take a long way around but you end back up essentially with a prescription. It's not on a prescription pad and it doesn't have the patient's name on it and the doctor didn't sign it and put his DEA number at the bottom of it.

But essentially you end up with a paper trail of a written prescription.

MR. TELFORD: Even for a diagnostic study.

MR. HAMMOND: Even for a diagnostic study, because Wayne is right. You cannot administer that, you can't handle that without --

DR. WIATROWSKI: You could not administer oral contraceptives to a patient without a patient-specific prescription and oral contraceptives are a legend item,

also.

So if you are going to require a physician to sign a prescription for Mary Jones to administer oral contraceptives, and you have another legend item, which is a pharmaceutical to which you put a radioactive tag, but it's also a legend item, then you need to have a written prescription that is patient specific.

I don't see --

MR. WHITE: That's not true of all the drugs. Physicians have nurse practitioners or nurse [illegible] whom they give the authorization to prescribe, cal' [illegible] pharmacy.

DR. WIATROWSKI: To get that p[illegible]maceutical out of the pharmacy, if it's a legend item, the[illegible] has to be a written piece of paper with a physician's name and DEA number and so forth on it.

That's a fact. I don't know what you do but I know that --

MR. WHITE: Within the State of Texas.

DR. WIATROWSKI: I think that's a federal requirement.

MR. HAMMOND: At which point does the patient's name get to that prescription or what does that prescription look like is kind of the issue.

I agree with Wayne that federal regulations require that you have a prescription for that patient.

Whether it's all on one piece of paper or it's done before or after, during the procedure... There's lots of things used in a hospital situation that are a legend drug that there's never a, quote, prescription written for, if it's an IDP or whatever it is.

MR. TELFORD: May I ask you to be careful about your terminology because, say it's a diagnostic study, then we're talking about a referral.

We have a definition of what we've considered to be the ideal referral.

It's written. It's dated and signed by a physician. It's patient specific.

Now I think you're saying that you don't do that. You don't necessarily have referrals that are patient specific.

MR. HAMMOND: Yes, we do. Referrals, yeah, we have specific referrals, but in Texas that's not enough to do a nuclear medicine procedure.

The referring physician can only request a procedure to be done. He can't order one.

MR. BOLLINGER: I think that one of the -- In the NRC regulations, one of the requirements or duties and responsibilities of the authorized user is to select the patient, the appropriateness of the patient for the study.

If a patient has suspected metastatic breast

cancer and maybe a liver scan doesn't sound like the appropriate thing to do but if it's a metastatic search, then it probably is exactly the thing that needs to be done.

So how does breast cancer relate to a liver scan? That's why we need the authorized physician in the loop.

The ideal situation would be that any physician would write a referral slip for a patient.

The authorized user or his designee, perhaps a senior resident or something, would review it and say, "Yes," initial it in some way and then send it on to the technologist, who will draw up the dose whenever they inject the patient.

We realize that that can't be done in all situations, especially probably in your situation, the mobile situation.

But what we would like you to do is for you to tell us how you cope with requests or referrals which don't meet our ideal.

Maybe there's another way. For instance, when you go to X hospital and X GI specialist refers a patient, you know that guy and you will handle his case differently from some Dr. Smith that you never heard of before, you don't know what his specialty is and you're not even sure if he's associated with the hospital on a regular basis.

Maybe that would send a flag to the technologist

to do a little extra checking on that doctor, whereas he wouldn't check on the first doctor that he was familiar with.

But we'd like you to tell us how you will deviate from some written protocol, like a procedures manual that says, "Liver scan, 3 millicuries, sulfur colloid."

If it's a baby, obviously you wouldn't give three. How do you intend to cope with something that appears to be not quite right, if there's a question?

MR. HAMMOND: I understand what you're saying but I think Wayne brings up a good point that this whole process can't take place in a vacuum, that there are other existing regulations, whether they're Medicare regulations or whatever, that require a lot of the things that you're talking about.

In some cases the things that we're talking about here are duplications of existing Medicare requirements or --

MR. BOLLING: JCAH requirements?

MR. HAMMOND: JCAH or whatever it is. A lot of these things are already in place, particularly the case that's been brought up twice today about if you don't know the physician.

Medicare has a requirement that if you don't know the physician, you have to verify his qualifications before

you can admit his patient to your hospital, either as an outpatient or inpatient.

MR. TELFORD: Let me see if I understand your point. You're saying that, first of all, you understand what we're driving at here.

In the case of diagnostic we would like a written referral.

But your point is that this is already required through a collection of other regulations, and that what we're saying here is not in conflict with that but, rather, just duplicative of that.

MR. BOLLING: Maybe what you can do is in establishing your QA procedure -- and I before said "book," but I should have said "folder" perhaps. We don't want you to create any books.

In your QA pilot program procedure folder, instead of even Xeroxing the JCAH requirement, perhaps you can just reference it and say, "We believe that we meet Objective (3) through XYZ requirement of JCAH."

But you would need to send us a copy of that so that we can see what it is.

MR. TELFORD: They need to say what they do.

MR. BOLLING: Right.

MR. TELFORD: They need to say that -- It's okay to say that's the reason for why they're doing that but they

need to say that for these kind of cases, it's not written, and under what conditions is it not written or not patient specific.

MR. BOLLING: I think that's why most of us believe that you're doing a lot of those objectives already.

It could be that perhaps you don't recognize, or maybe you do recognize that they are coming from different sources.

MR. SHARP: I think if you keep in mind the goal of the objectives. The idea is to have an inspectable record, something you can check back with, and so it can take different forms.

I think ultimately the word "prescription" and the way they've defined it might need some modification for electronic records, but an inspectable record is the goal.

DR. TSE: May I ask a question to people who are familiar with nuclear medicine procedures.

If you take a telephone order from a referring physician, do you at some time later ask him to send you a piece of paper of written or that's enough, the telephone is enough?

VOICES: Telephone. Telephone.

MS. WALKER: Our techs will not touch a patient without a piece of paper with a physician's signature on it.

DR. TSE: So different hospitals have different

procedures.

The question, though, is that if you only telephone, what happens if something goes wrong? How do you verify that's somebody else's problem or your hospital's problem?

MR. DADARI: If we have tried to get a prescription but we were very unfortunate on it, we never were able to get it, first of all, we know our physicians. We know this is a cardiologist. Any time he orders it, it's either thallium or...

I know five doctors. All are cancer doctors. Bone scan, liver scan, that's it.

If I get somebody I don't know that's out of town, usually we call and confirm the order.

If it's suspicious, we ask the patient, "What's wrong with you?"

They say, "Well, I've got a lump in my neck." So we get the idea where to look in the first place.

If it's iffy, we will investigate. So far we've never had any problem with it.

But with prescription we had a problem. We've never been able to get any prescription from anybody.

MR. JANICE: What we have done is in order to facilitate matters, we have come up with and have had a check-off system and we have distributed to most all

physicians that use our facility.

Nine times out of ten they will send that prescription back, or whatever you wish to call it, with the check and indication and that kind of stuff.

But it's really not signed by the physician. It has the patient's name and what they're looking for and what exam to do.

DR. TSE: So please indicate what you do in your specific QA program for your institution and then we can look at the various different pictures and we can see that much broader picture.

To your question, I was wondering whether what you said about non-patient-specific prescription is essentially the term we called clinical procedures manual.

That means the nuclear physician would indicate for certain types of procedures what isotope, how many curies are needed.

But in addition to that, would you also have to have somebody to say this patient needs what kind of procedure.

That is a diagnostic referral we're talking about. Mobile Service certainly does not know what this patient needs. Some physician has to say, "This patient needs a bone scan."

MR. HAMMOND: Yes, there is a referral from the

referring physician.

DR. TSE: Right.

MR. HAMMOND: That is patient specific.

DR. TSE: Right.

MR. HAMMOND: What there may not be is a -- it may or may not be in writing, depending on -- a lot of the hospitals we deal with are teeny-tiny and it may or may not be in writing.

It's not in writing to our office because it's all done over the phone, but as far as the actual medication that's given to the patient, that prescription for that drug -- that's where I was using the word "prescription" a while ago -- would be derived from the diagnostic procedures manual that says, "If a patient presents from a physician with this problem, give them this dose, if they're an adult. If not, call me." That kind of thing.

DR. TSE: Therefore, except the word "written," you are essentially doing what this objective says.

MR. HAMMOND: Correct.

MR. JANICE: In essence, people that are using the unit doses in this case would have two prescriptions, because they would actually have the prescription from the physician requesting it and they would also have the prescription from the radiopharmacy going back and detailing the same thing again, having the patient's name,

radiopharmaceutical lot number and everything else.d

MR. LOPEZ: Except that the doctor would not sign it. It would be just --

MR. JANICE: You could require that he sign it.

MR. LOPEZ: You could require it and that could be one of the solutions.

DR. FELDMEIER: The analogy has been made treating radiopharmaceuticals like any other pharmaceutical and the issue has come up, what happens when you call in a prescription.

The doctor's office, family practitioner, has someone in his office call the pharmacy and say, "I want to call in a prescription for tetracycline for Patient X."

When the pharmacist on the other end of the phone accepts that prescription, in all reality he should be speaking to the physician. It should not be some functionary within the doctor's office.

It shouldn't be a nurse. It shouldn't be a receptionist.

The pharmacist, if he chooses to take a prescription from some functionary in the physician's office is doing it at his own risk.

The pharmacist at the other end of the telephone should be writing all this down and saying, "Dr. Smith has prescribed 40 tetracycline, 250 milligrams, for Ms. Jones on

this date."

There should be a hard copy of that on a computer or card file or something so that there is a paper trail.

If you're going to use that as an analogy for radiopharmaceuticals, as required by the FDA, I think if a doctor calls in and says, "I want Ms. Jones to have a bone scan," it seems to me that at the other end of the phone, within the department, if you record all that and have the appropriate documentation of the name and number and everything of the physician that that ought to fill the requirement for a written...

On this case this is a referral. This is the requesting doctor asking for an imaging study.

Again, I'm coming at things from the perspective of a radiation oncologist where we do things a little differently.

We're giving higher doses. We're generally doing it over a prolonged time. We're not giving a single administration as nuclear medicine usually does.

It seems to me that there needs to be for the administration of a radiopharmaceutical, even if it's just ten microcuries of Iodine-131, or something like that, that there needs to be some sort of written indication from a nuclear medicine doc to do that.

If not right at the time -- I mean, if this is the

middle of the night and you don't want to get your doc in from 25 miles from home, at least on the telephone and the next day he signs it.

MR. TELFORD: And the analogy would include -- you started with a pharmacist receiving.

DR. FELDMEIER: Right.

MR. TELFORD: So we could say a qualified person in the Nuclear Medicine Department should receive it so they would know what might look funny and whether or not it might be an appropriate study.

DR. FELDMEIER: Exactly. Sure, because a pharmacist, if you order 100 milligrams of morphine, a trained pharmacist is going to realize that that's a potentially lethal dose and is not going to issue that amount of morphine.

DR. WIATROWSKI: Yes, but that relates to the misadministration you had earlier about the 30 millicuries of I-131 up to 30 microcuries.

I was pointing out if you had had a qualified nuclear medicine technologist, that person would have identified it.

This gentleman then pointed out, "Well, then, we couldn't have these procedures available," which may be the case. I don't know.

MR. TELFORD: What we're doing is we're fast forwarding to the second workshop.

[Laughter.]

MR. TELFORD: And, "Gee, I really like this. This is great."

I told you that I was going to be the only person in the room that said these were any good. So let me come back to the pilot program and say these are the ideals, that I'm convinced you've got the intentions here.

We'd like to have written instructions for what should be done.

MR. JANICE: What you're saying is you want us to say what we'll do when we come back in August and say, "This don't work worth a damn."

[Laughter.]

MR. TELFORD: "This doesn't work. Here's something better, and here's why I think that." I would love it.

Yes, Ed.

MR. KAPLAN: At Northwest Texas you tried getting these written referrals and it didn't work. I'm just curious why it didn't work and what happened.

MR. DADARI: Okay. Most of the doctors who order these tests are on the road. He's calling from his phone in the car, and he says, "Well, David, I'm sending so-and-so

over there, and I need a bone scan."

MR. JANICE: He talks to you directly, though. He doesn't call the receptionist or that kind of stuff.

MR. DADARI: If I'm not available, it's going to be the receptionist. That's for sure.

Or a patient had a surgery fifteen days ago and now has chest pains and is a possible PE over there.

Or "I'm sending somebody over."

And we have real problems. I mean, we basically -- we try to implement that, but it's practically impossible.

Now, something else bothers me. If our next thing is CAT scan. If an individual had a CT -- an incident of CT tests, they say, "Oops. Well, let's do this."

They do not go to anybody. And it may be a lot more radiation than three millicuries. They're not required to have a prescription, but we are being forced.

Well, I will understand on the therapy problem a hundred percent, and we require it.

But in diagnostic it's -- I believe it's a lot of too much push to nuclear medicine to require that and slow all of the procedures down.

We have to wait till patient comes in, now get the prescription, order the drug, inject the drug, wait for it, do the scan.

So we're talking about a whole day's work for a patient. It slows down what is already a slow process.

MR. TELFORD: You used the word "force." I don't think --

[Laughter.]

MR. JANICE: John, I don't think there isn't a one of us sitting here that's not like Colorado Springs. The physician doesn't pick up the phone and it comes into central office, and we don't know about it until late that afternoon or the next morning what we're going to do on a patient.

So by that time it's kind of late to start investigating what's going to take place.

But if we get schedules in mid afternoon where we can look over schedules and say, "Hey, this exactly doesn't sound right. What are we going to do about that?"

Then we can start doing some calling. I may be wrong, but like I said, I feel everyone of us gets telephone orders through a receptionist pool or through one scheduling person and that's it.

MR. WHITE: Well, it sounds like you've worked it out at your hospital, so you don't have to --

MS. WALKER: It's a product of the VA being very slow.

[Laughter.]

MS. WALKER: And not having outside referrence. In other words, if we get a call --

MR. WHITE: You can't lose patients because....

MS. WALKER: That's right. We can do whatever we want.

MR. WHITE: I don't want to make it sound like our hospital is ignorant. We purposely located central scheduling in the nuclear medicine department. That has really made a difference because we do get a lot of questionable scans.

The woman who is an RN and does the scheduling sits next to the chief of nuclear medicine technologist, because he knows about x-ray, knows about ultrasound.

I don't want to sound like a whiner about this. We have looked at that problem and made a shot at it.

But I think you need to understand that something that we try to do on a voluntary basis or to meet JCH requirements is very, very different than Nuclear Regulatory Commission requirements.

If I were to take what we do and put it into our QC program, I would have to document that when that RN was sick, another RN was there, you know. If we wanted to move the scheduling across the hall, I'd need a licensing amendment.

I mean, doing it is real different than having it

as a regulation license. I think that's something else the pilot program will clarify.

MR. TELFORD: Keep in mind that we're not forcing anybody to do this. I'm saying this is the ideal, to have written referral.

I want you to say in your QA program what you do and we'll find out how well it works.

Then if you're one of the eighteen, we'll confess to you what we think of it, in a no-fault kind of way.

[Laughter.]

MR. BOLLING: John, I think that your comment, and comments from anybody else in the room, you can put down what you do. But if you have some strong opinions, in addition to that, as to why the written prescription would give you a headache, we want to know that, too.

We want to know if you think it's going to double the time that it takes for you to handle the patient, that we need to know.

MR. TELFORD: Yeah. When we get to the discussion on the evaluation forms, you'll see that we have blanks and lines for you to fill in, what's wrong with it and how to fix it.

MR. SHARP: John, before you move on, one last point. One thing, at least in this state, that will confound this situation is that the pharmacies are able to

deliver a dose without a patient name on it.

They can legally deliver a dose that says "for physician use only." They've got that written into the nuclear medicine section of the Board of Pharmacy Act.

That may be true of other Boards of Pharmacy around the country. So there's one bit of paper evidence that you're not going to have here, so don't build it into your system.

MS. WOOD: It's there to fill in.

MR. SHARP: But it's not required here. They can issue "for physician use only," and not name the patient on the dose.

MS. WOOD: But you write in the patient's name; you fill in the blank.

MR. SHARP: We don't make them write that in. I'm with the State.

MR. DADARI: Well, ironically, our pharmacist has been building a code for this, and decided for this reason, because they had been required -- The State required him -- the State of Texas required him to issue every dose on an individual patient basis.

You have to have the full name. We have right now problem with that.

MR. SHARP: Well, the Board of Pharmacy couldn't have done that because it's their rule.

MR. DADARI: The State of Texas has done that just recently.

MR. SHARP: All right. We'll work on it.

MR. TELFORD: Okay. Let's see if we can get through these next four objectives before lunchtime.

Number five says to ensure that the medical use is in accordance with either the referral in the manual or prescription. The intention here is to have the administered dose to be as prescribed, or as described in the referral in the manual.

Six is to ensure prior use, the patient's identity is verified, as individual names on the referral or the prescription.

You've seen a lot of cases now where the patient's identity is mistaken. So I think that's a good idea, to verify the patient -- that patient's identity.

Seven is ensure that unintended deviation from either the referral in the manual or the prescription is identified and evaluated.

Now, the intention here is to -- like in the case of teletherapy, if the patient is prescribed to get 200 rads per day as the fraction. So if you're documenting, "Okay, the patient got 210 today." Tomorrow you write down that he gets 180, et cetera.

So you're identifying this unintended deviation,

however minor.

The purpose of this -- the intention here is to have this information available for the audit at the end of the year.

You know, this is in the world of having this be a final rule.

So for the pilot program, you won't have to go through an annual audit. But it will be sufficient to have the prescribed dose, or the dose for the diagnostic study to be written down, and then what was administered to be recorded, so that any deviation could be identified and evaluated, which is something that we can do for the eighteen sites.

MR. BELLEZZA: Excuse me. Did I misunderstand what you're saying there? For seven, in therapy you want deviations done on -- noted on a daily basis?

MR. TELFORD: In teletherapy that's correct.

MR. BELLEZZA: So, for instance, if someone got ten rads too much today, then that should be noted even though it's going to be made up tomorrow?

MR. TELFORD: No, not noted. You would simply record the dose administered, dose or dosage. I'm not attaching any significance to the deviation.

There's no --

MR. BELLEZZA: Just write it down?

MR. TELFORD: Yeah. There's no reporting requirements associated with the pilot program. There's very few record requirements or ... that we request.

We're using the funny phrase here of "unintended deviation," meaning this is like a slight, slight mistake.

DR. PICCONE: I can think of another example for unintended deviation from diagnostic referral. If, when you get a diagnostic referral, either written or oral, and a physician says, "I want a bone scan on Mrs. So-and-So," and he requests that you do the bone scan with 50 millicuries.

Well, when you're looking at that referral, you're not going to use 50 millicuries, or you're going to talk to the physician and find out why is the 50 millicuries there.

Most frequently they don't put any dose, do they? They say "bone scan" or tell you they want a bone scan.

But in the case where you get written referrals, you may have a physician who puts an activity on there.

Like one of the misadministrations that occurred, the physician requested -- I don't recall the particulars -- 100 microcuries instead of 10 microcuries or whatever.

Well, in your review of that diagnostic referral, you're not going to do that. That's going to, hopefully, turn on a light.

You're going to either talk to that physician, or you're going to do something, and you're going to deviate

from the diagnostic referral.

And you're going to have a reason why you're deviating. The physician, you know, he did -- he thought that was the right dose, but -- you know, whatever you say needs to be done, that's what I want done.

So there could be those kinds of deviations as well.

DR. FELDMEIER: A referral by a nonlicensed, a cardiologist or endocrinologist, I mean they could ask for something really bizarre and ridiculous.

They can ask you to -- I think that just because your referring doc is not very sophisticated in the ways of radiation safety, nuclear medicine, radiation oncology, diagnostic radiology, I don't think that it should be a burden on the nuclear medicine department, the radiation oncology, diagnostic radiology to have to answer for the naive mistake of a referring physician.

I think if number seven is being interpreted to include such a deviation from the request of the referring physician that there is a substantial difference.

You know, if the guy sends you a patient with a note attached to the lapel that says to use 150 millicuries of Iodine 131 for a thyroid scan, I mean, I don't think that the nuclear medicine department should be held accountable for his naivete.

So it could be in the case of nuclear medicine, either diagnostic or therapy. It could be teletherapy; it could be brachytherapy.

It could be it was brachytherapy, and you were supposed to load two twenties and two tens, and you loaded two twenties, a ten and a five.

All right. So maybe it's a big deal; maybe it's not.

The intention of number seven is just to record the fact that you loaded two twenties, a ten and a five.

In the pilot program we're attaching no significance to the deviation. But the intention is to have the department itself to be able to know how well it's doing.

Tony.

DR. TSE: John, I want to make two points on this objective number. One is the word "unintended deviation." That means the intended deviation. If a physician wants to change a prescription after -- or for some reason, if he said, "No, I want to change it," that's fine. That's not including those.

Second --

MR. TELFORD: And that will become clear this afternoon when Tony goes through the reg guide. This would be our vision for how prescriptions could be changed,

I think that -- you know, for the prescription, yes. If the nuclear medicine physician prescribes a certain activity of Iodine 131 and there's a deviation from that, then, yes, that's a mistake that the nuclear medicine department should be accountable and attributable for.

But referring physicians not having the wherewithal, not having the sophistication to know what's appropriate -- you know, there are exceptions -- but in general not having at least the responsibility and not having the licensure, I don't think that the nuclear medicine department should be held accountable for that type of mistake.

MR. TELFORD: Yeah, we agree.

What we're really trying to catch is -- not "catch," but we're trying just to be able to identify --

MR. JANICE: A play on words there.

MR. TELFORD: I used the wrong pronoun there.

What I want is for the department itself to be able to interpret how well it's doing.

I mean, the intent of seven is to say, after each administration of a dose or dosage, you record it so that the department itself can say, "How well are we doing."

So it's the deviation from what they were supposed to do, as directed by the department in one way or the other, as directed by the authorized user physician.

especially for brachytherapy.

DR. TSE: Second, if the intended deviation is greater than the -- the dose -- let's say the dose is greater than the misadministration or wrong radiopharmaceutical, it fits in the misadministration, then that becomes a misadministration.

If it's less than the criteria of misadministration, then this objective it's essential to ask the licensee to take a look to see whether you have any problem.

That's the purpose.

MR. TELFORD: Okay. Number eight is rather straightforward.

The intention is to have the treatment planning, either for brachytherapy or teletherapy, to be in accordance with the prescription.

I know it's another way of using that the authorized user physician is in charge.

Let me -- Yes.

MS. RUDOLF: I have a question.

The wording is different from the information that was sent to us on the objectives and what's here that you've posted.

MR. TELFORD: Right.

MS. RUDOLF: I can interpret them slightly

different. For instance, number four refers only -- on the new one we were handed today, refers to a diagnostic clinical procedures manual.

But if I interpret what was mailed to me on number four, it looks to me like -- I deal strictly with therapy. I would interpret number four with the stuff that was mailed, to say that I have to ensure that prior to any use, the prescription and the clinical procedures manual is understood, meaning I should have a therapy clinical procedures manual.

MR. TELFORD: Which gives you a big problem.

MS. RUDOLF: But over here it doesn't say that, so now I'm confused.

MR. TELFORD: This is what we intend: a diagnostic clinical procedures manual. We did not visualize a clinical procedures manual - therapy.

MR. JANICE: You're off the hook.

MR. TELFORD: So you can breathe a sigh of relief.

MS. RUDOLF: I was wondering how you thought we could do that in a month.

MR. TELFORD: You know the old adage about getting smarter as you go along? See, this is our fourth workshop.

When people have said, "What? You want me to have a procedures manual for therapy? I can't write that."

MR. JANICE: I think we ought to go to San

Francisco.

MR. TELFORD: Also, in number two, you'll notice a little bit of difference. We have (a), (b), (c), (d). Well, that's for the same purpose.

We're trying to clarify that yes, we mean a prescription for (a), for (b), for (c), for (d), for all these cases.

In the actual writing of the verbiage that either appears in the Federal Register notice or what was sent to you, we had a committee working on that. That included two lawyers. They helped us write things, you see.

So it's clear to them --

[Laughter.]

MR. JANICE: Enough said.

MR. TELFORD: -- how it should be written.

So for the pilot program and for the workshops, we said, "Okay. We'll be simple. We'll drop back: (a), (b), (c)."

That's not a reflection on you, but rather on the fact that we tried to write in more simple language.

So the purpose here of me discussing all of this is so you really understand the intention of what we're shooting at, what we're trying to do.

So it's this language --

MS. RUDOLF: I should address this?

MR. TELFORD: Yes.

MS. RUDOLF: On the definitions, those haven't been changed. What we were sent in the mail is still what we're to go by?

MR. TELFORD: Yes.

Ed.

DR. KAPLAN: One of the things that seems to have evolved over the course of the workshops is that objectives number four and seven are diagnostic related.

DR. TSE: Not seven.

MR. TELFORD: Seven is anything.

DR. KAPLAN: Maybe we have to think about that --

DR. TSE: If prescription is for the therapy, (b) is a prescription, is for the therapy.

(a) is for diagnostic.

DR. KAPLAN: Let's spell that out. Let's be specific about that today.

DR. TSE: In the objective two, prescription is needed for therapy at iodine greater than 30 microcuries.

For objective three, either prescription or diagnostic referral for diagnostics.

In objective seven, it says --

DR. KAPLAN: Now four.

DR. TSE: Four is for diagnostic.

DR. KAPLAN: Diagnostic, right.

DR. TSE: But seven, I'm talking about seven. (a) is for diagnostic referral and (b) prescription, meaning all prescription.

DR. KAPLAN: Okay. Now, I just want to point out that the new wording of four -- because you brought this out, and this is the first time we're using the new wording. What I sent out to you was different.

So the new wording of four and the new wording of seven are very similar to the one in nine.

DR. TSE: Modification; correction.

Four is also for diagnostic and also for therapy.

DR. KAPLAN: What Tony is -- If I can paraphrase what you're saying is that in four and seven, (a) means diagnostic procedure, (b) means therapy.

DR. TSE: Right.

DR. KAPLAN: We have to be clear here that we're covering both.

So in answer to Carrie's comment, seven is almost the same. She doesn't need a clinical procedures manual --

MR. JANICE: It seems to me like you've got five, four and seven.

DR. KAPLAN: But I think we should clarify this.

MR. TELFORD: Okay. Seven applies to both diagnostic procedures and therapy procedures.

DR. KAPLAN: As does four.

MR. TELFORD: So the only change is, is that which -- from which there is a deviation, like for therapy you would be deviating -- a deviation could be from the prescribed dose or dosage.

For the diagnostic you would be deviating -- a deviation would be from the combination of the referral and the manual.

But I'm glad you brought that up because that's what we're trying to do, is clarify the language. So what we handed out today I think is more understandable.

And in a minute I'll ask everybody else if they understand it.

DR. KAPLAN: Let me pursue this just a little bit more.

MR. TELFORD: Okay.

DR. KAPLAN: Because I want to get to Carrie's point.

Number seven, if unintended deviation in therapy is from a prescription -- is only from the prescription, that's the only deviation that we're talking about, whereas for diagnosis we have a referral and a procedures manual.

I think that clarifies that point.

MR. TELFORD: Yeah. For example, if it's a liver scan and you're using technetium, maybe they didn't use -- you could deviate from the referral.

The referral asks for a liver scan. They say they didn't do a liver scan; they did a bone scan. Well, that's a deviation from the referral.

What if they used the wrong amount of the radiopharmaceutical or the wrong radiopharmaceutical? That's a deviation from the manual. Right?

MS. WOOD: It's a misadministration.

MR. TELFORD: Don't use that word.

[Laughter.]

MR. TELFORD: Maybe if you get the wrong radiopharmaceutical, that's the part that s the misadministration. All right. I mean, that's just an example of a deviation then.

MR. JANICE: Unintended deviation.

MR. TELFORD: Unintended even.

Yes.

DR. TSE: We did not use the word "diagnostic" or "therapy" in (a) or (b) because it's more complicated than that, because there's 30 microcuries of Iodine 131, which is a diagnostic procedure, but requires a prescription.

So you need to refer back to objectives two and three to see which one requires a prescription and which ones are permitted to have diagnostic referral.

It's not a simple cut. Otherwise, it would be simple.

DR. KAPLAN: I was hoping to clarify it.

[Laughter.]

MR. JANICE: Get the lawyers back into it.

MR. TELFORD: Well, we've come to the time where I want to ask if everyone understands this well enough so that they can implement a modified QA program that meets 35.35.

So is there somebody that doesn't understand? Or maybe I should go the other way.

Does everybody -- Oh, you have a question.

MS. WOOD: I have one question. What do you use Iodine 125, 30 microcuries --

MR. TELFORD: For? You may not.

But if you do -- Well, there's one strategy here, and that says that if you're ever going to use a very large amount of iodine -- that's sodium iodine really -- we want a prescription.

So each time that occurs in a department, it's done under a prescription, just so people get into the pattern of doing it the right way.

That's really the intent behind including 125 in there, particularly when we see a lot of switches from 123 to --

MS. WOOD: I-123.

MR. TELFORD: I-123 to I-131.

MS. WOOD: Not I-125.

MR. TELFORD: That's true. I mean, they just haven't seen those yet.

And it may be that's a radiopharmaceutical not of choice, not used.

Can somebody else comment on that?

MS. WALKER: The only thing I've seen it used for is some metabolic studies that are research oriented.

MR. TELFORD: See, we have to include it for completeness because NRC regulates 125 and 131, but not 123.

MR. GOMEZ: 123 is the cyclotron?

MR. TELFORD: Yes.

MR. GOMEZ: It's not regulated by NRC.

DR. TSE: But the reason Iodine 123 is not included is -- Let me put it the other way.

Iodine 123 provides a much smaller dose to --

MS. WOOD: Correct. You can use larger amounts.

DR. TSE: Right. You use millicuries amount. It wouldn't provide as large a dose, maybe one thousand times less than as Iodine 131. Therefore, it's not necessary --

MS. WOOD: My question is that we don't use Iodine 125, so why was it included?

DR. TSE: The answer is that somebody, somewhere, sometime may use it.

MR. TELFORD: If they do --

MR. DADARI: Iodine 125, glow fill, for renal

studies. We get it once a year, and we try to refuse it.

[Laughter.]

MS. WOOD: 125?

MR. DADARI: 125.

MR. TELFORD: You don't have to go out and get any.

MS. WOOD: I don't want any.

MR. TELFORD: Yes.

MR. WHITE: Any intention -- How do we apply this to bone densitometers and lexiscopes and things like that?

MR. TELFORD: Those are diagnostic studies?

MR. WHITE: Yes.

MR. TELFORD: Ideally it should have a referral, a written referral. But just document in your program what you do with it.

MR. WHITE: Is dosage a question? I mean, usually the technologist essentially decides on the patient dose by deciding on the colimeter size and scan speed.

Are you intending to address that?

DR. TSE: I think you could say, if you use those diagnostic devices, you could say how you want them to improve your QA program.

MR. TELFORD: The only records that we would request for the pilot program are the prescriptions. In

other words, just retain -- Over the 60-day period, retain your prescriptions someplace; the referrals and administered dose or dosage.

Just retain those. I'm not saying make extra copies, and I'm not saying create any extra records.

Like if those are in the patient's chart, and the chart is in the central file, you've got it. Just keep a record so that if you're one of the eighteen sites, then we can come and look at those.

Okay.

MR. JANICE: How are you going to determine who your eighteen sites are? Pick them out of a hat?

MR. TELFORD: Yes, sir. One of which will be from Texas.

MR. JANICE: Oh, good. Let it be Houston.

[Laughter.]

MR. JANICE: Or Northwest.

MR. DADARI: It's too cold to go there.

MR. JANICE: It will be the middle of summer, so forget it.

MR. TELFORD: We're being overwhelmed with volunteers.

Okay. Do we need more discussion on these objectives, or do you really understand them well enough to implement a program to meet...

Okay. Everybody can implement? No, nobody can?

[No response.]

MR. JANICE: We'll write something down.

MR. TELFORD: Well, I mean the question is about the understanding of what these are supposed to say. If you're up with me to this place --

MR. JANICE: I would suppose, as you said earlier, you would want something written following those general guidelines --

MR. TELFORD: Oh, yes.

MR. JANICE: And if it does not work, then you come back and you say why it does not work.

MR. TELFORD: Well, no, the first part of what you said was a key point.

What we're asking is that you take your current program and modify it so that you can say it meets 35.35. We didn't ask for a manual. We didn't ask for anything glorious.

Just take your program. It may be in six parts.

The one thing that we'll ask for is a one-page outline that says, "Section X of my program as it exists today" -- and you're looking at the copy here -- "meets number five here. Section Y over here in some other place meets number six."

That's all we'll ask for. And the purpose is so

that when we go through all these programs -- all 67 of them, we don't spend an eternity trying to find everything.

That will be like a road map that will show us where to go to look. That's all we'll ask for.

Well, let me go around the room. Does anybody want to ask more questions about the intentions of these?

No? Any more questions?

[No response.]

MR. TELFORD: Can I get somebody's attention over here? Any more questions about these?

MR. GOMEZ: The only thing, if we're saying Puerto Rico, the Department of Health there they do not care for any nuclear material. They do care just for x-rays. That's all.

MR. TELFORD: Okay.

MR. GOMEZ: So anything related with nuclear energies is controlled by NRC. Okay.

But you are controlling the use of a cyclotron.

MR. BOLLING: We're going to talk about that after lunch.

MR. GOMEZ: Okay. So my point is that the state is not controlling the use of any other nuclear material different, if you want to include in the QA program those materials also?

MR. TELFORD: I don't think so. I mean, we only

want --particularly since you're an NRC licensee, you would only include those materials that are regulated by NRC, not x-rays, not 123.

MR. GOMEZ: No, excluding some of these, the nuclear material that was used by the cyclotron, Iodine 123 and Thallium 201.

MR. TELFORD: We don't regulate 123. And Lloyd promises to cover more of that after lunch.

But do you have any questions about -- any more questions about these eight objectives?

MR. GOMEZ: No, I don't.

MR. TELFORD: Any more questions?

MR. BELLEZZA: So long as you get to brachytherapy and how the prescription changes --

MR. TELFORD: All in the reg guide. Okay. We will talk about that this afternoon.

But this basically says the ideal case is to have a prescription for brachytherapy. We haven't said yet when that's done.

MR. BELLEZZA: Sometimes the prescription develops as the implant is going on.

MR. TELFORD: Right. We'll cover that.

Anything else?

MR. JANICE: If as these things are being written, and some light bulb goes up for a question, is it possible

to call one of you --

MR. TELFORD: Most definitely.

MR. JANICE: -- and get some information?

MR. TELFORD: Most definitely.

MR. JANICE: Are you going to give us a list of telephone numbers of this mecca of information?

MR. TELFORD: Well, let's get it organized a little bit.

You already have Ed's phone number --

MR. JANICE: Watch out, Ed.

[Laughter.]

MR. TELFORD: -- because he has probably called you several times.

I'll give you my phone number. Tony's phone number is in the Federal Register. We'll give you a copy of that this afternoon.

So if you would call one of the three of us with any question you have, we'll get you an answer.

MR. JANICE: Thank you.

MR. TELFORD: Any more questions?

MS. WALKER: No.

MR. TELFORD: Any more questions?

DR. FELDMEIER: Not right now.

MR. TELFORD: Okay. If there are no more questions, let's break for lunch.

Let's go off the record.

[Whereupon, at 12:10 p.m. a luncheon recess was taken, to reconvene at 1:15 p.m. of the same day in the same place.]

AFTERNOON SESSION

[1:15 p.m.]

MR. TELFORD: Okay. We'll get started.

This afternoon, as you can tell by the agenda, we want to talk about first the particular aspects of conducting a pilot program within an agreement state.

We want to make sure that everybody understands what to do if they have any requirements that might be either in addition to, or potentially conflict with the objectives of the pilot program.

So Lloyd Bolling is going to talk to us about that.

I'll turn it over to Lloyd.

MR. BOLLING: Okay. I was making some notes this morning, and some of the things that were said were from my little talk this afternoon. But I'll go over them just a little bit again.

The first thing I'd like to say is that the agreement states were informed about this and have been brought on board more than a year ago.

We didn't discuss the program in any great detail with them at that time, because we were still formulating it ourselves.

We have visited the Organization of Agreement States, which meets annually.

We also had presentations before the Conference of Radiation Control Program Directors, which also meets annually in May.

As I said, we were designing this program to have as little impact as possible as far as personnel and dollars on the agreement states while encouraging participation as they were able to do so.

Although at this time we don't see any unanimous agreement with the entire QA program on the part of the agreement states, the general level of cooperation has been as we expected; that is, the states have been providing us information on who their licensees are, where they are, the size of the institution and characterizing them in that way.

We will be inviting agreement state persons, hopefully senior persons, to go out on the six site visits at agreement states.

Just before we broke for lunch, there was a question about accelerator-produced isotopes and lin accs, linear accelerators.

As you know, the Atomic Energy Act is mute on the point of radioactive materials that are not produced by the reactor, as well as radiation from electronic sources. So we will not be addressing that in this rule.

One of the arguments put forth by some of the people who thought early on that this rule was not such a

good idea was, "Well, we're going to have a dual set of requirements for essentially a modality of therapy that's the same."

In one of the tours that the Chairman of the NRC had at the NIH facility in Bethesda, Maryland, strangely enough, the two units were in the same room: the cobalt unit right alongside a lin acc.

They didn't look a whole lot different, but obviously the sources of radiation are different.

We hope that the QA procedures that will be developed as a result of this rulemaking process will extend to the accelerator-produced area and the lin accs. But we're not going to insist on it, even when we invoke the magic compatibility with respect to the agreement states.

Compatibility is invoked on regulations where NRC believes that there is some health and safety significance to them. So it has been determined very early that this rule is of health and safety significance, as two-thirds or so of the medical license facilities in the country are in agreement state territory. So compatibility was invoked.

Another question was raised this morning, as well as in one or two of the other meetings of this type that we've had in the other regions, and that was the training of agreement state inspectors and their reliance on the regulatory guide as being a regulation.

Now, we hope that the regulatory guide is not being used as a regulation. It is our intent that the guide will be just that, a model that can be used, but that alternates can be used as well.

We're getting away from these prescriptive requirements as much as possible, and the guides are to be used just as guides.

As far as training of the agreement state inspectors, we have a very active program which last year we trained about 320 or so agreement state and non-agreement state inspectors and licensing personnel.

We spent some $625,000 doing that, and we hold workshops as well. So we have a very aggressive program on training.

Obviously, when new things come up, like the revision of Part 20 and the metrication process where we're going from the English system to the metric system, we will be doing a lot of training of agreement state staffs for that as well.

Another thing that came up this morning was references to the misadministration reports which are generated yearly. And there's also a composite report that summarizes all the data that we've collected between 1980 and '88.

If any of you would like to have a copy of that

composite report, I can perhaps take your cards and get some copies made and sent out to you.

That kind of data is very useful in training technologists and your other staff members on what are the root causes of misadministrations and how they can be avoided.

Are there any specific questions on the role of the agreement states in this process?

[No response.]

MR. BOLLING: Okay. As I said a little earlier this morning, if you have any questions whatsoever as to whether or not the requirements of your license and your regulations and your state conflict with what you're doing in the pilot program, please call your state agency right away.

You will still be held to the commitments you made in your license applications. However, I believe that the requirements of the pilot program are icing on the cake.

We think that anything you'll be doing in the area of the pilot program will be far above and beyond what your minimum requirements are in your license.

So we don't foresee any problems. But if they should arise, please contact your state agency right away.

Any questions?

[No response.]

MR. BOLLING: Okay. Thank you.

MR. TELFORD: Thank you, Lloyd.

Next we will have Dr. Ed Kaplan from Brookhaven talk about the questionnaire. It's really a draft of a set of questions and an evaluation form that we will ask you to use at the end of your 60-day trial so that you can tell us what you think of each of the objectives and how to make them better.

I'll turn it over to Ed now.

DR. KAPLAN: First, let me say -- and I'll say it again later on -- that I really want to thank you for agreeing to participate, because without you this program wouldn't be possible.

I've seen a lot of skeptical faces here today and in the other three workshops that we've had, where people who are volunteers don't believe that this is really a performance-based rule -- proposed rule.

People want to know, "Just what is it you want us to do, and we'll try to do it."

We're trying to say to you, "No, no, no. You've got" -- As Lloyd just said, you're probably doing eighty-five to ninety percent or maybe even a hundred percent of what it is that we're talking about.

So you tell us how your plans fit into what these objectives really are. What we're really trying for here is

an optimal set of objectives.

We really want your input. This is a proposed -- It's really just a proposed rule right now.

This is one of the few times where a regulatory agency is coming to the potentially regulated community and saying to you, "Tell us what you think, and not only that, try it for a short period of time. If you like it, fine. If you don't like it, tell us what's wrong."

So much thanks to you. And you've been nice -- you and your institutions -- when I've been calling.

As John said, we tried a stratified random sample based on certain attributes. For example, are you in an urban or rural area? Are you large or small? Are you public or private?

And we've had -- You know, we got information from the agreement states. We have information from the NRC.

We truly tried to do this as randomly as possible. And it involved a great deal of trial and error, choosing an initial group of institutions, calling, finding the right group.

That brings me to another point which we discussed over lunch. I'd like to point it out to you, and maybe you can be of some help later on.

Many of you represent institutions which are

involved in more than one activity, you know, maybe the brachy or teletherapy or what not.

But we'd like to know what parts of institution are participating, because we've ed your institutions on the basis -- on the institutional basis, not on whether or not you're doing brachytherapy, for example.

That came into the stratified random sample. But basically it's an institutional license that we've got.

So we need to know just which groups within your institutions are participating, and I'm sure you'll let us know. We'll get on to the schedule later on, when you send us back or you give me today what you brought -- the quality assurance.

I hope you got the letter. We sent the letter out last week on Monday.

So you may not have gotten it, but it was sort of a reminder to bring something here with you, to bring some type of QA plan.

Okay. Let's see.

We're talking about our -- Up until now we've been talking about our evaluating your plan. We have two ways we're going to do that.

One, of course, is you're going to give us your plan. We're going to sit down in an office setting and evaluate each and every one of your plans.

Then there will be another random selection process where eighteen institutions, private practitioners or hospitals, will be chosen and visited.

But this is your opportunity to evaluate us. So this is where we're going to get your input.

We're doing it in the form of a questionnaire, so that within a few weeks -- a couple of weeks, you'll get a finalized version of a questionnaire.

But we're talking to you now about what the elements are that the questionnaire will have.

And what we're talking about is this. There are eight objectives.

We want you to tell us what you think, based upon your experiences, of these eight objectives. We want you to look at it in the form of both an overall grade (we call it) -- and I'll talk in a moment about the procedure for grading.

But think of it both in terms of just, generally speaking, what do you think of this objective. But also think about it -- Give us a little fine structure and think about it in terms of benefit to prevent mistakes, whether or not there's an incremental cost associated with meeting these individual objectives, and are we putting a strain on your personnel or aren't we?

Do you have enough people available to you to do

this particular -- to meet these particular objectives?

So for this part over here, and for these boxes over here, this is what we'd like you to do. We'd like you to think of things in terms of a grade -- a letter grade: A, B, C, D, F.

For example, if you're interested in telling us whether or not objective three is of benefit to prevent mistakes, grade us from A, which is very likely to prevent mistakes, it's a good objective and it's very likely to prevent mistakes; or if you think it's worthless, just tell us it would not prevent mistakes.

Now, I will say this: If you give us grades that are more towards the C, D and F side, we've provided you with this second part over here.

So if you think -- if you really feel strongly, particularly in the negative sense -- we'd like it also in the positive sense, but if you feel particularly negative about something, and you give us a letter grade of an F or a D or whatever, please fill this part out down here.

Tell us precisely what it is that caused you to think of the objective in that way. It's very important to us.

So this part of the questionnaire that you'll be getting will give you an opportunity to look at the eight objectives and to think about them both in some specific

ways, which are close to your own hearts, and also in a general way to tell us what you think.

So we can use that at the second workshop to tell -- to talk to you about what you think about this in relationship to your colleagues.

Then there's a little bit more information that we'd like you to provide to us. Here, for example, question number three, we're talking about objective one. But we really mean, do this for all the eight objectives.

For example, does your existing QA plan meet objective number one, number two, number three, all the way down to number eight. So let us know.

Now, of course, you're going to let us know by providing us with this road map that we talked about earlier, because we're going to take your QA plans and we're going to evaluate them.

So, please -- and I'll mention this later on again, just to repeat this -- but we need a road map to tell us where in your QA plan, if at all, you've met the objectives.

And if you do meet the objective, on this evaluation sheet let us know to what extent it already exists. So that's the first thing here.

This, of course, will go for all eight. So you're going to repeat these for the eight.

Now, as I mentioned before, we're looking for an optimal set of objectives here. So we would like you to answer again for each of the eight objectives.

There are three particular things that we're interested in.

First of all, do you think enough of this objective to retain it? It you do, please let us know why.

If you'd like to retain it, you think it's important from a professional standpoirt, but it needs modification, let us know.

Likewise, if you don't think this objective is really worthwhile, by all means put it on the front part of this evaluation sheet and put it over here, too.

So in section four there will be eight of these where you'll provide us with whatever your thoughts are on these objectives.

Of course, we may have forgotten something. If we have, and you've included it in your existing QA plan or in the QA plan that you've designed as a part of this process here, let us know.

Let us know if there's something that you think is important that we have not included.

Then, lastly, we'd like to know for information purposes that relate to how we selected you in the first

place, we'd like to know how many patients you processed during this 60-day period in each of these areas over here.

So please keep some notation somewhere in your folders, and let us know at the end how many patients you processed during this trial period, and how many mistakes did you catch.

As opposed to misadministrations, just mistakes. How many mistakes were caught before they became a misadministration during this trial period, if any.

We would like -- This, of course, is very important for us; and we'd like to know that.

Then, of course, if you had any misadministrations, if you could just give us a brief description as to what they were, we'd like to have that, too.

What this whole thing will give us then is an opportunity to evaluate not only the objectives that have been discussed -- the eight of them, but whether or not you, through your own practice over the 60-day period, think that they're of any use or not, whether they're redundant, whether or not they put too much of a burden on the delivery of medical care, whether or not they've helped you in your practice, and whether or not we've neglected something.

So we're looking to you to provide us with this type of feedback. And then at the next -- The post --

How did you phrase that?

The post workshop, the two-day workshop, that's when we're going to all get together, and you'll share verbally your experiences.

But we'll have these that we can use to compare you all as one large population and talk to you about, generally speaking, what are the responses of all of you -- all 72 participants in the program.

So this is what we have in mind. You'll be getting a questionnaire very shortly of this nature.

Any questions?

MR. BELLEZZA: How are you going to count therapy patients? Like if you treat 30 patients a day times the number of treatment days, or are you counting individuals?

DR. KAPLAN: That's a good question.

MR. TELFORD: Count the person. Whether or not it's a current patient or a new patient. You don't count -- We didn't visualize that you would count daily fractional doses, but that might be helpful because that would be sort of a number of administrations. I think it's an interesting index.

So what we had visualized is you would count patients. But if you wanted to, say, during this period, these patients got 20; this guy got 30 and this guy got 10, that would be helpful, too.

Any more? Yes, John.

MR. SHARP: I'd like to ask Ed something.

When you were setting up the study, presumably you were working with some number of expected misadministrations per, say, hundred-patient cases.

How did you design the study so that contributions from, say, a smaller institution where they only have a fraction of the workload of a larger institution occurring in this two-month period would be still a significant contribution to your overall result in terms of -- well, with respect to, say, patient load or study load?

DR. KAPLAN: Well, on a region-by-region basis, we looked at the distribution of institutions that fit into the each of the three categories I mentioned: the rural/urban, large/small, public/private, and we tried to reproduce the sample by drawing from the larger sample, so we would get roughly the same type of distribution inside the pilot project.

But we didn't look at it from the point of view of what is the optimal number of participants to catch misadministrations.

If we did -- This is one of the first things we did very early on in the project just as a mental exercise.

It turns out we would need a much larger population of participants.

MR. SHARP: I'm thinking too -- let's say for argument -- do you expect one misadministration or one interesting occurrence to occur per thousand patient studies. In a smaller institution in the two months, they may only do 50 patient studies.

DR. KAPLAN: You're right.

MR. SHARP: So they haven't got much of a chance of helping you on that side of it; that is, how their trial QA program would address a misadministration.

I'm wondering if they can emphasize the design and setup, because they may simply in that time period not have the experience to actually put anything into operation.

MR. TELFORD: I would look at the cumulative number of patients treated by all such small -- so-called small licensees; and there's a goodly number of them.

Of the 67 participants, there's a large number that are small.

So I would look at the cumulative number of patients for that subset.

MR. SHARP: Because otherwise the experience of a smaller licensee may not be properly taken into account here.

MR. TELFORD: Okay. We tried to get their experience in by the proportional representation.

If you look at all the number of licensees we

don't have -- The NRC has maybe 2000 licensees, and most of them are not the broad-scope kind of licensees. They don't do everything.

Some people just do nuclear medicine; some people just do nuclear medicine plus lin acc.

And, of course, to us the most interesting cases are the people in the larger institutions, the teaching hospitals that do everything, you know, because we go there and we can find about all their programs.

But we couldn't just concentrate on them so we got a proporcion of each type. So I think through the gross number of each type, we'll have that experience.

But I once calculated that there will be something like 5000 to 10,000 patients that will be seen by the volunteers during sixty days.

But we're not really after just misadministrations, you see. We're after -- I think it would be a big payoff if we could detect procedures or objectives that would catch mistakes that are intermediate-step kind of mistakes that don't become misadministrations.

To me that's more interesting than catching one misadministration. I mean, I would rather prevent -- See, that's the whole emphasis of the proposed rule is to prevent misadministrations.

So I think it would all be successful if we could

at the end say, you know, "We understand what it is. We tried it. It was, we think, helpful in preventing these intermediate step kind of mistakes."

But what I wanted to get was -- There's two points. One is I hope you can tell from the questionnaire that we have so far, that what we're asking you to do is to both grade what we have and then, you know, you're making up your own.

You can just turn this one inside out. You can say, "No, I don't like this one; I'd throw it away. I don't like this one; I'd throw it away. I'd keep this one, but I'd greatly modify it. I'd keep this one, but I modify it."

So each volunteer has the opportunity to tell us what they would do.

It is kind of non sort of routine way to do business for a regulatory agency to come to you and say, "How would you write your own rule?"

But, collectively, that's really what we're doing.

Now, Ed talked about the questionnaire for the eight objectives. We will have a separate questionnaire, structured almost identically to the way this one it is, but it's for the reg guide.

So for any of you who use any part of the reg guide, then we will give you a similar opportunity to evaluate each section of the guide that you used.

I had a hand over here. Yes.

MR. BELLEZZA: It was that topic. So far the focus has been on the eight objectives and how we would develop our own program to meet these objectives.

Yet, in the same package there was this guide, which hasn't been addressed at all. Are we supposed to take this guide and implement or ignore it?

MR. TELFORD: Oh, no, that's next.

DR. KAPLAN: We paid him to ask that question.

[Laughter.]

MS. RUDOLF: That's your transition.

MR. TELFORD: You're foreshadowing to the next topic on the agenda.

So that's next is my answer.

Any other hands?

DR. TSE: The pilot program is not really specifically designed to detect whether we can prevent certain misadministrations, because the frequency or the probability of a misadministration is very low.

However, we still want to try hard because this is a set objective and to see whether it would interfere with certain medical practice, which are those questions we have this morning.

Plus, we can say -- we have a question of how many mistakes -- mistake which is not misadministration -- how

many errors this specific QA program will be able to detect.

That may not be a misadministration, but there's a lot more little errors than the misadministration.

So the question there we prepared essentially is how many mistakes you catch. We did not say how many misadministrations id you catch.

But if somebody has a misadministration, please indicate that also. But the chances is very low.

MR. TELFORD: Well, Tony, I think you're being called. They want to hear about the guide.

So next Dr. Anthony Tse will talk about the reg guide.

We published a notice that the guide was available when the rule was published on January 16th of this year, I believe.

We intend this guide to be for your use, if you want to use it. In this case, because it's a performance-based rule, we do not mean this guide as a prescriptive rule, but rather than setting you off on your own, in the case that you need guidance, we thought we would provide something.

Dr. Tse.

DR. TSE: This morning somebody asked the question about where to call and who to call. So John and I put our business cards in the back there on the table. Whoever

would like to pick up a card, please help yourself after the meeting.

We already emphasized that this is a performance-based group, which is different than our proposal published in 1987, which specifically said one, two, three, what you should do.

Here, as we discussed this morning, we only provide objectives -- proposed objectives, how we approach the problem of reducing essentially human errors.

And that's -- It's difficult to understand what these simple objectives mean. Therefore, we prepare a more detailed guidance to explain a little bit more fully what do we mean.

And, of course, you can use those guidance to prepare your QA program or you can use other guidance to prepare your QA program, as long as you think it will meet those objectives.

But the guide will give you a little more detailed insight what we think about it.

I think each one of you already has a set of this guide. I believe you have had a chance to look at it.

So today I will go through briefly on each section and see if anybody have any questions, comments, suggestions. Then please raise them at that time.

The first page of the guidance essentially says,

"This is only a guidance." You can have your program tailored to such as that to fit your own specific situation.

We ask for public comments, and we will modify that.

Let's go to second page. It's stated, "The guide may contain more specific QA procedures," if somebody suggests or supposes it would be good during the pilot program.

So that's the first part of so-called Section A. Does anybody have a problem or questions?

[No response.]

DR. TSE: No. Then we go to Section B, Discussion. We essentially tried to briefly state what the purpose of this -- because of misadministrations, and we discussed that most of these misadministrations we hear are due to simple human errors, mainly somebody misunderstood the prescription or miscommunicated between the two persons and so on.

Then page three. Again we emphasize this is a -- We provide the flexibility needed for the medical community. We propose a performance-based rule.

Also, in the last paragraph of Section B, we indicate that this we called basic quality assurance program is not a comprehensive one. We're only dealing with a specific portion, mainly related to the human errors.

In our regulations there are other quality assurance requirements already required. We also have an advance notice on comprehensive quality assurance program published also in 1987, but that's way down the line.

Any questions on Section B?

[No response.]

DR. TSE: No. Let's go to Section C. Section C is called the "Regulatory Position." We said that again -- We iterate that this is a guidance for you to develop your QA program.

You may use other guidance as well to develop your program.

Then the next page --

MR. WHITE: Excuse me, a question.

You're making this procedure a matter of -- What do they call it with the agreement states?

DR. TSE: Compatibility.

MR. WHITE: You also consider making the statement that this regulatory guide is a guidance as a matter of compatibility. Do many states find it easier to take NRC guides and require them?

MR. BOLLING: We're trying to convince them not to do that, especially in this case, because we want you to have programs that are easily adapted to your situation.

And to the extent that agreement states will use

this guide as the law, we want to discourage that as much as possible.

MR. WHITE: But discourage is different than make it a matter of compatibility. I mean, you're not encouraging NRC states to adopt this program. You will require them to do so.

MR. BOLLING: Yes.

MR. WHITE: And what I'd like to suggest is that you require them to show evidence that they have in fact reviewed other QC programs and analyzed them on their merits with the same stringency, same audit enthusiasm that you have required to show that they -- because I see that as a big problem with acceptance in the medical community.

I'd feel a lot different if I thought you guys -- the two of you -- were going to be looking at my license application, but neither of you will.

DR. TSE: We will have -- Like John said this morning, we will develop a so-called QA program evaluation criteria. That will be -- could be used in the future as a precursor of the licensee --

DR. WIATROWSKI: I think the point that you're making is an excellent point even for an NRC licensee. Although when you propose a regulatory guide, you don't intend that to be a regulation, the license reviewer who looks at my license, however, accepts that as law.

If I ask for an exception to what was stated in the licensing guide or provide what I think is an alternative program, it's very difficult to get that approved.

DR. TSE: Well, that's one of the reasons here, to state that if you identify an alternative which may satisfy certain objectives, we may want to include that as part of the regulatory guide.

That will avoid those questions -- I mean, your problem.

If we say to meet an objective, you can either do one or two or three or four.

DR. WIATROWSKI: Or we can add number five, which is mine, or somebody else's proposal. But that still gives me a problem with the licensing reviewer who doesn't have your --

DR. TSE: Doesn't have my guide?

DR. WIATROWSKI: Doesn't have your perspective on the fact that this is a guide and not intended to be prescriptive.

You removed the prescriptive requirements from the first proposal that was published in 1987, and many of those prescriptive requirements are contained in this draft document. I checked against the '87 rule, as a matter of fact.

DR. TSE: Right.

DR. WIATROWSKI: So now I'm going to go ahead and I'm going to file a QA program. And some license reviewing official in Dallas who doesn't know you and doesn't know you is going to come and they're going to look at my quality assurance program.

They're going to pick up the licensing guide, which is your final document; and I'll bet they're going to review my license application using this as a prescriptive document because that's what has happened to me for the last fifteen years. That's pretty commonplace.

I think everybody is shaking their heads, and they know what it's like to try to get a license review.

DR. TSE: Well, if --

MR. TELFORD: If I understand this correctly, you're saying it would be difficult if the reg guide did not contain alternatives which you found to be acceptable in meeting these objectives.

So I think that should be something that we should strive for in the next workshop is to make sure that we have sufficient alternatives in the guide that would meet your needs and that then could be looked at by your peers here and say, "Yeah, we think that's good."

We could all go on the record and say, "Good. Let's have that in the guide."

Therefore, any licensing body would have to say, whatever is in the guide -- if they're going to use the guide, they'd either have to say those alternatives are acceptable or say why not.

So I think that would solve your problem.

DR. WIATROWSKI: Well, I guess perhaps partially. I mean, you can put more than one alternative in a licensing guide.

My feeling is, after fifteen years of writing license applications for the U. S. Nuclear Regulatory Commission, as well as the State of Texas, I always find that unless I specifically agree with the regulatory guide, I am going to get a multitude of questions back on that application.

My feeling is, if this is implemented, it's going to be the same thing.

And although your intent, as stated here, is not prescriptive, the effect of even publishing this document will be to make this prescriptive.

MR. WHITE: I think it's even easier than you're suggesting. The intent of this, as I understand it, is to allow us some flexibility to propose specific steps that will meet your intent.

And what we're saying is that that's fine when we're talking to you folks, but when we're trying to get

something approved by a guidance state who, quite frankly, doesn't understand what goes on -- I mean, doesn't have a medical background and hasn't spent two years looking into this; he's going to look at this document and say, "It has got to say this."

It's no longer a guide. It's a regulation.

What I'm suggesting is you can fix that by enforcing that compatibility as vigorously as you enforce other compatibility.

I talk to the guys at the State, and they say, "You need to wear red tennis shoes because the NRC says in their regulation red tennis shoes."

I want to be able to say, "The NRC said that you need to consider alternatives. That's regulation. If you don't consider my alternative, I'm going to call them and have them cite you for that in the next compatibility inspection," because you're going to cite them if they don't make me calibrate my survey meters on a schedule or if I don't have a teletherapy expert.

I want you -- or I suggest that you cite states for noncompatibility for states that use guides as regulations, and that will end that. The first state that gets cited for that, it will essentially end that problem.

MR. BOLLING: Let me say that compatibility really refers only to regulations, not to procedures per se.

But I think how we can get around it is by talking about it constantly and by your challenging it.

You know, be gentlemanly about it, but insist that -- you know, the whole foundation for this operation here is flexibility.

If we lose that through somebody's insistence upon using a set of written procedures in the guide, then, you know, what we're all doing here is for naught.

MR. JANICE: I have never seen the reg, but isn't there a foreword or something that says exactly what they're about, that they're intended to be a guide more than a law?

MR. BOLLING: I think they all say that.

DR. WIATROWSKI: But it's the use by the reviewing officers. And I think that's something the NRC needs to emphasize with its own ranks, really.

MR. BOLLING: Well, these regulatory guides are basically for the licensees.

Now, we do have internal procedures which are directed to the licensing people. Maybe we need to get into those -- you people generally don't see those -- and underline in red or something, "guide only," so we have a set of --

DR. WIATROWSKI: I think that would be excellent.

MR. BOLLING: -- very specific procedures, how to license a well logging operation, how to license a

brachytherapy operation.

And so somebody with a general science background and a B.S. degree, with a little bit of HP training, can do those operations until they become really proficient.

But I wouldn't expect you'd have trouble like that out of John.

MR. CHARP: No. Ask Wayne.

MR. BOLLING: I think I understand what you're saying, though. A junior-level person doing that kind of licensing could possibly get into a rut -- and probably they are getting into ruts where it's much easier for them to go along with one of these guides and say, "This is from the NRC. Therefore, this is what you have to do."

But in the past we had prescriptive regulation. We're trying as much as possible to get away from that, especially in the medical area.

This is a real departure from what we've done before.

I think the fact that we're all here is something brand new in the medical area.

Now, in proposing new regulations we have hearings in the uranium mill area; we have hearings in the low level waste area; we have hearings having to do with reactors. We very seldom have workshops like this where we can get together and talk about medical things.

So I think we're really serious about getting your input and using your input. And to lose it by somebody's dogmatically using a reg guide would just wipe us out.

I guess we're going to have to use education to reinforce that.

MR. JANICE: Or a two by four, whichever comes first.

MR. LOPEZ: I just wanted to say also that this is a draft --

DR. TSE: It is a draft.

MR. LOPEZ: -- and it will probably be modified to include whatever resolutions come out of this pilot program. So....

DR. TSE: Right.

There's two points I want to make. One is that compatibility is generally to say that the states should have a regulation at least as restrictive as the NRC.

It doesn't say you cannot be more restrictive than the NRC. So the states, based on their local conditions, they always can impose additional regulations that are more restrictive than the NRC even in the compatibility.

Therefore, it's depending on individual locality.

Second, even when we put in big letters, "for guidance only," and you put the yellow, red, black, whatever lines, people may still misuse it.

The best solution is just like everybody has said here. Let's come up with the good alternatives. Let's put some alternatives acceptable in the guide.

If I have five alternatives -- we may miss the sixth one, but we certainly do not miss the two, three, four, five.

Let's minimize the impact that somebody may use this as a regulation. Hopefully, that will not occur, but it's difficult to tell ahead of time.

At least that's not the intention.

Any questions on this particular point?

[No response.]

DR. TSE: Okay. Now we go to the details on page four.

The first item is a general QA -- kind of a general item. 1.1, of course, says that the licensee shall say who's responsible, who has the authority and so on.

1.2 says that you shall have audit of your QA program within twelve months -- an annual audit essentially.

Now, does anybody have questions on these two items?

[No response.]

DR. TSE: This, of course, applies to every licensee. Generally, the QA program always starts with that: who has authority, who has responsibility.

John has already talked quite a bit about feedback, the annual audit, the management review of all the corrective actions, is to let the licensee correct himself before it gets into much of a big problem. So to keep track -- keep tracking on the QA issues with the institution.

Any questions on these two?

Yes.

MR. BELLEZZA: On management, who is management? I mean, is the physicist who is doing the QA, and maybe the only one understanding what it's all about, is he the management perso: reviewing his own quality assurance? Or do you have an administrator --

DR. TSE: No, you can't --

MR. BELLEZZA: -- who doesn't know what you're talking about?

DR. TSE: Well, when you make the audit it should be somebody knowledgeable to make the audit, except you don't audit yourself.

If I make some mistake one way, if I audit myself I keep making the same mistake because I did not even see that mistake. It has to be another qualified person check on me.

But the management review of the audit is the hospital administration, because some action -- after your audit you may recommend certain action to be taken, and that

would be the management would -- could have authority to ask the department head to take certain actions.

So that's the -- The management may not have to be an expert in radiation safety, but he has authority to take the actions.

Any other questions?

Yes.

MR. WHITE: It says, "Audits will be conducted ... by qualified personnel," as you mentioned, "not involved with the activity being audited."

DR. TSE: Right.

MR. WHITE: It seems to me that would be a problem in many hospitals.

DR. TSE: That's a thing which I'm talking about. Suppose I come up with a procedure, teletherapy procedure myself.

And then I check on myself. I would be auditing myself. It would be difficult to find out what error I made.

So if I can ask you to come, say you maybe in another department within the institution or another physicist or somebody -- If I don't have another person, I go to another hospital.

I say, "You check on me; I check on you." That's what we mean here.

Now, would you think a person who developed this procedure himself, checked himself, would be able to find the errors he made?

MR. WHITE: Maybe I don't understand what an audit is. Is an audit going through the charts and rechecking the calculations, or is the audit --

DR. TSE: No, the QA procedures.

MR. WHITE: To see that the procedures were followed.

DR. TSE: Or the correct procedures.

MR. BELLEZZA: It's not clear to me then how a physicist from another institution, first of all, could take time away from his responsibilities to come over to my institution?

DR. TSE: If you don't have another physicist or you do not have another person who's qualified to check on your procedures --

MR. JANICE: It doesn't have to be a physicist. Either that or a qualified individual.

DR. TSE: Right. Qualified individual, but it's somebody who has to be knowledgeable in the performance of whatever the procedures are.

Like nuclear medicine, for example. You really do not have to have a physicist to check that.

But if you have elaborate treatment planning --

teletherapy treatment planning, then somebody else maybe -- m[illegible] dosimetry can check that. It may not be physicist, if he s qualified in the management's view.

Or if you have only one person in that particular institution, then you need to try to find somebody else to check it for you.

Now, that's the suggestion.

MR. SHARP: These are some of the problems of performance-based guides and rules. You don't dare say more than that because you limit the licensee's options to come up with something that represents a qualified, independent check, anything.

DR. TSE: And note we did not say independent -- We did not say from outside organization. So inside the organization, if you have another person who you believe is qualified -- or management believes is qualified who could check the procedures.

MR. SHARP: You might have to sort through five or six different possibilities that you can think of to find one that works for you.

But if Tony says more in the guide, he has limited somebody else's options.

MR. GOMEZ: A physician from the same institution?

DR. TSE: Yeah, a physician may be --

MR. GOMEZ: A technologist --

DR. TSE: Right. It depends on which procedure, how much involved it is.

MR. JANICE: It's just like any set of guidelines you're writing. These are broad-based guidelines. You can plug in anything to see how it works.

DR. TSE: But the ideal is that if I made the procedure a check on myself, I'm liable to make the same error.

And if I did not find it, I did not see my error.

Just like I write a paper, and I read -- I did not even see my spelling errors or whatever type of errors.

John always finds them for me. I say he's much smarter than I am. How come he always finds my error?

Actually it's just I do not see it. In my mind I always think it's a correct way, so I did not see my error -- my own.

DR. WIATROWSKI: I think the issue is -- and I think the issue was raised correctly. In doing the audit, for example, most of us have been through a JCH accreditation and a physician comes in to audit.

He comes in, and they want to look at quality assurance data in physics.

They say -- well, he has a checklist, or she has a checklist -- "Show me this."

Give them a piece of paper. They check it off;

they don't know what they're looking at, and they don't know whether that document actually fulfills the requirement.

And that physician -- and am I correct? I mean, I think most of us have been through this situation -- goes down the list and identifies -- because, you know, if you have a hematologist looking in radiology he or she may not have one foggiest idea what you're looking at.

I think what you were getting at is the point, you can get somebody who really is just marginally qualified. Management says, "All right. You are qualified to do the audit."

Show that person pieces of paper, and we have a meaningless exercise that fulfills your paper requirement, but doesn't significantly contribute to quality assurance at all.

DR. TSE: That's depending on how responsible is the management.

DR. WIATROWSKI: Well, it depends on the availability of qualified personnel and whether you want to bring in an outside consultant.

These are some very significant issues. You just can't say, "Well, management will identify somebody who is qualified." That person may not be available.

DR. TSE: Well, let me ask Dr. Feldmeier.

DR. FELDMEIER: I think it's a very difficult

problem. You know, you have situations with isolated practices with perhaps a physician and a part-time physicist.

And how you're going to arrange an audit in that situation, I don't know.

We have sort of a unique situation where we have five or six different groups practicing within one center. If these quality assurance procedures are taken -- and we have some independent physicists -- and it's a situation where actually these people are in competition with each other.

So I mean, you don't want your competitor auditing your records.

MR. SHARP: Probably get a good audit.

[Laughter.]

DR. FELDMEIER: So I mean, I don't think there's a simple solution to this situation.

DR. TSE: No, where there isn't -- where it would be useful to conduct an annual audit.

DR. FELDMEIER: I think that as a compromise position about all that you can sort of universally establish or have broad guidelines, I think that what you can do is make sure that the paperwork exercises are being done.

You know, whether they have substance or not, I

guess is dependent upon who is doing the paperwork exercises.

It has been my experience in quality assurance programs in the past, a lot of times all you do is you get a stack of papers and you say, "Well, was this audit done?"

"This audit was done."

You know, your regulation says that you should do this quarterly, and make sure that was done quarterly.

You go through a paperwork exercise that doesn't necessarily have a very close relationship to ensuring quality work or quality assurance or good calibrations or good dosimetry.

But to have a program that's going to be universally acceptable and a program that is going to be able to be widely conducted, sometimes I think that's all you can settle for.

DR. TSE: But do you do your teletherapy or brachytherapy audits some --

DR. FELDMEIER: See, it's fairly easy for us. I know like the guidelines that the American College of Radiology has put out in regard to just something as simplistic as checking a radiation therapy portal, make sure you're treating the field that you want to treat, the guidelines that have been published for the ACR for quality assurance is that someone other than the treating physician

should check the portal to make sure that it corresponds to the simulation film.

Well, if you're in a multi-person group, it's fairly easy. I work in a medical school, so we have several staff doctors.

You know, I put films up, and my colleague looks at it and says, "Yeah, looks all right to me."

He puts one of his films up and I say, "Yeah, looks okay to me."

But in a situation where you have a solo practice, especially in an isolated situation or you have -- in our situation at the Cancer Center where you have a lot of solo practitioners or small groups that are competitors, it's -- I don't know.

To come up with universal guidelines for how you audit and how you have qualified people.

You know, the intent -- I mean, the intent is obviously a very constructive thing. You want to have someone with like credentials, like qualifications, like abilities, looking over your work to make sure that you're not making stupid errors.

As you were using the example of proofreading a paper, you know. I write a paper, and I leave a comma out one time. I proofread it a second time, and I don't think the comma goes there -- I leave it out the second time,

third time, fourth time.

Someone else looks at it and they might find that comma very easily.

But if it's your competitor, or if you're in a situation where the best person that you can get -- or the best qualified person is not someone of like qualifications or comparable qualifications, I think the intent of the program really -- you get sidetracked and you get into a paperwork exercise.

But I don't know what -- I don't think there's an easy answer, and I don't have any suggestions for a solution.

(Transcript continues on page 156.)

DR. TSE: At some point, that's a performance-based rule, we have to trust the hospital. In fact, we do trust the hospital management to make a right decision but this is one area we must trust the hospital management to make a right decision.

But if you have any good suggestions, please let us know during the pilot program period.

Any other questions on this?

[No response]

DR. TSE: Okay. Let's go to the second item, "General Elements for All Medical Use." I hope this is not confusing. "Diagnostic and Therapy."

This morning we had a little problem relating diagnostic and therapy prescription and referral.

The difficulty is that prescription is not one-to-one corresponding to therapy.

All therapy, plus certain diagnostic, requires prescription, based on the proposed objective.

Then for the rest of the diagnostic, we mean iodine more than 30 microcuries -- Let me start again.

All diagnostic, except those diagnostic procedures with 30 microcuries of Iodine-125 or -131.

For those you could even use a diagnostic referral or a prescription.

You have a problem? For the diagnostic

procedures, other than the high dose rates (we take that out), you could either use diagnostic referral or you could use a prescription.

MR. JANICE: Maybe I misunderstood everything, because my understanding was that anything above 30 microcuries of I-125 or I-123 needed a prescription.

DR. TSE: Right, that's what I say, except those.

MR. JANICE: That's not what I just heard.

DR. TSE: Okay. Let me repeat again.

For diagnostic procedures involving all radiopharmaceuticals, except those diagnostic procedures involving more than 30 microcuries of iodine (take that out), for all the others you could either use diagnostic referral or your physician could write a prescription, too.

It cannot be only tied in to diagnostic referrals, because in some cases the nuclear physician writes it himself.

So it's not so clear-cut, therapy tied in to prescription; diagnostic tied into referral is not that clear-cut.

We were trying to write clear and we tried it one time and still somebody confused. So I just explain it.

That's the intention. The wording, we can always change it later.

Here we do the same thing. You will see those

words.

Now, 2 is applied to all procedures. This is essentially motherhood kind of statement.

2.1 says records have to be clear and legible.

2.2, if you don't understand, if a technologist sees micro and milli, it's close enough, that a physician did not write clearly, you should stop and ask first before go ahead.

2.3, if you see something obviously that's not right, then go ahead first and ask first.

And No. 4, essentially you have to follow the prescription, you have to check.

So that all applies. These are the four items applied to all procedures, but for diagnostic procedures, other than those Iodine-131 30 microcuries, those are all there are. There's no more.

But for therapy, for iodine with 30 or more microcuries, there are more suggestions in the later sections.

So this Section 2, does anybody have any question?

Yes, please.

MR. SHARP: Tell me what this is not. 2.4, verify you don't expect records of that?

DR. TSE: I don't think we said that we need that. Your procedure may say you need to doublecheck the patient's

identity.

So the technologist should be trained to say, "Mr. Jones." You've got to ask where you live, how old are you or something or your social security number.

Somehow they are to check so that Mr. Jones is not -- maybe two Mr. Jones are sitting there.

MR. SHARP: One of the reasons I ask is that one of the precepts of compliance work is that you don't ask the licensee to do something that you don't ask him to make a record of so that you can verify he's doing something, but here we're off into the area where we're suggesting that licensees do quite a bit and yet to really make this practical I don't think you can have records at most of the stages of it.

DR. TSE: Well, later you will see some place we think records are needed

MR. SHARP: Right, some.

DR. TSE: We will say, "Record needed in this case."

Maybe the licensee wants to say, "I want a record," but in this case it is not required.

MR. SHARP: When you say "verify" and other things in this guide, you are not assuming that we are reading "verify and record"?

DR. TSE: No. The specific items says "record."

Any other questions?

[No response.]

DR. TSE: Then let's go to No. 3 on Page 5.

Item No. 3 is additional elements for radiopharmaceutical therapy, nuclear medicine therapy and diagnostic involving more than 30 microcuries of iodine.

So additional elements are proposed.

Item 3.1, the nuclear physician should personally review the patient's case, meaning that if somebody sends a referral that says that this patient needs ten millicuries or thirty millicuries of Iodine-131 for his thyroid, the nuclear physician should not take that as given.

He should first look at the patient to make sure that's a correct dose, a correct indication and correct dose.

3.2, you need a written prescription.

3.3, as we mentioned this morning, the physician could change the prescription for some reason. He changes the judgment. After examination he may change it, or whatever. He could change it.

That's not unintended deviation, because the doctor intended; because of his judgment he intended to change it.

3.4, we emphasize again that you need to have the right patient.

3.5, here comes the record. It says that after administering the dose, you should write down how much you gave to the patient.

MR. JANICE: The question was raised on that. Our practice is that as the nuclear medicine physician is dictating a report, the amount given to the patient is dictated onto the report.

Does that satisfy this requirement?

DR. TSE: You mean you have a written report or tape?

MR. JANICE: Pardon? Oh, it's a typed report.

DR. TSE: Typed report, sure.

MR. JANICE: The interpretation of the test and in the interpretation he says, "X amount of millicuries of MDP was injected IV," and that kind of stuff.

Does this satisfy this portion here?

DR. TSE: I think so, but signed --

MR. JANICE: You think so?

DR. TSE: Yes, because it says under the supervision or himself. Sometimes, we understand, the physician is busy. His hands are busy so he wants someone else to write down what he does.

MR. JANICE: We actually put it on the request that the patient receive so much of what but he reiterates it in his report?

DR. TSE: Yes, I think so.

MR. DADARI: I believe it's a requirement to put amount of dose, isotope and chemical form on the report.

DR. TSE: Right.

MR. JANICE: What I was looking at was not another report to have to generate.

DR. TSE: No. If you already have a sheet of paper and somebody signs it where the doctor has written down and says this is how many millicuries I administered to this patient, that meets this particular item.

I did not say "requirement."

Why I say "probably" is that I'm not sure exactly what -- this says you have a date and signed. Now, if the report is not --

MR. JANICE: I read all that. That's the reason I raised the question.

MR. TELFORD: The answer is yes.

DR. TSE: Yes. In that case it will be yes.

There's several words after this. I wonder if anybody has any questions.

It says toward the end of Page 5 this patient will record agreement or lack of and so on.

Do you have any questions on these few phrases or you have no problem?

[No response.]

DR. TSE: Okay. The question raised by other people in the workshops is they say do they have to have another column after they write down the dose given to the patient, another column to say whether he agrees or does not agree, say another few words.

The answer is that certainly is not necessary, because you can already compare the prescribed dose versus the administered dose.

You need to compare that but it's clear whether agrees or doesn't agree; you don't really have to say "yes, agree," or "no, doesn't agree."

MR. SHARP: But are you saying that both pieces of data need to be there in that record, because that might not be occurring.

They might have recorded, for instance on this patient report, simply the dose administered, not the dose prescribed.

MR. DADARI: Exactly.

DR. TSE: In the teletherapy you always have dose prescribed/dose administered.

DR. FELDMEIER: On our charts, yeah.

DR. TSE: Yes, on the charts.

In the radiopharmaceuticals, in that case some --

MR. DADARI: The administered dose.

DR. TSE: But this particular item is to say you need to compare with the prescribed dose to see whether they are the same.

If not the same, either if exceeds the administration criteria, then it becomes a misadministration; if it is lower, is it unintended?

MR. DADARI: I'm getting kind of confused.

DR. TSE: Okay, please.

MR. DADARI: If I see it's not the prescribed dose while I'm giving .. to the patient, it's a live action. I'm catching myself while I'm doing it.

I have a prescription in my hand for 7 millicurie Iodine-131 and my dose calibrator shows me 15 millicurie.

Obviously, I'm not going to give it.

DR. TSE: Right.

MR. DADARI: Why do I have to write down it was 7 millicurie but anyway I gave him 15 millicurie and this is a misadministration?

DR. TSE: Correct. If you find it's 15 millicuries, you may not give it to him.

If somebody did not look at -- you looked at your prescribed dose and you said, "This is different. There's a discrepancy."

Somebody may not look at that. If he didn't, he writes it down.

Later somebody compares the two doses and "Ha, that's different."

Then at least he discovered that s different.

MR. DADARI: So in the patient's report, if you see just one item, it says "7.5 millicurie, Iodine-131," it means it's prescribed dose and administered dose exactly.

So we don't deal with two numbers, have to write two numbers, if both of them are the same.

DR. TSE: Right. If both are the same, there's no problem, but before you check it, you are not too sure.

MR. JANICE: More and more I'm hearing that we're going to need another piece of paper to satisfy this.

That's the reason I raised the question as to whether or not on the report would satisfy it and what I'm hearing, it's not satisfying what this says.

MR. SHARP: Well, consider what you want. You want a quality assurance step, which by itself means you're comparing one against another.

At whatever point in the cycle of this you do that comparison, you've satisfied this.

DR. TSE: Right. You need to compare.

MR. SHARP: But indeed, it may be in some of these that it's not really being done.

In other words, you looked on the syringe. It said "7 millicuries." You injected.

In a way, you don't have a QA step there at all. You've assumed that the printing was right and you didn't check it.

Now, if you look at 7.0, you put it in the dose calibrator, 7.2, then you've got a before and after there.

It didn't happen to occur or even need to occur after administration, but at least that was a QA step that met the intent of this.

If you don't have that step in your cycle, then you don't have a QA step.

MR. JANICE: Then why did we say earlier, though, that you are not required to drop it in a dose calibrator.

MR. SHARP: Well, that's Texas' rule.

MR. JANICE: That's what I'm saying.

MR. WHITE: There's nothing here that requires that.

MR. SHARP: No, but you would be trying to develop a QA step and that might be it.

For those licensees who have set it up according to our rules, where we haven't required double-ended calibration, they may need to come up with something.

We haven't, indeed, required anything like this.

DR. TSE: The idea is to check administered dose against the prescribed dose and there should be a record of this.

If not the same, it either becomes misadministration or becomes an intended deviation and you need to look at the procedure.

MR. JANICE: But what you said, though, Jon, just looking at the label, that says that you've checked it.

MR. SHARP: Would you call that an independent check? For instance, what are you checking that gainst?

If you don't have a second bit of data there, it's not really a check against anything.

If you're checking against what you ordered from the pharmacy and you got back that, that's a check.

A dose calibrator is even a better check, because that's a physical check.

MR. JANICE: Or you go back to your procedures manual and it says thus and such.

MR. SHARP: But I think in this sense "check" does imply two numbers. Somewhere you've got to pull that other number in and check in.

MR. JANICE: That's what I'm saying. This says that you're going to have to have another sheet of paper somewhere saying that you've done that.

MR. SHARP: No, it doesn't require --

MR. TELFORD: I think what this says is you have a -- think of it as a prescribed dose and you have an administered dose

What this is really saying is you have your choice. You can write down both of those numbers or you can write down the fact that in this gentleman's case he has the administered dose and, yes, it agreed with the prescribed dose.

MR. SHARP: Yes.

MR. TELFORD: You've done the check and you say "yes."

MR. SHARP: If it's not self-evident by two numbers there on the paper, then you need to say, "Yes, it agreed."

MR. TELFORD: One way is you write down both numbers and it's self-evident that there's agreement.

Therefore some folks in previous workshops have said, "Look, I've got both numbers on the paper. It's obvious they agree. Why do I have to say they agree?"

Okay, you don't.

On the other hand, you can write down the administered dose but the prescribed dose is not there on your report.

Therefore you could say, "Yes, it agreed," or, "It disagreed by a tenth of a microcurie but who cares."

All right, and you've done it. So that's the only point here.

DR. TSE: Any questions on this

radiopharmaceutical therapy and iodine greater than 30 microcuries?

[No response.]

DR. TSE: Let's go to teletherapy then. Wait a minute. The next one is brachytherapy, Item No. 4.

Again, the first two are the same, like Item 3.

4.1 says the nuclear physician -- the oncologist, radiation oncologist should personally review the patient's case and an oncologist should write a prescription.

DR. FELDMEIER: As we were talking about nuclear medicine prescriptions, when a nuclear medicine prescription is written, it's generally written for an activity, millicuries, microcuries.

When we write a prescription, we write a prescription for an absorbed dose, rads or centrad.

One of the problems we have, especially if it's a permanent implant and we drop in 30 millicuries of encapsulated Iodine-125, we're not going to get our dosimetry back until after the seeds are dropped in.

Any resemblance between what we end up with in, say, a prostate gland and what our preplan indicated is sometimes not much more than coincidental.

I don't know how we write a prescription in that case. If we can write a prescription in terms of number of millicuries we put in akin to what nuclear medicine does, I

have no problem writing the prescription.

If I need to write a prescription in terms of dose to the minimum tumor volume in the prostate gland, then I have a problem.

DR. TSE: Right. If you look at the page related to definitions, under "prescription," there are some specific items related to each different modality.

In terms of brachytherapy, we said that either dose, and then you have a parenthesis -- who has that?

What does it say, brachytherapy?

MR. JANICE: The total dose entry; in brackets are treatment time, number of sources and combined activity.

MR. WHITE: I think the point is oftentimes none of those are determined prior to the application.

Many times all of those things are determined after the application.

DR. TSE: Okay. Now, let me ask Dr. Feldmeier where he, as oncologist, do you normally write something ahead or time or you don't write it ahead of time?

DR. FELDMEIER: Yes, we do a preplan where we determine how much of the isotope we're going to order and generally how we're going to approach it, but until you actually -- This would be sort of akin to a surgeon saying how many sutures he's going to use to close a wound.

I mean, until you actually get there and you do

the -- I did a prostate just yesterday. How many needles I can get in is determined on the patient's anatomy and when you're bouncing needles off the pubic symphysis, you don't always get all the needles in.

If I had written anything prior to actually going and doing the implant, it would not reflect what was really done.

DR. TSE: That's correct and that's why we have another item.

DR. FELDMEIER: 4.4, for a change in the prescription?

DR. TSE: 4.6, to reflect the actual loading. We realize that's a problem of the brachytherapy oncologist, so we permit the changes after you implant and you reflect actual loading.

The reason, in my view, why we need a prescription ahead of time is such that you can convey to your people, whether technologists or whoever, or purchase agent, to get you the proper number of sources and proper curies that you need.

You will not be able to check when they give you the source whether it's one millicurie, ten millicurie or five millicurie. You wouldn't know.

DR. FELDMEIER: Right.

DR. TSE: But if you give them an order, verbal

order, they may remember for a while, and then after while they have forgotten and they give you a source, which is not easily verifiable at the time when you insert, when you implant.

Therefore, if you can write down what you like to do, how many sources, what kind of sources, what kind of activity you want, that's good enough for this particular.

DR. FELDMEIER: For something like this, since we generally try to do -- and I think this is state of the art. You try to do a computer preplan.

You do the dosimetry. You show the isodose curves with your ideal implant, what you'd like to do.

Would such a preplan satisfy the requirements of this 4.2? I would hope so because that's as accurate and as precise as we can possibly be in this situation.

DR. TSE: Right. If you have a preplan, either you say the dose or you say what kind of sources are needed, what kind of location I want to put it in.

That would meet the prescription definition. That certainly satisfies that but, also, you have to sign it and so on, because the prescription has to be signed.

MR. JANICE: What it's going to do is just mean more paperwork in the end, because you'll write a prescription and then you'll have to go back and change the prescription.

DR. TSE: But otherwise, what do you do? If you don't have a written sheet, how are you going to convey that information to the purchase agent? He's supposed to go out and buy the sources for you for a certain date.

MR. BELLEZZA: You just send him a piece of paper that says that on it, but that piece of paper doesn't go in the patient's chart.

MR. WHITE: Sometimes we'll buy two or three hundred iridiums. We'll buy 20 ribbons of iridium and keep them for a month and cut them up as we need them.

It's not always for an individual patient. We don't do many implants.

DR. TSE: Okay, but then you still want to send a technologist downstairs in the vault to pick up those sources.

Like this morning we saw the misadministration where somebody picked up the wrong sources.

Will the physician be able to tell right at the time, "This is not what I want because this is the five millicuries"?

MR. WHITE: I think those are different kinds of implants. I think what the doctor was suggesting is that there are some implants that you don't know ahead of time what you're going to do.

If you're suggesting that any written record of

the physician's intent is added to the patient prescription, then saying to deliver 2,000 rads by interstitial boost would be acceptable, I would think.

DR. TSE: Right.

DR. FELDMEIER: Yes, if something as non-specific as that is okay or a preplan is okay, I think the intent of this is all right, but if you do something like a permanent iodine or permanent gold seed implant, it's a guesstimate.

Generally what you do is you make up the difference by -- since this is almost always done in conjunction with external beam radiation therapy, if there's any disparity between what you end up with and what you wanted to give, you can touch it up a bit by adding or subtracting to your external beam radiation therapy plan.

MR. WHITE: You will have one misadministration balanced out by the other is the way the inspector will look at it.

[Laughter.]

MR. SHARP: Misadministration is unintended.

DR. TSE: We specifically said that when a physician implants the sources, sometimes -- if you put it in a computer, you can precisely XYZ-1, XYZ-2 and so on, location and how many seeds he needs.

But when the physician starts to insert, starts to have the operation insert, you really cannot say, "I'm going

to put this exactly in this location."

He does the best he can under the circumstances and he doesn't have to worry about whether I'm going to call it NRC misadministration.

He should be concentrating on putting the best he can on the sources.

If he ordered 30, he used 10, that's fine. That's the best he can do at the time.

And if he orders 30 and he wanted 20 more, that's fine, too.

All he has to is later, after he finishes, he will put in his so-called actual load. He can say, "I ordered 30 but I only used 15."

That's not an intended or not misadministration because of physician's judgment or whatever at the time. That's the best he can do.

DR. FELDMEIER: I think the objection is really before administering the byproduct material.

It would be much more flexible and I think would prevent some duplication of paperwork exercises if it could be somehow allowed to be broadened to say either before or immediately after an implant procedure is done, the physician will specify the brachytherapy prescription, something like that.

DR. TSE: Right, but the problem is whether you

will get the right sources you want. That's a problem.

You think the technologist or whoever goes down to the vault and picks up some sources for you. You think it's a 15 millicurie each.

MR. JANICE: They need a written order.

DR. TSE: Right. It not easily can be told that's 15 millicurie. If that's the case, that would be fine.

DR. FELDMEIER: Well, is that what the word "prescription" here means is that the activity of the isotope you're ordering is what you want to utilize?

The problem with "prescription," when you talk about it in medical terms, when you talk about it in terms of a drug or you talk about it in terms of a radionuclide or you talk about it in terms of external beam radiation, it means slightly different things.

If a prescription in this case means that you have ordered the activity of the radioisotope that you want -- if I say that I want to get three-millicurie gold seeds and I call up Best Industries and they don't have three-millicurie seeds. They have 3.4-millicuries seeds.

Is that a departure from the prescription?

DR. TSE: Then you write another one. You just change your prescription.

DR. FELDMEIER: Then I do three or four different paperwork exercises for one procedure.

MR. WHITE: That's a problem therapy people are going to have with this. I don't want to seem like we're picking nits.

That's the problem therapy people are going to have with this concept is that therapy prescriptions are done differently than radionuclide prescriptions.

For a large part, most of these procedures and many of the regulations in the Code don't fit clinical practice today.

You're saying two different things. You're telling him that, yes, he can prescribe a rad dose ahead of time but, yes, he also has to prescribe a seed activity ahead of time.

Those two things are not consistent, I don't think.

DR. TSE: No, I think the definition did not say you've got to prescribe both. You can do one or the other.

MR. WHITE: If you can do one or the other, you can't make a mistake doing it. If he says 2,000 rads and orders 3.4 millicurie seeds, which of those does he have to change later on?

DR. TSE: You mean which one is your prescription?

MR. WHITE: Yes, which is the prescription?

DR. FELDMEIER: Yes. It this could be modified to say something like before administering the byproduct

material, the authorized user or the physician under the supervision of the authorized user will personally select and see to it that the proper activity of the radioisotope is ordered, words to that effect, then I wouldn't have any problem with it.

DR. TSE: Let me suggest another case.

Some physicians maybe say, "I want 5,000 rads to this particular region or to the contour."

So the technologists or dosimetrists take your ordered prescription, go to make a dose calculation.

Then he made an error. The error may be by a factor of two.

So, therefore, he calculates 24 hours or 48 hours implant but instead of 5,000, he had 10,000 rads, except the calculation shows only 5,000 rads.

Now, if the physician says, "This looks good. Let's do it," after finishing it's too late. It becomes misadministration because the person, dosimetrist, made an error, missed it by a factor of two and the patient received twice as much dose.

That's a misadministration. Without your prescription, if you don't have a prescription, how would the dosimetrist know what he's going to plan for.

So you need some kind of written down information to tell the dosimetrist you plan for 5,000 rads contour.

DR. FELDMEIER: But without doing the plan you don't know what the contours are.

There is a big difference between looking at an external beam isodose contour that you can look at at your leisure and you can control and you can modify and you can add a few more seconds of cobalt time, and having a procedure, especially with a permanent implant.

With a temporary after-loading implant, you always have the element of time that you can partially control things but if you're going to put a permanent implant of iodine or gold seeds in, even though you have the most wonderful intents and even though you do the most careful preplanning, what you get at the time of the procedure only approximates in most cases what you set out to.

For me, if I want to give a prostate 2500 rads and I drop in 50 or 60 millicuries total activity, and instead of getting 2500 rads, I get 2800 rads, it's not a big thing clinically, because I can mop up the difference by modifying the external beam, even though it might be off by well more than a factor of ten percert.

I think that with brachytherapy it's going to be very difficult to be rigid in defining this type of prescription prior to the procedure.

I think we have to have some flexibility and we have to have the realization that in most cases clinically

we can adjust to this very readily by just adjusting the external beam dose.

I can get around this because all I have to do is have my physicist do an isodose plan for me and if you're going to hold my feet to the fire and say 2500 rads, I can just pick an isodose curve that gives me 2500 rads.

I can go subterfuge the whole process by selecting an isodose curve, even though it's not the one that I would normally pick that I would think would be indicative of the dose that the tumor volume got.

MR. TELFORD: You would make a preplan then. You would say --

DR. FELDMEIER: If it's a complex implant, we always try to do a preplan.

MR. TELFORD: So you would rather do a preplan than a prescription?

DR. FELDMEIER: Yes.

MR. TELFORD: That's what you're basically saying?

DR. FELDMEIER: I think the word preplan is a much less precise word that allows for some flexibility and interpretation.

I mean, we're always going to do some sort of a preplan. It might not always be a computer-generated isodose preplan, although in many cases it is.

It might not always be that.

The Baylor group does a lot of gold seed implant. Although you try to be absolutely as precise as you can, you just can't do it with the precision that we can be held to in external beam radiotherapy.

MR. TELFORD: You would specify the treatment site.

DR. FELDMEIER: Yes.

MR. TELFORD: You would specify the radioisotope.

DR. FELDMEIER: Yes.

MR. TELFORD: Would you specify the dose, the total dose?

DR. FELDMEIER: Not necessarily.

MR. TELFORD: Okay. Would you specify --

DR. FELDMEIER: Not within ten percent.

MR. TELFORD: Would you specify treatment time and number of seeds, then?

DR. FELDMEIER: No.

MR. TELFORD: Would you do that approximately?

DR. FELDMEIER: Yes, but it depends on -- it really hinges on how much leeway you're going to give me with an approximation.

MR. BELLEZZA: You might ask for so many seeds.

DR. FELDMEIER: It really depends upon the type of implant.

MR. TELFORD: You would ask for a certain number

of seeds to be brought to you at a certain activity.

DR. FELDMEIER: Yes. I might have 20 brought into the OR and I might use 8 or I might use 12 or I might use 15.

MR. TELFORD: Okay, we've got it. We understand what you are saying.

DR. FELDMEIER: But that's a permanent implant.

Now, with the temporary implant, you can control the element of time.

The thing is, if I do a perineal template and I have maybe 50 holes that I can push needles through but the patient's anatomy gets in the way and I can't drive through bone.

So if it's a lady with a large cervical tumor that I want to implant from sidewall to sidewall, I put as many needles as I can.

But I don't have any way of telling anybody beforehand how many needles I'm going to use.

I am going to specify the activity of the iridium and how many iridium seeds per ribbon but I have no way of telling you how many ribbons I'm going to use because I don't know how many needles I'm going to be able to insert.

MR. TELFORD: I think what we're searching for is some sort of written directive so that exactly what you asked for is brought to you in the OR.

DR. FELDMEIER: I understand. The problem I have is with the term "prescription," because I think prescription has a fairly precise connotation.

If you say a preplan or a range of dose or --

MR. BELLEZZA: What they're describing I wouldn't even call a preplan. It would be more of a requisition, an isotope requisition to the curator.

MR. TELFORD: I think that's a misdirection, in my opinion. I think preplan is very close to the mark.

We've heard about this word prescription here in other workshops as being a little too tight.

Let us take this under advisement. What sounds very good is the description of a preplan where you talk about the site and the radioisotope and the number of seeds that you want and specific activities, because we want to get those to the OR exactly as directed.

We want a written directive from the nuclear physician that says, "This is what I want."

MR. BELLEZZA: To the isotope curator who is going to deliver the isotope.

MR. TELFORD: No, no. Forget where it comes from. Forget where it comes from.

DR. FELDMEIER: You're just saying there needs to be a written record.

MR. TELFORD: A written directive that says,

"Bring these to the OR."

MR. BELLEZZA: Where does that piece of paper ultimately have to wind up?

MR. TELFORD: Anywhere where it needs to go. I don't care.

MR. BELLEZZA: It doesn't have to be in the patient's chart. It could be in the isotope --

MR. TELFORD: All we need is a written directive that anybody who needs to look at it can follow.

MR. SHARP: That can check against what happened.

DR. TSE: It doesn't have to be in the patient's chart.

MR. SHARP: As a brief end point of this, I hope, what kind of tolerances would you expect to be successful with a preplan?

DR. FELDMEIER: It really depends. If you're talking about iridium, you can be pretty precise. A hundred rads, perhaps, out of --

MR. SHARP: No. Permanent?

DR. FELDMEIER: With permanent, it can vary quite a bit. You can vary a thousand rads pretty easily.

MR. SHARP: Fifty percent?

DR. FELDMEIER: Fifty percent would be -- I would hope that we could stay within 50 percent tolerance.

DR. TSE: But in any case, the guide is

structured, supposed to be the intention to permit a physician to have that flexibility.

Maybe the word "prescription," in your view, has too specific connotation in the medical field.

DR. FELDMEIER: Yes, right.

DR. TSE: John suggests different words or perhaps we can use "written directive," or something, which still is a written kind of order for those sources that's needed such that the people who take the sources to the OR know what to do.

MR. TELFORD: Let's see if we can get through Section 4 here and then maybe take a break.

DR. TSE: Okay. And 4.3 is somebody to verify the sources are the ones which the doctor has required.

4.4 is a change. If the physician needs to change something, they can change their prescription without limitations.

4.5, do you have a problem with 4.5?

DR. WIATROWSKI: Yes, for templates we normally don't --

DR. TSE: Right. I think we already -- we just did not put that the common sources. It should be common sources in there, also, with that.

DR. WIATROWSKI: Yes, but for the template implants, you take the template pattern that's built into

the computer program.

You don't need the radiograph type to generate the isodose lines.

You may want to verify that the needles are approximately parallel but the actual dosimetry is not done off the radiograph in the template, such as a prostate that John was talking about a few moments ago.

DR. TSE: I see, but then you still need a radiograph to show that --

DR. WIATROWSKI: Yes, but it does not form the basis of dosimetry.

DR. TSE: Does not form the basis, okay.

MR. WHITE: The same thing for GYN after loading.

We put in dummy sources, take films and then load the application in the patient's room. Is that unusual or do other people do that?

VOICES: No, not at all. That's standard.

MR. WHITE: So we would fail to meet that and in fact I would think there would be a decline in radiation safety if we -- I would normally forbid this particular thing to be done in my hospital for most of our implants.

DR. FELDMEIER: What you're saying is rather than reading "after implanting the brachytherapy sources," we ought to say something like, "after installing the appliance," or in the case of a permanent implant,

"implanting the brachytherapy sources," because many --

MR. WHITE: Why not leave out the first phrase?

MR. SHARP: Why not just say "dosimetry radiograph"?

MR. WHITE: Just say "radiographs will be obtained."

DR. FELDMEIER: Just take out that "after implanting the brachytherapy sources."

With an after-loading system, whether it's a fletcher suite or iridium template or something like that, you don't take the localizing radiographs with a hot isotope in place.

The appliance is in place but the isotope is not.

DR. TSE: Does the appliance include a dummy source?

MR. BOLLING: May or may not.

MR. SHARP: Some are visible without it.

DR. TSE: Okay. Then 4.6, that's essentially what Dr. Feldmeier is talking about, that you could change a prescription after the implant. Update your prescription after the implant.

4.7 is record of administered dose. It's the same as Section 3.

Next page. 4.8 is a doublecheck of the calculations of computer program inputs before 50 percent of

the prescribed dose has been administered.

Anybody have any questions on this?

DR. WIATROWSKI: I guess that would be almost irrelevant in a permanent implant, since you're not going to go back in after the sources anyway.

DR. FELDMEIER: It's actually pretty liberal for Iodine-125 because that gives you 60 days to do it.

DR. TSE: That's for permanent implant.

Any other questions?

MR. WHITE: I have a question about the misadministration.

DR. TSE: Yes.

MR. WHITE: In the actual regulation it talks about a 20 percent window for acceptability.

For some brachytherapy placements where the reference point is quite close to the --

DR. TSE: Excuse me. John is signaling.

MR. TELFORD: Go ahead and ask your question, but that's the next workshop.

MR. WHITE: Okay.

DR. TSE: I'm going to hand out a proposed regulation, which includes the misadministration provision of administration to you all before today's workshop is over.

The intention is that today we are concentrating

on the quality assurance aspect.

The other, when you have a chance to read it, think about it, when you come back next time, we'll have more time, two days.

Then you can offer your comments. Those comments will be in the record and will be part of the public comment. We still would consider those comments for formulating the final.

Any more questions?

[No response.]

DR. TSE: Then 4.9 is an emergency case. We say in an emergency case, you just go ahead and do it first without worrying about checking and doublechecking of a dose calculation, but you need to do it after two days of the completion of the treatment.

Any questions?

[No response.]

DR. TSE: Ten minutes break and then we'll come back and finish the teletherapy.

[Recess taken.]

DR. TSE: Let's resume.

We now go to Page 8, Item 5 for teletherapy. 5.1, 5.2, 5.3 and 5.4 are the same as previously in the brachytherapy.

5.5 is a weekly check. That's because of the

different fractions involved. This is a special item in the teletherapy.

5.6 is a calculation doublechecking the calculation again.

MR. JANICE: On your 5.5, who actually does the weekly check?

DR. TSE: I think we did not say who. It's without saying it has to be a qualified person, people who can add or who can detect an error.

Maybe a technologist, maybe a dosimetrist, maybe a physicist or a physician.

Any other questions on this page?

[No response.]

DR. TSE: Then go to Page 9. This first portion, also, the part of the doublecheck procedures.

5.7 is different. 5.7 says after full calibration measurements you should do an independent check.

This full calibration measurement does not include annual measurement. The annual measurement can be checked against the decay but if you change a source or there's some problem with the spot check, then you need to check the -- independent check of the calibration.

It can be done in two ways and 5.7.2 is either by an independent person with independent instrumentation or by a TOD, like M.D. Anderson kind of check.

Anybody have a problem with this one?

[No response.]

DR. TSE: It's okay? Okay.

[Laughter.]

DR. TSE: Then 5.8 is another item related to transmission factor.

This item says that the annual full calibration measurement should include the transmission factor for beam modifying devices.

During the year something could happen, that pieces could drop and so on. The transmission factor may be modified or changed.

An annual full calibration to check it and make sure they are correct.

Any problem with that? Physicists?

MR. BELLEZZA: Does, for instance, blocks, transmission factors -- you're just looking at your complete block library and picking out a representative sample of blocks and checking transmission factors for them, or do you have to get really picky and start going through every single block?

DR. TSE: What would you think?

MR. BELLEZZA: Hopefully, just a representative sample.

DR. TSE: How about wedge?

MR. BELLEZZA: Wedges can shift on the device that they're mounted on but I would not expect a blocked transmission to change.

DR. TSE: To change that much, right.

MR. BELLEZZA: Normally, I wouldn't check that transmission at all on any block.

DR. WIATROWSKI: That's right.

MR. BELLEZZA: So I'm not sure why I'm doing it in the first place, if I'm not doing it all?

DR. TSE: Maybe not necessary?

MR. BELLEZZA: Yes.

DR. TSE: Maybe that's a chance for you to say so, if you want to make it your evaluation and say for whatever the reason, blocks are not necessary to be measured.

Do you measure them when you purchase them? Maybe you want to make a suggestion like that.

However, would you think that wedge should be modified -- sorry -- should be measured every year?

VOICES: Yes.

DR. TSE: Okay. This pilot program is a chance for you to make suggestions of the proper way of doing this.

Any other questions on 5.8?

[No response.]

DR. TSE: 5.9 is if for some field size and you have not measured it before and you have to use it, you

should measure, also, but it gives a 25 percent dose time.

So you could start doing that but then later you need to measure it.

Does anybody have a problem or a question? Please.

MR. WHITE: I guess I'm not sure about the intent of 5.9 when it says "measurement of the output."

Can you give me an example of what you had in mind for that?

DR. TSE: What's a measurement of output in rads?

MR. WHITE: No, give me an example of when you would want to do the 5.9 task.

DR. TSE: For example, you have a certain field size. You measure certain field size during your annual calibration.

If you need to use a field size which is outside, not inside -- suppose you measure from this mini amount to this maxi amount during the annual calibration.

Suppose you want to use some field size outside that range. Now you need to measure that again before 25 percent dose is given.

DR. WIATROWSKI: I think realistically it would only be for extended treatment distances, like for TBI, for total body irradiations.

That's the only time, because normally you

wouldn't measure your output as a function of field size out to the largest field size of the machine at isocenter or SAD.

So the only time that this would come into play, I think, is it you're doing a whole body irradiation against the wall or you have some other strange extended treatment

It would be rare and many institutions wouldn't even do those sorts of procedures.

DR. TSE: But if you've already measured those distances during annual calibrations, then you don't have to worry.

But if you never did it, you should do it.

Do you have a problem with that?

MR. WHITE: No.

DR. TSE: Anybody else?

[No response.]

DR. TSE: 5.10 is a computer program. John this morning mentioned that the hospital cannot change their computer program after they change the source.

Here the item says that if you use first time your computer program or after you change a source or some modification of your machine, you need to do a calculation under certain conditions and then make a measurements in the same conditions and then compare the two.

They should be pretty close.

Just to verify that the computer program coincides, that the calculation made by the computer program matches the measurement.

That's the intent. Anybody have a problem or have questions?

DR. WIATROWSKI: This is awful detailed. It makes me feel real uncomfortable with this.

MR. HAIDER: I do have a question on number two. You want to check against a phantom measurement, in a field to do that at the greatest angle in water, at a 45-degree angle.

First of all, how am I going to measure at a 45-degree angle in water with a wedge and without a wedge.

DR. TSE: Okay. Let me put it this way.

MR. HAIDER: And what is the intent to it?

DR. TSE: Let me put it this way. The suggestion of this one, two, three, all these examples of conditions were suggested by some oncologists and ACR's and so on.

We have the same kind of questions from the earlier workshops.

My response is that the intent is to measure, check the measurement versus calculations. How should we do it?

Some people suggest that we use that. You are the oncologist. What do you think of to suggest?

Or everybody else, maybe you can give us some suggestion.

DR. FELDMEIER: What do the physicists say?

DR. TSE: Physicists say that they don't understand.

[Laughter.]

DR. TSE: Do our oncologist friends understand?

DR. FELDMEIER: I'm not sure I understand the intent of this.

DR. TSE: Let's do it this way. If you think this is a good item, you may not even do it, because you may not even have a new program or so on.

MR. HAIDER: I don't know how to do it. I need to learn how to do it at 45-degree angle coming in and have a water phantom without being tilted and worrying about water falling.

DR. FELDMEIER: If you have a real narrow phantom, you've got to think practical if you're taking these measurements. This is not real practical.

DR. TSE: How do we change this such that we will fulfill our intent?

DR. WIATROWSKI: We're not even sure this is required yet. Obviously, some check against the computer's generation of isodose lines against the actual radiation pattern is important but, clearly, this is so detailed.

I think if you referred this to the AAPM, for example, they wouldn't agree necessarily that this is at all essential.

So my judgment is, this is not all essential.

DR. TSE: Right, but what suggestions can you make such that the check can be made?

DR. WIATROWSKI: A different kind of check.

DR. TSE: Right.

MR. TELFORD: The situation is you have got a new computer program or you've made modifications to a computer program or, secondly, you've just changed source.

I told you about the Cumberland event this morning.

This is an attempt to say here are some checks you can do that you can --

DR. WIATROWSKI: I agree with the intent. There's no question about the intent. Most people do that and most Board-certified physicists do that.

The question is, these particular suggestions I don't think came from a physicist because I don't know anybody who does this.

MR. TELFORD: It won't bother me a bit if you say this is overkill.

What I would like to hear is what you would do in your institution or what you would recommend to your clients

that they do for an overcheck so that, number one, you're checking out the machine and, number two, you're checking out the ability to deliver a dose using the wedge and, number three, you've got some sort of hard case.

The basic question is, are you getting what you're supposed to be getting. That's really the intent.

So if you could give us some suggestions of what you would do, we'd greatly appreciate it.

MR. SHARP: On the first one, is that an attempt to be a check on the unit or the computer program?

DR. TSE: I think this Item 5.10 is a check of the computer program because the unit has been checked under full calibration.

MR. SHARP: Then why eight angles? What are you looking for?

DR. TSE: I said that's a suggestion from certain people. I'm not sure. I really do not understand myself, because I'm a nuclear engineer instead of a physicist.

It's your suggestion. We want to listen to see how we can modify to be more understandable and practical.

MR. SHARP: I think if we knew what the agenda was behind these, the suggestions would be more to the point.

DR. TSE: I don't think I understand it. Maybe Dr. Feldmeier could --

DR. FELDMEIER: No, I don't.

MR. WHITE: I would fear that my question -- I'll go back to both 5.9 and 5.10.

DR. TSE: Yes.

MR. WHITE: I asked about 5.9 a minute ago.

I now find myself in the unusual position of suggesting that these two things, rather than being too detailed, are probably woefully inadequate to assure the functions that I think the NRC is trying to assure.

If someone purchased, for example, a new treatment planning system, the items outlined in 5.10 would, I think, be trivial and/or irrelevant tests of the treatment planning computer's function.

In 5.9 the output measurement for even moderately sophisticated blocking devices or demodifiers is really not nearly as important as the depth of those characteristics and profile and all sorts of other things like that.

The down side of these is that people may read these, buy a treatment planning computer, and say, "Oh, gosh, I've checked my wedge at four different angles."

In fact, that's not something that the computer is ever sensitive to in many cases. They think they have done something that's going to guarantee patient safety.

You want to have regulations that guarantee patient safety.

On the other hand, you don't want to have

regulations that give the appearance of providing adequate level of medical care.

You've written in two whole paragraphs here things that if you read the medical physics literature occupy, I'm just going to guess, two, three, four or five hundred pages of effort of different people.

I would question whether this is a task that can be outlined in this kind of document.

DR. TSE: To respond to your question, first, the intention of 5.10 is just that, to check the computer program to your output, whether they are in certain conditions of geometry such that they match each other.

The detailed software check is not included in here. That will be in what we call the basic quality assurance and, therefore, it's only the most important things.

The other detailed checks will be addressed elsewhere.

MR. WHITE: Just that the output of the cobalt source is properly --

DR. TSE: No, that the computer calculation results matches the output of your cobalt unit.

MR. WHITE: When you say "output," that's the thing that I find confusing.

When I prepare a treatment plan for a physician,

it's an isodose plot that contains somewhere between 1,000 and 4,000 separate dose points.

We like to think that most of those are reasonably correct.

What this is suggesting is that we choose one point on the central axis under a wedge.

DR. TSE: Right.

MR. WHITE: Is that right?

DR. TSE: That's it, because the intention of this is trying to avoid the problem generated in the Maryland case.

MR. SHARP: But what he's saying is, you can have an equally severe error if --

MR. WHITE: The Maryland case could have been prevented by somebody checking a ten-by-ten field.

DR. TSE: Maybe.

MR. WHITE: If that's your goal, that's clearly the thing to do.

DR. TSE: Right, but if you did detailed computer software, it's much more complicated than this.

That's not addressed. I think AAPM and some other people have those, but it is not addressed here. Here is to address to avoid those human errors.

DR. WIATROWSKI: Why don't you request a suggestion from the AAPM? They would be the appropriate

people to go to.

We're talking about people who have protocols that we all use in practice.

DR. TSE: We have discussed it with Dr. Tong and Nash but they have not yet made suggestions on this.

DR. WIATROWSKI: You need to talk to Dr. Fullerton, who is president of the AAPM in San Antonio.

Their suggestion, I think, would be appropriate.

DR. TSE: Yes, we'll work on it. Your suggestions are important, too, because you are a practical physicist.

You know the intent. How do we get to the intent?

DR. WIATROWSKI: Well, I don't want to speak for my fellow physicists.

I think the appropriate thing to do is to go to the professional organization, because there are existing protocols.

What you need to do is reference the existing protocols and get rid of this, is what you need to do.

Go to the president of the AAPM and say, "I need some help to get this done. This is important to all of the physicists."

So let me make that as a suggestion for the project.

DR. TSE: Okay. Any other problems on this or questions?

Yes.

MR. BELLEZZA: Just a question on the wording of No. 1 on 5.10, "an open field in air."

I'm not sure what that means.

DR. TSE: We already said that.

You can make a good suggestion yourself when you provide evaluation and, also, the suggestion made here for us to talk to AAPM and try to modify these to be more appropriate.

MR. BELLEZZA: I guess I don't understand what --

MR. TELFORD: You're saying it should have been water?

MR. BELLEZZA: The sentence makes no sense at all.

DR. WIATROWSKI: We usually don't calculate dose to air. I don't know what they're getting at. I have no idea what that is. It's nonsensical to a physicist.

DR. TSE: All right. We understand your concerns. I don't think I will be able to answer the question here, so we will check with AAPM.

MR. SHARP: Would you suggest, then, that they simply propose their own alternative for the pilot study?

DR. TSE: Oh, yes. If you want to, you can propose your own suggestion how to meet the intent, how to best in your case to meet it.

MR. BELLEZZA: Just sort of an over-all question.

DR. TSE: Yes.

MR. BELLEZZA: During the pilot study, do you necessarily want us to go through all of this calibration if it's normally not on our regular schedule during the 60-day period?

DR. TSE: No, I don't think so.

But if you happen to have these scenes, like you change your source, maybe you want to try it out on these. Then you can give us your experience.

If nobody tries it, then we still are thinking process and do not have actual experience.

So if somebody wants to try it, please do, but we will not request you to purposely create a situation to try this.

5.11, again, is emergency exemption similar to the brachytherapy case.

The "Implementation" essentially says that this is guidance, repeats the guidance again.

Anybody have any over-all or any other comments, questions, suggestions on the guide?

[No response.]

DR. TSE: Okay, John.

MR. TELFORD: Thank you, Dr. Tse.

I'm referring to the agenda. We've come to the

point on the agenda where we would like to review the schedule of future activities.

There's a couple of points that I would like to remind you of.

During the pilot program the only records that we'd like to ask you to keep are those that you saw up here on the evaluation form.

That is, how many patients did you treat; what instructions went with this patient; keep the prescription or keep the referral or whatever directive that you're using; keep the record of the administered dose or dosage so that there can be a comparison.

Have your clinical procedures manual so that if you're one of the 18, we can look at it.

The pilot program, the actual 60-day period, will be from May 14 to July 13.

Anybody have a problem with that? We can all do that?

[No response.]

MR. TELFORD: So the clock starts May 14 on the 60 days.

You implement your modified program and try it out for 60 days. The 60 days is over July 13.

Now, July 13 to July 31, we'll ask you to do the evaluation prior to the next workshop.

The next workshop will be two days. It will hopefully be during the month of August.

We will try to avoid conflicts with all society meetings. It will be back here in Dallas for this meeting.

Ed, you had your hand up.

DR. KAPLAN: May 7.

MR. TELFORD: Oh, okay. The letter that you received initially from Brookhaven and the reminder letter that you got probably this last week asked you to bring a copy of your quality assurance program to this meeting, to this workshop.

If you didn't do that, we would ask you that if you need to make some changes to your program or you need to go back and do one now, then go do it and send us a copy no later than May 7.

The reason for May 7 is that is your program is one of the 18, our QA team will be scrambling like mad to review those programs in depth before they come to your location, to your site.

So they need a couple of weeks to go through those 18 programs.

MR. GOMEZ: Where do we send the program?

MR. TELFORD: Ed.

DR. KAPLAN: I will see you later.

MR. TELFORD: Please send your copy of your

program.

If your program is sort of many pages and if you're pulling together parts from one procedure manual or forms you use or other descriptions, then we would greatly appreciate this one-page outline that just kind of directs traffic.

It says, "For this Objective No. 2, go over here to these sections. For Objective 3, go over to these sections."

So that would just expedite our review.

So I've touched on May 7, May 14 to July 13, and July 31.

By then you have filled out your evaluation so that you're ready for the next workshop.

Did I miss any dates? Anybody have any questions about those dates or anything else?

MR. SHARP: For those states where you're going to do the followup, will you inform them at least two or three weeks in advance if they're going to accompany?

MR. TELFORD: You mean the site visits?

MR. SHARP: Site visits.

MR. TELFORD: We will notify the state of the fact that we've chosen Licensee A in Texas as soon as we know it.

MS. WALKER: Will you notify just the state or will you also notify the victim?

[Laughter.]

MR. TELFORD: Notify the licensee?

MS. WALKER: The person you are coming to.

MR. TELFORD: Oh, definitely. Definitely.

In the words of one of the QA team members, we'd like to give that person as much advance notice as we can.

We don't want any surprises here. We will definitely notify you.

There will be six Agreement state licensees. I can almost guarantee there will be one from Texas.

Any other questions? Oh, yes.

We'll hand out the copies of the Federal Register notice and the guide.

The purpose of handing you this is because contained in this publication are the recordkeeping and reporting requirements for diagnostics and therapy procedures.

That's not really a subject of your trial program or the pilot program.

However, come final rule time, I would really like to know how to improve those reporting requirements.

Every time I gave this talk last year, most of the smoke and the heat and the fire came from those reporting requirements.

So I absolutely know that you're going to have

really good suggestions for how to fix those things, because that's probably something you won't really like a lot.

So that's why I'm giving this to you.

At the next workshop we'll have a block of time and we'll talk about those things and how to fix it.

That was your question about 20 percent for brachytherapy. Since we have experts here, they can tell us a better number.

Any other questions?

[No response.]

MR. TELFORD: What we're going to do last is the concluding remarks.

So I just go around the table again and let everybody have five or ten minutes, if that's what they want, or one minute, if that's what they want.

Before we start, I would like to say that I thank you very much for coming.

I think we're going to enjoy this. I think we're going to learn a lot.

I really, really appreciate your participation.

You're going to find out that at the next workshop, that we're going to listen very carefully and we're going to try to adopt your suggestions, and that's why your participation is so important, that we can develop a record of what you think is the optimum program that has

minimum impact to your institution but yet meets the intent of what we're trying to do.

So, again, thank you. I'll let everybody talk and I'll start right over here.

MR. LOPEZ: Just to reiterate the fact that we always hear gripes about the regulations after they have been published and this is the time to do it before that.

I hope that everybody takes advantage of the opportunity.

MR. DADARI: I don't have basically any remarks. I'm hoping to digest the whole thing in the next month or so.

Basically we have everything in place, I would say 99.9 percent, but it needs a little bit of attention to bring it together and evaluate to see what's going to be a benefit to the patient in the situation.

Our particular situation, kind of a rural hospital, it's going to be a little different.

MR. HAIDER: I think it's a really great program but a lot of confrontation could be avoided if we somewhere put the word "commonsense applied," and that would have taken a lot of argument out.

But it's great. Appreciate the NRC for looking into it.

MS. WOOD: I'd have to sort of reiterate that.

It's nice to have a say-so in what happens to us.

MR. WHITE: Yes. I think most of the things that you've talked about today are good ideas.

It will be interesting to see if the program shows that they also get to be regulations and I think it's really impressive.

Being able to participate in this is really a nice thing and I think that clearly on the professional side, those of us who are physicists need to find out why the AAPM, again, seems to be asleep at the wheel and if we can get them to put in some substantial input into these regulations, which apparently you have asked for and not received.

MR. GOMEZ: Let me say that this is a very good program and for me this is a good compliment for any radiation safety program.

I think that the most important is getting the instructions to the people, to the physician, to the technologist and to the managing people in order that everybody will help to implement the program.

I have found out that anything which will put more work on the people, they will not collaborate on.

Implementing this program, they will have much more work to do.

MR. BELLEZZA: I second what's already been said.

I personally find it enlightening to see how the process of developing regulations goes on. It's been a nice experience.

MR. SHAFFER: I guess I'd just like to say I appreciate the opportunity to participate in the program and I think our Medical Center, after going through the exercise, will be one step ahead of the others who get the actual regulations, in that we will already know what to expect.

I appreciate being able to participate.

MR. JANICE: Did you hear the one about -- No, I don't have anything to add.

MS. WALKER: No comment.

DR. TSE: I want to thank you for coming and giving us a comment and I'll expect to see more comments next time when we have the second workshop.

DR. KAPLAN: I'd like to reiterate that I'm really impressed with the professionalism displayed by joining into the program, especially taking the opportunity to participate before something becomes finalized.

This is a good opportunity for some of you to update your formalized QA programs.

To make our life simpler, really, that road map that John talked about is very important to us.

If you have a QA plan, I'll take it today. If you

don't have one or if you want to wait until you formulate this road map, that's okay, too.

Remember, May 7 is the cut-off date so that we can get started right away.

One other thing, if you could also let us know what departments are participating, it would be very useful.

Thank you.

MR. BOLLING: I would also like to thank all of the volunteers for participating and I would like to say that your participation in this rulemaking I hope would extend to your participating in rulemaking in your states, because in many cases there is an opportunity for the public to review and comment on regulations before they go into effect.

Quite often the states will have the equivalent of what we have in the Federal Register. They'll have some kind of a state record which announces regulations that are coming up for revision or to be implemented.

It's typically a 90-day period and if you'd scan those records from time to time or maybe call your State Rad Control Office and ask if there are any new regs coming down the road, you might be able to get some input and have some regulations that you can live with.

DR. PICCONE: I'd just like to reiterate as well the time that you've spent today and more so the time you

are going to spend in the next three months in this effort to help us in this rulemaking.

As the first gentleman pointed out to you, it is just so much easier to use your comments and your suggestions -- i to take them into account on the front end of the rulem. ng than it is to try to make changes once the rule has become final.

I'm looking forward to reviewing some of your programs and visiting your facilities as well.

MR. LEE: I'd like to just thank the Government the opportunity in letting rural America participate in this rulemaking.

Anybody can see the major hospitals and the big universities getting a hand into this and I'm from a small hospital and several of the others here are from small areas and I appreciate the opportunity to participate.

MR. DESAI: I think this is a great idea. We all do basically everything that is listed on this list in pieces and bits.

This is going to be a good comprehensive program, I think, and I really appreciate and thanks for inviting me here. Thank you.

MR. HAMMOND: I think I just wanted to reiterate that I think this is an excellent idea for the pilot program, as opposed to having regulations handed to us on a

platter or what was proposed in 1987.

It definitely gives us an opportunity to have a hand in our future and to interact proactively to decide what's going to happen to us.

A lot of us probably have some of these things already in place. We do.

For us in the mobile business, it's going to be really unique to try and figure out a way to get the client hospitals to participate in this program where we can't be on site to make sure they do but we'll be charged with their compliance as their contractor.

MR. SHARP: I don't think I have anything to add, except that the meeting has been unusually productive for this many groups put together and I think it's a real good beginning.

MS. RUDOLF: I just have one comment about the objectives.

At our facility the physics staff and dosimetry staff spend quite a bit of time chasing down prescriptions and we were thankful to see this coming along because perhaps this may save us a bit of time.

DR. FELDMEIER: I agree with everything that's been said generally. I think it's a good concept to be able to interact with this prospectively and have some impact on the regulations.

The only thing I might suggest is when you have your post-trial meeting, that you might want to, rather than regionally divide it up, perhaps divide it up along specialties and maybe it might lead to a bit more productive input if you had several nuclear medicine physicians and several physicists coming from the same perspective.

I think one of your intents is to have a manageable group, which I think you need to have but I think if you had -- and I'm prejudiced -- several radiation oncologists, you might have a more productive interaction in that situation.

DR. WIATROWSKI: I think maybe the only comment I would make is to reiterate what I said before.

If you're going to include specific technical requirements in a Regulatory Guide that are related to the radiotherapy physics, then I think you need to solicit the input from the appropriate professional societies.

MR. TELFORD: I would like to respond to that comment. We have issued requests or invitations, if you will, in public several times to every medical society, AAPM, ACNP, SNM, the whole alphabet soup.

If there exists a medical society that wants to discuss this rule and this guide, we will do it.

You name the place; you name the time; we'll be there.

Again, thank you.

Meeting adjourned.

[Whereupon, at 3:56 p.m., the workshop was concluded.]

- - -

REPORTER'S CERTIFICATE

This is to certify that the attached proceedings before the United States Nuclear Regulatory Commission in the matter of:

NAME OF PROCEEDING: Pilot Program Objectives (35.35)

DOCKET NUMBER: None

PLACE OF PROCEEDING: Irving, Texas

were held as herein appears, and that this is the original transcript thereof for the file of the United States Nuclear Regulatory Commission taken by me and thereafter reduced to typewriting by me or under the direction of the court reporting company, and that the transcript is a true and accurate record of the foregoing proceedings.

Betty Morgan

BETTY MORGAN
Official Reporter
Ann Riley & Associates, Ltd.