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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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MEETING: NRC QUALITY ASSURANCE FOR MEDICAL USE - PILOT PROGRAM WORKSHOP

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Days Inn

777 Airport Boulevard

San Francisco, California

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Friday, April 20, 1990

9:20 o'clock a.m.

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ATTENDEES:

Joseph Hellman, Madigan Army Medical Center

Donna Marciano, UCLA Medical Center

Donald Bunn, CA Department of Health

Elbert Huen, Coastal Radiation Oncology

Sandra Sulloway, San Joaquin General Hospital

Anthony Tse, NRC

Edward Kaplan, Brookhaven National Laboratory

Jack Hornor, State Agreements Office, NRC Region V

Darrel Wiedeman, NRC Region III

Jim Montgomery, NRC Region V

Terry Frazee, State of Washington, Radiation Protection

Dean Chaney, NRC Region V

Beth Riedlinger, NRC Region V

P R O C E E D I N G S

[9:20 a.m.]

MR. TELFORD: Good morning. My name is John Telford. I'm from the NRC in Rockville, at Headquarters. I'm the guy that's responsible for this rulemaking, and a few others that you may have heard of.

We're here today to talk about the pilot program and by the end of the day, I hope that you all understand what it's all about, what everybody's role happens to be.

We usually start out these workshops by letting everyone introduce themselves. That's the topic here, the first topic on the agenda. What we ask is that you give your name, your title, your hospital or the organization you're from, its size in terms of the number of beds it has, what combination of practice that you represent here today, whether it be teletherapy, brachytherapy, nuclear medicine, therapy or diagnostic, or a combination of those.

I note that we have several folks from Agreement states, as well as some Region V NRC folks. I'll just go around the table and let everyone introduce themselves. Start here.

MR. HELLMAN: I'm Joe Hellman. I'm the Medical Physicist out of Madigan Army Medical Center in Tacoma, Washington. We're a 450-bed hospital; primarily therapy, but I'm here representing kind of the whole thing.

MS. MARCIANO: I'm Donna Marciano. I'm the Administrator for the Nuclear Medicine Clinic at UCLA, which is a 711-bed hospital.

MR. TELFORD: What combination is it? Is it all the modalities, therapy --

MS. MARCIANO: No, no. Just nuclear medicine.

MR. TELFORD: Just nuclear medicine. Just wanted to clarify that.

MR. HUEN: I'm Albert Huen. I am a Chief Physicist at Coastal Radiation Oncology. It's a freestanding group of physicians. We have about seven or eight clinics along the coast in Southern California, as far as to Westlake Village and as far north as to Salinas. And we do really radiation therapy and brachytherapy.

MS. SULLOWAY: I'm Sandra Sulloway. I'm from San Wakine General Hospital near Stockton, California. We have a 250-bed hospital. I do nuclear medicine only.

MR. TSE: I'm Anthony Tse. I'm from NRC in Washington, D.C. I'm the Program Manager for this program.

MR. KAPLAN: My name is Edward Kaplan. I've been in touch with many of you. I'm with Brookhaven National Laboratory.

MR. HORNOR: My name is Jack Hornor. I am the Regional State Agreements Officer here in Region V, over the Agreement states.

MR. WIEDEMAN: I'm Darrel Wiedeman. I'm the Technical Assistant to the Director for Radiation Saf cy and Safeguards for NRC Region III Office in Chicago, and I'll be one of the persons in the Site Team visits.

MR. MONTGOMERY: I'm Jim Montgomery. I'm with the local NRC Region V Office from here in Walnut Creek, and I am a Materials Licensing Inspector for the Region.

MR. FRAZEE: I'm Terry Frazee from the State of Washington, Division of Radiation Protection. We have 350 licensees overall, of which approximately 100 are medical licensees. As an Agreement state, we would adopt the final rule as a matter of compatibility with NRC.

MR. BUNN: I'm Donald Bunn. I'm with the California Radiation Program. I am the Senior Health Physicist in Compliance. We conduct inspections of all licensees in California. Like Terry, we would adopt the rules here as an Agreement state.

MR. CHANEY: I'm Dean Chaney, Acting Chief of Nuclear Materials Safety, Inspection, and Licensing in Region V.

MS. RIEDLINGER: I'm Beth Riedlinger and I'm the Licensing Reviewer in Region V.

MR. TELFORD: Thank you. Let me go through the agenda so you'll understand what's coming and when. First, I'll talk about the pilot program to kind of give you an

overview of its objectives and the outline of the entire thing. what you can expect to be asked to do and what you can expect to receive from all of this, and basically go over some current misadministrations to show you the kind of problems that we're trying to address.

Then I'll talk about the proposed Rule 35.35 and certain records to keep. Now, let me carefully distinguish that the subject today is the proposed 35.35, just the quality assurance rule itself.

I'm sure you've looked at the Federal Register and you've noted that there are two other sections; for instance, 35.33, which are the recordkeeping and reporting requirements for diagnostics, and 35.34, which are the recordkeeping and reporting requirements for therapy.

Those will be on the agenda at the followup workshop, which we would like to hear suggestions for how to modify or otherwise improve those reporting requirements.

We'll have a brief session following after lu It will cover any potential conflicts that the volunteers may have with the state requirements. Then we will discuss the evaluation forms that we'll use to give you an idea of the kind of questions and the range of questions that we would be looking for answers to on your experience and your suggestions on the pilot program; in particular, how to modify or improve the proposed 35.35.

Then we will discuss the regulatory guide and give you a chance to comment on that. The real purpose today is to give you an understanding of the intent of proposed 35.35, as well as the guide.

While we are not trying to fix it today, if you have any suggestions, we would certainly like to hear them. But in the next workshop, that will be the focus, is how to improve both of those things.

So we're after an understanding and intent so that the volunteers can carry out their trial program of their quality assurance program.

Then we'll review the schedule one last time at the end of the day. And you'll notice that we have little breaks here for questions and answers after each topic. So if you think of something as we go along, feel free to ask, but I guarantee you you'll have ample opportunity to ask all the questions you'd like.

Let me give you a little bit of a background. Some of you are familiar with this, but back in the fall of 1987, our five Commissioners -- when I refer to the Commissioners, I'll say the Commission, and I'd like to make a careful distinction between the staff proposes and what the Commission approves.

I can think of them in the corporate world or analogue with the Board of Directors a company. But the

Commission requested a rulemaking in 1987. In the fall of 1987, the Notice of Proposed Rulemaking on the basic quality assurance program was posed, as well as advanced notice on a comprehensive quality assurance program, rule.

The basic quality assurance rule is where we are today. This one is still there, but it's on hold. The way I think of this is the basic quality assurance rule doesn't do it, then my feeling is the Commission will ask us to look into the comprehensive rule and see what else needs to be done.

From today through the next several months until March of 1991, we'll be focusing on the basic rule. The staff provided this final rule to the Commission in 1988, and it was a prescriptive rule and some of you are familiar with that.

The medical community made their views known to the Commission in 1988, and basically they said that they were not terribly enthralled with this rule because it was too prescriptive; it not only said what to do, but how to do it. One of the conclusions was that they should not be told how to do it.

So the staff provided rulemaking options to the Commission that gave them the option of doing a proposed rule. Now, with this proposed performance-based rule, the staff had meetings with the Advisory Committee, Quality

Assurance Subcommittee of the Advisory Committee on the Medical Use of Isotopes.

We had workshops with the medical licensees. That was in January of 1989. We met with the American College of Radiology primarily because they were developing a model quality assurance program that could be used voluntarily by their members, of course, for therapy.

The staff briefed the Commission in June of 1989 and provided essentially the proposed rule that you have now. The Commission had a lot of deliberations about this particular proposed rule and asked for at least a couple iterations. They said to us, why don't you fix a couple things and we'll take another look at it.

We did that in August. The Commission finally gave us a directive in December of 1989, and the proposed rule was published in the Federal Register on January 16 of this year.

Part of the directive from the Commission for this proposed rule was to conduct a pilot program. The basic thought is you propose something, you have a strawman, why don't you try it out and fix it, bring it back to us as a final rule. And the Commission has requested the final rule in draft form as a staff proposal to them in March of 1991.

So that's the timetable. I'd like to give you just a thumbnail sketch, an overview of the pilot program.

The first topic here is probably the key ingredient. What we said to the Commission was that we wanted -- if we're going to do a pilot program, we would like to make sure that we have proportional representation from each NRC region, of which there are five, each Agreement state, of which there are 29, each class of facility, whether or not you do teletherapy, brachytherapy or nuclear medicine, and each type of location, whether you're urban or rural, and basically whether you're kind of public or private or whether or not you're a government kind of facility, or whether you're a large, what might be called not-for-profit institution, but you're fairly large nevertheless.

So there are about 2,000 NRC licensees and about 4,000 Agreement state licensees. We were able to get authorization, you might say, to have 24 NRC volunteers and 48 Agreement state volunteers, for a total of 72 to represent this population of licensees.

I might add including Army, Navy, Air Force and VA hospitals. So we went through an elaborate selection procedure. Dr. Ed Kaplan is the one who deserves the credit for having pulled this off, because it was a lot of work to, first of all, go through the selection procedure to follow the arcane criteria that we had to give him in order to say, I've got to have one of these and one of these and one of these. and don't give me one of those in the selection

procedure.

So it was an iterative process, but he did it. I'll say a little bit more about that in a minute. Basically, the pilot program, after the volunteers have been identified, the volunteers have a month to "develop their quality assurance programs and a month to implement;" that is, to train and fix up any daily procedures that they have.

They'll have two months, a 60-day period with some actual trial period for using this modified program, and then we'll have one month to collect the results and hear all the suggestions.

As part of this, we'll have workshops before the trial period and workshops after the trial period. As part of this, we'll have what we call the QA Team of four people from NRC that will do an in-depth review of the subset of all of these programs, there are 72; both for a program review and a site evaluation, and I'll be saying more about that.

Let me back up to the agenda so you can keep track of where I am. Next, I'm going to go into these three topics here for the pilot program, a little more in detail.

When I call these the pilot program objectives, I don't mean that the objectives are limited to these, but they're probably among the more important ones.

We want to understand how the volunteers structure

a program, how they do it, to meet the objectives of 35.35. The groundrules here are that this is a performance-based rule, so all you'll hear from us is here are the objectives, here are some worthy objectives that we think your program should meet.

How you do it is totally up to you. All I'll ask from you is that you tell me that your program meets the objectives of 35.35 and we'll be satisfied. So it will be very interesting to find out how 72 volunteers do their program.

Number two is how they carry it out in actual practice; what does it look like within their hospital; how is it really implemented. And what individual procedures they use would be something else that we would like to understand.

Three, we'd like to find out if the objectives that we have have the desirable effect of catching what you might think of as intermediate step kind of mistakes before they become misadministrations.

Lastly, on this viewgraph anyway, is we'd like to find out if these objectives have the effect or if the collective opinion is that these objectives could have the effect that they could prevent misadministrations if adopted. If not, we would like the volunteers' help in determining what set of objectives wou.d provide high

confidence that misadministrations can be prevented.

This is a rather detailed outline of the entire pilot program. Now, this selection process to achieve this proportional representation of the 6,000 licensees went on in January and February.

One of the difficulties that we learned was that whenever Ed sen -- after going through this scientific selection procedure, then Ed sends a letter to the chosen volunteer. You get a letter that says Congratulations, you've won the lotto. Wouldn't you like to be a member of the pilot program.

And the letter says in a week I'll call you and see if you have any questions. So in a week he would call. Gee, well, Ed, it sounds like a pretty good idea, but I have to check with three other people. He calls back next week and, well, two of those says yes, but one of them wants me to check with three other people or four other people.

So he would call back the following week and find out finally after getting six or seven okay's, that this person could say yes. So that took two months of time to round up all the people that we have rounded up. No small chore.

This is the next month or the first month in the five-month overview I showed you. This is where the volunteers would review the 35.35 that Ed sent to them,

along with the guide, if they want to use the guide.

They would determine that their program currently meets proposed 35.35 or they would modify their program to meet it, here I say basically during April. But you'll see that it will go into May.

Then we'll have the pretest workshops. The first one on March 29 was in New York; April 4 was in Chicago; April 6 was in Atlanta; April 18 was in Dallas; and, today, we're in San Francisco.

This next item is the following month, after the pretest workshop. The volunteers have basically a month to modify any procedures that they use day-to-day or to do any training. And I say if required, because many folks have told us that their program already meets these objectives. So they have very little to do.

On the other hand, we've got volunteers that come from rural communities and they have very small clinics, which is evidence that Ed did a good job in getting the representation, that they come in and say, well, we don't really have a quality assurance program, it will take us a little bit.

So let's look at these various monthly periods before just to give them the opportunity. Then the actual 60-day test period or trial period we would like to be between May 14 and July 13. So the way it goes is you look

at the proposed 35.35, you modify your program, you say it meets 35.35, you send us a copy, and on May 14 you start using it.

It may be no change for you, but, on the other hand, it may be a change. And the "end of the trial program" is July 13.

Now, during this trial period, the NRC QA Team says they will visit 18 volunteers. That's the subset I was talking about. There will be 18 out of these 70-odd volunteers for which the QA Team will do an in-depth review of their program on paper. They will ther follow it up with the site evaluation.

Now, the letter that you received made note of that fact, but there's a couple of potential fears that I would like to lay aside. First of all, the QA Team will be there for that site visit -- if your facility is selected, the QA Team will be there only one day. They have a lot to do. They want to look at only the quality assurance program. They will not be -- first of all, it will not be an inspection. Secondly, it will not be a review of your total radiation safety program.

It will only be a review of your proposed or -- yes -- of your quality assurance program which meets proposed 35.35. So they'll have a lot of records to check. They'll have a lot of questions to find out the answers to.

The basic question they will be asking when they review these programs, these 18 on paper, will be do we think that this program meets proposed 35.35.

Because when they get to the site, they will be asking the basic question is the volunteer implementing the program that's on paper.

We think of these 18 as being an insight into the larger group of the 70 volunteers. So that whatever we find there, we would like to make an inference to the group of 70.

After the trial period, the 60-day trial period, we'll have a post-test workshop. This will be a two-day workshop, which I anticipate that we will find out a lot of information, and there will be some participation by both the Quality Assurance Team and by the volunteers.

The volunteers will tell us about their experience in trying out this program. Their evaluation, we'll have a written evaluation form and you will have the opportunity to discuss that among your peers. And last, but probably most important is suggestions you have for how to modify both the rule and the guide.

It even says here the recordkeeping and reporting requirements. Now, at the end of the day, we'll give you a copy of the Federal Register Notice just to make sure you have one, just so that you have these recordkeeping and

reporting requirements on the proposed 35.33 and 35.34.

So at the post-test workshop, we'll go into those in detail and find out your suggestions for how to improve those. The Quality Assurance Team will provide you with the discussion of the criteria they used for program evaluation, site review, and you'll find out the results from those two endeavors.

I have a little bit more of that here. This is what the participants can expect. First of all, you will understand the criteria that the QA Team used to do the program review on paper. So to me, if I were a volunteer, this would be an inside view as to how licensing might be done in the future for this regulation.

If I were a state regulatory, then I would say, well, okay, this is how the NRC does it, right? So that might be a little bit of insight. And you will find out the results of the program evaluations for those 18.

This item is you will understand the criteria that we used for the -- that the QA Team used for the 18 site visits. The fourth item says you'll learn the results of those site visits.

Now, again, let me assure you that both of these will be done in a very no-fault kind of way. What you will hear is that your program was selected. You will hear that, okay, your program has the following strong points, the

following weak points, and the following points need work. So we're not here to embarrass anyone and we're not here to make anyone feel bad.

We do want to confess to you how we would review these things, because it seems like to you it's completely no-fault. There is no penalty whatsoever for having learned this information. We would be just that much further ahead of everybody else.

Now, the fifth and sixth items; I've put those there to convince people that we were really interested in your suggestions; that we really want to hear from the volunteers. If the previous four workshops are any indication, I have no fear that we will hear a lot of from the volunteers, which we have already.

The previous four workshops have been very helpful and we've already gotten more benefit from that than I ever expected to.

Now, this is what we expect of the participants. We would like you to develop a program or modify your existing program such that you can tell us that it meets the proposed 35.35. In the pretest workshop, provide either written instructions or trained personnel; again, I say as necessary, because it may not be necessary.

This it to prepare for the 60-day trial period in which you actually use your modified program. Fourthly, to

conduct that 60-day trial, and, fifth, to evaluate it. Evaluate the proposed rulemaking. We'll discuss the evaluation forms this afternoon, the questionnaire.

We have a draft one that we'll discuss with you so that you can get an insight into what kinds and how much in-depth we are going to ask about. You will discover that we will give you a carte blanche to turn this thing inside out.

Lastly, to attend a post-test workshop in which you can provide your experience and your evaluation and your suggestions. And because we will be keeping a transcript of that workshop, even though the public comment period expired April 12, your comments that you provide to us in the post-test workshop will be part of the public rulemaking record. Therefore, the staff can use every one of your suggestions.

Now, let me say that we're down to this point on the agenda. Before I go into the current misadministrations, let's sort of pause for any questions or comments you might have. Does anybody have any comments they want to make so far?

MR. HUEN: I just want a question to clarify, in my mind, this particular pilot program. It seems to me that it pertains to two things that we're doing. One is the practice of medicine. The other one is the physical measurements. Are we talking about the same thing or --

MR. TELFORD: When you said practice and medicine,

could you amplify on that a little bit? How is that involved?

MR. HUEN: For instance, some of these items that I read on this proposed 35.35 seem to me to say all the physicians must do this, cross-check, certain dosage was done by the second person before we administered, before the 25 percent of dose is achieved, we have to do this. So that's practice of medicine, to me.

Now, the other aspect is quality assurance. It's like, well, I've got to make sure that the dose that I delivered to the patient is correct. So those are the physical measurements.

So does this particular part of rulemaking consist of these two ventures or are we just talking -- emphasizing on the one part?

MR. TELFORD: Well, let me note that, for instance, you're saying the 25 percent; before 25 -- I think I remember that one from brachytherapy.

MR. HUEN: Yes.

MR. TELFORD: Before 25 percent of the dose is delivered, double-check the calculation. Let me note that's in the regulatory guide. It's not one of the eight objectives. So that guide is for your use. If you want to use it, we'd be very happy to give some input, some experience with somebody using that. But it is in no way

one of the eight objectives.

Just for the eight objectives, there's a basic thing here that says we are very purposefully trying to stay out of the practice of medicine. We would be very happy to have the nuclear medicine physician, a person that we call the authorized user, we would like that person to be in charge.

So that person could issue, ideally, a written directive that says do the following; whether or not it's teletherapy, brachytherapy or nuclear medicine; do the following so that clear instructions go to the technologist or to the physicist or whomever needs to know.

Those persons would have clear directives as to what to do so that if, in the end, the administered dose were as prescribed, and I'm just talking loosely now, I'm using those words very loosely; if that happened, this would be a success.

So if you detect that if, in your opinion, any of these objectives get into the practice of medicine -- this item on the agenda here -- when we discuss the proposed 35.35, we will talk about each objective and I will do my best to explain the intent of each objective.

If you think that part of them are infringing upon practice of medicine, please say so. We are purposefully trying to stay out of that. We want the authorized using

physician to be in charge, not the required physician, for example.

Any other comments or questions? Yes.

MR. HELLMAN: I think you answered it for me. I just want to clarify that as part of the implementation of these eight objectives in the pilot program, it will not require us to adopt the draft reg guide as -- we will not have to choose to adopt that draft reg guide. To me, it's unduly restrictive in some areas.

MR. TELFORD: Exactly. We will not require you to use the guide at all. Whenever the Commission -- I'm speaking of the NRC now. Whenever it gives a rule that's a performance-based rule, then some licensees would like specific guidance, and we consider it fair to provide some guidance to those folks.

But in this case, we will be making a pointed effort not to use this guide ever as a prescriptive. Come final rule time, we will try to get a lot of alternatives into this guide, such that it will say you can do A or B or C; such that you can do one of those or you can do something else, as long as what you're doing meets the objective of the rule.

So yes, you're correct. We don't want anybody to be forced to use this guide, especially in this pilot program. You're completely free. Each volunteer can

structure any program that they like, that's tailor-made for their hospital or their clinic, such that it meets the objectives of the proposed 35.35.

If they're convinced of that, fine. We'll go with it. So the purpose of -- there are many purposes of the pilot program. We'd like to find out how it works to do a performance-based rule like this for the 6,000 licensees across the U.S.

We would like to see the various ways that people can implement this. We'd like to have these all tried out and, therefore, use those results to fix our proposed rule, make it better. Because in the end, we would like a sufficient rule that's enforceable, especially against the folks that are slow learners, that seem to have a problem, because, as a side to this -- if you have a program that works and never has a problem, this rule or the final rule means nothing to you, because you just go straight on.

It's nothing to you. It has almost no impact. As a performance-based rule, that's the way it's intended. But if your program is one that has a bunch of misadministrations every year and a bunch of folks are getting overdosed, this should be a rule that's enforceable, that says, ah, tell me what's wrong with your program, tell me how you're going to fix it.

Because currently, in 10 CFR Part 35, we have

reporting requirements on misadministrations. If you make one of those six mistakes, you have to report it. And as of April 1 of this year, it has become a matter of compatibility for the 29 Agreement states to start reporting those. Prior to April 1, it was voluntary.

Some other objectives of the pilot program are to find out what do we do with -- we the NRC, the staff, what we would do with a performance-based rule, how we would license it, how would we inspect it. Because if you give this much latitude to the licensees, our job is a lot more difficult.

If we had a prescriptive rule, like are many of our regulations are prescriptive, sure, you just have a guide or you have a standard review plan and it says, boy, you do the following 18 things and you know you've done it. So we do the 18 things, we come and check you out on the 18 things, and it's pretty straightforward.

But with a performance-based rule, all is not so simple. You're granting a lot of latitude to each licensee for the primary purpose of minimizing the impact on each licensee. If each licensee can structure a program that's sufficient, meets the rule, if they can minimize the impact on themselves, so much the better.

So there's a whole bunch of purposes to the pilot program to find out if all of this works.

Any comments?

MR. HELLMAN: I've got one more question.

MR. TELFORD: Sure.

MR. HELLMAN: Keep changing the subject. The basic eight objectives which I read in this seem, on the nuclear medicine side, to only address iodine. Is there a reason why it's avoiding technetium, or are we getting to that?

MR. TELFORD: That's this item, but I'll answer your question. Those words need fixing because it address all radiopharmaceuticals. By the time we get done with this item, I hope you understand all of that.

Let me bore you with a few current misadministrations. When we were doing this rule, starting it back in 1987, we looked at all the misadministrations for 1980 to 1988, and we did a retrospective analysis and said if the items in the prescriptive rule were followed, how many of those misadministrations over the last eight years would have been prevented.

Our answer was 80 percent, but you will recognize that today a lot of the stuff we had in the prescriptive rule are now found in the guide. So the guide is optional.

Let me rush through a few misadministrations. This was one in Cumberland, Maryland, and which -- the nature of the misadministration was that over a 13-month

period, 33 patients received the wrong teletherapy dose. Now, here it says greater than 100 percent of the prescribed dose, but that's rather an understatement because the cause was that the Cobalt-60 source was changed, but nobody updated a computer program.

So the computer program thought it was using the old strength, so all 33 patients go the time based on -- time of exposure based on the old strength. So the action taken to prevent reoccurrence is the licensee has implemented over-check procedures to prevent his, in additional to hiring some qualified people.

MR. HELLMAN: What's the insurance carrier doing now, too.

MR. TELFORD: Now, this is another teletherapy. It was March of 1989. I call these recent misadministrations, so you can check me out on these dates. But this is the Indiana University School of Medicine in Indianapolis.

This patient was administered the therapy treatment of 300 rads to nine sites on the left hip and groin, but it should have been the right hip and groin. The cause was that there was miscommunication among the technologists. They didn't notice the absence of the tattoos for the site on the left hip or groin.

The patient received 2,700 rads that was to the

wrong site. The action taken to prevent reoccurrence was they now have procedures to verify the treatment site.

Now, you'll notice that some of these are Agreement states and some are NRC states. I didn't select these. I just took them out of a report. The only thing I did was not use several nuclear medicine misadministrations that aren't nearly as interesting, because of the potential consequence to the patient.

This is Worchester City Hospital in Massachusetts in July of 1989, teletherapy. The patient was administered teletherapy dose to the spine instead of the right lung. The cause is the technologist failed the confirm the patient's identity, even though there was an available photograph. The technologist failed to recognize the absence of position tattoos.

The probable consequence was the patient gets 250 rads to the spine that they weren't supposed to have. The actions taken to prevent reoccurrence was they have a new procedure which requires each patient's identify be verified by a photograph. In questionable cases, the physician would verify the patient's identity prior to treatment.

This is February of this year at Geisinger Medical Center in Danville, Pennsylvania, teletherapy. The patient received additional treatment fractions beyond the number they were supposed to get.

The technologist either misunderstood or didn't remember the number of fractions to be given, and they didn't keep a record showing which fractions had been given, so the technologist just kept giving them.

MR. HELLMAN: Amazing.

MR. TELFORD: So the patient received 4,200 rads to the spine instead of the prescribed 3,000. The action taken to prevent reoccurrence is the licensee has implemented new procedures that require clear markings on the patient's chart when the treatment is completed; check them off as you go along.

The staff has been instructed to review all the prescriptions prior to initiating treatment so they are familiar with the case before they begin.

Now, this is brachytherapy, January of 1989, Yale New Haven Hospital in New Haven, Connecticut. You may be noticing that these places are not exactly small rural locations.

The nature of the misadministration here is the technologist entered the wrong decay factor of 267 instead of 128. I believe this was the high dose rate after-loading device. The cause was the technologist simply misread the number and there was no over-check procedure. The patient got 1,000 rads instead of 500. To prevent reoccurrence, the licensee established new procedures for over-check of input

like that.

Here's another brachytherapy misadministration, also January of 1989, St. Lukes Hospital in Kansas City, Missouri. There were two cesium source strengths to be loaded; 25 and 20, but the 25 and a five were actually loaded.

The cause was the storage drawer containing the sources, one drawer contained two different strengths. This patient was 56 percent underdosed. The action taken to prevent reoccurrence, the licensee now has the sources arranged so that each drawer contains sources of one strength only.

Now, this is March 14 of 1989, New England Medical Center, Boston. The nature of the misadministration is that the patient received the wrong radiopharmaceutical and the wrong dose. The patient did receive one millicurie -- I'm sorry -- was to receive the prescribed one millicurie of I-123. The switch was to five millicuries of I-131.

The cause was the technologist misunderstood the wording in the notes made by the referring physician. Note referring physician here; I'll come back to that later. The patient, as a result, got 5,000 rads to the thyroid. The action taken to prevent reoccurrence is they now have procedures to verify that each diagnostic study requested -- they don't merely --

MR. MONTGOMERY: John?

MR. TELFORD: Yes.

MR. MONTGOMERY: I had a question. 123 is accelerator-produced. The NRC does not regulate that

MR. TELFORD: Right.

MR. MONTGOMERY: Agreement states do. 131 is byproduct material. We do regulate that. When we define a misadministration, in this case, the patient was to receive an accelerated-produced isotope. Instead, he received a byproduct isotope.

MR. TELFORD: Right.

MR. MONTGOMERY: In terms of NRC jurisdiction and enforcement in a case like this, how do we look at a misadministration? Do we look at what was intended or what was actually given?

MR. TELFORD: In my opinion, we've got two things to look at, only one of which might be suspicion. Just look at the dose. That would be sufficient. Now, even it were the right isotope, he got the wrong dose, dramatically lower. 5,000 rads to the thyroid may not be all that horrible, but may not be all that good. So that's probably enough for enforcement.

Darrel, what do you think about enforcement?

MR. WIEDEMAN: It's the wrong chemical-physical form, number one, and it's a dose to the patient that was

not intended.

MR. TELFORD: Okay.

MR. WIEDEMAN: Now, if they would have prescribed one millicurie of I-123 and gave five millicuries of 123, we wouldn't even be involved in that because that's strictly an accelerator-produced.

MR. HORNOR: Two questions. On your cause, maybe the solution would have been to improve the doctor's handwriting, because we just went through one recently that it was very hard to read prescriptions once in a while. Two, the technologist probably should have gone back and asked the doctor, I can't read your handwriting. So maybe that was -- maybe there's more than the corrections we need to do on some of these other areas.

MR. WIEDEMAN: One of the other things is standardization of terminology in medicine is what's really needed. Many times, a physician will order a thyroid study, whatever that means, and another time he may order a thyroid scan. Well, a thyroid scan is different from one facility to another.

If you have a new technologist, before, maybe the previous hospital he worked at, a thyroid scan was with technetium or may have been with iodine. So there has to be some standardization.

MR. TELFORD: Well, look at this one. This is

October of 1989 at the May Foundation in Rochester. The dose was ten times what was prescribed. The referring physician -- note referring physician again -- ordered a scan using one millicurie of I-131 instead of a 100 microcuries.

The guy checked the wrong box on the diagnostic referral form, so no handwriting involved. He just checked the wrong box. The patient got 1,000 rads to the thyroid. The action taken to prevent reoccurrence was the hospital has now a procedure to require the nuclear medicine physician to review and approve the request and to write the prescribed dosage on the referral form.

In other words, this hospital now puts the nuclear medicine physician in charge, not the referring physician.

MR. WIEDEMAN: Another thing with Mayo Foundation, they were the pioneers of I-131 for research back in the 1940's and 1950's.

MR. TELFORD: Yes.

MR. WIEDEMAN: So they knew all about it.

MR. TELFORD: Okay. May 23 of 1989, Abbott-Northwestern Hospital, Minneapolis. The patient was to get a three millicurie dose of I-131. They were intended to get 300 microcuries of I-123. So there's another switch.

The cause was the technologist misunderstood the referring physician's request, didn't understand about the

radiopharmaceutical and didn't understand dose.

So the patient, from this three millicuries, got 3,000 rads to the thyroid roughly and this licensee took the action to implement a new procedure that no I-131 will be administered without prior approval by the nuclear medicine physician. So they've learned to put that person in charge.

November 1, 1989, Desert Good Samaritan Hospital in Arizona. The nature of this misadministration, the patient was to get 100 microcuries of I-131. Instead, the patient got 100 millicuries of I-131.

There were probably several causes. Among those, the radiopharmaceutical ordered was done so over the phone, a verbal order. The dose was not measured in the dose calibrator. There was miscommunication between two technologists. I'm sure there were others, but the probable consequence is -- more than probable -- the thyroid was destroyed.

The action taken to prevent reoccurrence in this case is the State of Arizona suspended I-131 use at the hospital until the licensee can show how future misadministrations can be prevented. They subsequently gave them the condition that they could use up to 100 microcuries. If they wanted to use more than that, they'd have to go to the state and ask permission.

MR. HORNOR: On this one, John, the pharmacy -- I

saw the prescription that was taken over the phone. You couldn't read it. You couldn't tell the difference between a microcurie and a millicurie because of the handwriting.

MR. TELFORD: Handwriting.

MR. HORNOR: But that didn't slow them down from going ahead and filling the order.

MR. TELFORD: Did they check the label, the package label that came with the 100 millicuries?

MR. HORNOR: Well, the hospital was at fault, too. I'm just saying it was a handwriting problem.

MR. TELFORD: Okay. Among the causes, it was the handwriting. Here we have November 1989, Kuakini Medical Center in Honolulu. The wrong patient received nine millicuries of I-131. This is the case where the technologist called Patient B, Patient A responded, and took the nine millicuries of I-131.

On the other hand, Patient A was to get 20 millicuries of technetium for a bone scan. So the probable consequence is one patient, the wrong one, gets 9,000 rads to the thyroid. The action taken to prevent reoccurrence here is that this licensee now has -- this is an NRC licensee, by the way. This licensee now has a procedure to require that a single technologist be responsible for identifying patients and to handle all aspects of I-131 therapy.

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

Now, one of my reasons for going through these misadministrations is so that you can look at a current crop of problems that we see so that you have at least as much insight, probably more than we do into these problems.

The second purpose is it's my opinion that what's happening today is even though the rate of misadministration is low and even though the industry and most hospitals have a really exemplary record, what seems to be happening is some hospital has a problem and we're going around solving this one hospital at a time or one clinic at a time.

Maybe, eventually, we'd get through all 6,000. But, logically, you might ask why should we do that; why not just try and make an attempt at solving it one time, one generically, with the rulemaking. So that's what we may be doing or trying to do.

Let's go back to the agenda. Any questions or comments on these things, by the way?

MR. HORNOR: Well, John, this is a good point. Why don't you give us a little more view of the big picture. Are we dealing here with a serious problem or are the rate of misadministrations such that we want to really improve this, maybe there's one in a thousand, we want to go to one

in ten thousand, and what kind of a resource are we going to put forward here to improve that, and what kind of damage are we doing to these people?

Now that we've moved from protecting occupational and public health people to protecting the patient, I wonder what the big picture is. Could you explain that? That's the question I'm always asked.

MR. TELFORD: Well, you've asked several questions.

MR. HORNOR: It's the big picture and I --

MR. TELFORD: I like every one of them and it would help me a great deal if you would allow me to pick off those one at a time.

MR. HORNOR: Sure.

MR. TELFORD: I have the answers to them, but they're part of the agenda.

MR. HORNOR: All right.

MR. TELFORD: So let's not steal the thunder from the various parts of this. NOw, we're up to here for questions and answers.

Jack wants me to talk about the big picture as we go along. Anybody else have requests, questions, comments?

MR. HELLMAN: I think you summarized it pretty well. There are always mistakes in any clinic, but is our rate increasing, is the error rate we're having now

different from what we had ten years ago? I don't think so, and, yet, now you're coming down on us.

MR. HORNOR: As a matter of fact, I think it's getting better. California now requires that new med techs be certified. They have a standard for certification so that from one hosp to the next, some of these things like Darrel was talking about will be corrected.

These things are -- have you taken this into -- contemplated this aspect of it? Because all those almost are human error that you're showing us up there and with good training that probably would have gone away.

MR. TELFORD: Let me make two comments. First of all, the rate. We looked at the rate over an eight-year period. It was on the order of ten or eleven therapy-level misadministrations per year.

However, what I just showed you were eleven misadministrations. I have one here that I didn't show you. There are five or six nuclear medicine procedures that were foul-ups in labelling that I didn't show you. For 1989, there were more than eleven misadministrations. For 1990, so far, Lloyd Bolling informs me that if the rate continues, we'll have about three times the normal amount, of the usually expected amount.

So I don't think the rate has gone down. It may have gone down in the state of California, but nationally

the evidence I see says it's either the same or it's going up.

However, you might ask the question how many of these are being reported? Are all of them being reported? That's sort of open to debate. Nobody can prove that they're all being reported. Nobody can disprove that. That's sort of a nagging fear that's in the back of your mind.

States are now required, as a matter of compatibility, to report these. Across the United States, do you think they're all uniform? Probably not. But that's really -- and the bottom line conclusion you can draw from all that is, no, it's not going down. If anything, we see many of the same problems reoccurring again and what we're doing is running around each hospital whenever that particular problem occurs.

If it occurs in nuclear medicine, then Hospital A. We get over there and we saw the nuclear medicine problem, but we don't touch teletherapy, we don't touch brachytherapy, even if they do it. We're only solving it piecemeal.

From the logic point of view or good utilization of resources point of view, that doesn't make any sense to me, but I don't make the decisions. But that's my -- I mean, that's what I know about the rate.

Now, you mentioned that it looks as if we're coming down on people. By the end of the day, I hope to be able to convince you that we have a performance-based rule that says you'll just have to have a program.

As a matter of fact, that's a great lead into looking at proposed 35.35. The theory here is to have a performance-based rule that really says, number one, each licensee would have to have a written basic quality assurance program. Its aim is to provide high confidence that errors in medical use will be prevented.

The principal amount of room that each licensee has is quite large. Each licensee can develop a program that meets the needs of their hospital, is tailor-made to their hospital or clinic, as long as it meets these objectives, they can minimize the impact on themselves. So all we're saying really to all these 6,000 licensees, and it is 6,000 because the Commission has decided that this rulemaking would be a matter of compatibility.

So it affects not only the 2,000 NRC licensees, but the 4,000 Agreement state licensees as well. Part of this proposed rule would say on the front end, it says, okay, you have to have a quality assurance program. Here are eight objectives that would be worthy of being met. If you do these things, we think they'll be useful. So please put into your program something that meets each of these

eight objectives.

But here's the back end of the rule, here's the feedback loop that allows -- first of all, it would require an annual log. The licensee management would have an audit done. Then they would do an evaluation and results. And then licensee management would have a finding that the program is effective.

So there, owning up to their responsibility for having an effective program. Now if, in their opinion, it meets -- you know, the problems that they see are small. They're not disturbed by them, but they just use that the following year. But if they discover they have some large holes that need fixing, then this rule would require -- if it's final -- would require modifications to prevent reoccurrence.

So that instead of, first of all, the NRC going around or the Agreement states going around through a lot of inspections and a lot of enforcement conferences, etcetera, and saying, okay, Hospital A, you've got a problem in nuclear medicine, why don't you fix it; why don't you tell us what you're going to do and we'll sign off on your procedure to prevent this reoccurrence.

Here, you put the licensee management in control. So we're trying to stay out of the loop as much as we can.

MR. HUEN: Excuse me. Can I ask you a question

about that?

MR. TELFORD: Yes.

MR. HUEN: Who is going to do the audit?

MR. TELFORD: The audit --

MR. HUEN: The annual comprehensive audit?

MR. TELFORD: Okay. First -- well. That's part of this afternoon's discussion. I don't want to seem like I keep putting you folks off. Licensee management decides if a person is qualified to do this audit or not. There does not have to be an outside organization.

I can give you a couple of examples. You may have two neighboring hospitals. You may exchange RSO's. It could be -- there is a Dr. Brickner who is a member of the Quality Assurance Committee for the American College of Radiology. He has a practice in Oklahoma. He was 12 technologists. He does a monthly audit.

Each month, he chooses one of the technologists and says you do the audit. The basic idea that we want to -- the basic thing we want to prevent is a person auditing himself or herself. Now, that's all we want to prevent.

But anybody that's qualified can do this audit. It doesn't have to be outside your organization. It can be from within your organization. You don't want unqualified people, but anybody that's qualified, they can do that.

There's one of the objectives in the rule that

gives -- that points out one thing very succinctly to look at. So you can go look at those.

But here's the key. The management has to evaluate this and have a determination that the program is effective.

The proposed 35.35 itself has these eight objectives. I'd like to go through these eight and make sure that everybody understands the intent, regardless of the fact that it may be poorly worded in the version you got. You'll notice some word changes here.

This is our attempt to clarify. But my basic purpose is to explain the intent to you so that you understand the problem we're trying to fix and what objective we're really thinking of when we wrote these words.

Yes, Ed?

MR. KAPLAN: I just want to make sure that everybody has a copy of this.

MR. TELFORD: Does everybody have --

MR. KAPLAN: Which supercedes what I sent you in one of the earlier mailings, which had four enclosures. The wording is changed slightly and answers some of the questions that were brought up before.

MR. TELFORD: Just make sure that you have a copy of the words in the two-page handout. It's these words

exactly. Would anybody object to taking about a ten minute break?

[Brief recess.]

MR. TELFORD: Back on the record. I'd like to discuss the objectives of the proposed 35.35. My intent here is to give you the insight into what we're trying to do, what we would like to see happen.

The first objective says make sure that the medical use is indicated for the patient's medical condition. What we really have in mind is that there should be some thought process that the authorized using physician, the nuclear physician should in some way enter into the process that says yes, this is the patient, this patient should receive this dose of byproduct material or radiation from it.

It's nothing to do with -- we're not trying to get into the practice of medicine. We're trying to stay out of the practice of medicine. We would like to give the responsibility to the licensee to decide which patients get the dose of material, how much, in what chemical form, what rad, etcetera.

So all this really asks for is that some thought process has gone on to say yes, this patient should get a dose.

Number two is all about therapy. I would like you

to associate with therapy what we have called a prescription. In just a minute, we'll look in your handout to look at the definition of a prescription. Number two says you have to do something for therapy.

What it says is you have to have a prescription; namely, a written directive, the way we define it. This is the point where we have clarified the words to you, what we sent you, what Ed sent you originally.

So now we go A, B, C. We say please have a prescription for, A, any teletherapy procedure; B, any brachytherapy procedure; C, any radiopharmaceutical therapy procedure; or, D, any radiopharmaceutical procedure, whether it's diagnostic or whether it's therapy, if it involves more than 30 microcuries of I-125 or I-131, please use a written directive.

Now, if you would turn to your definition section of your handout, there's a few details that I would like to point out to you. We've chosen the word "prescription" here. That may not be the optimal choice. We defined it to be a written directive.

The key here is that it's dated and signed by the authorized user physician. It is not signed by the referring physician. It should be signed by the nuclear physician. That's our attempt to put the authorized user physician in charge.

So the intent here is, okay, if you want to do therapy to this patient, have a written directive, have the authorized user physician sign it, all else should follow from there. If the patient gets treated as described in this what we're calling a prescription, all is well.

Here we're saying I-125 or I-131. In previous workshops, people have said what about Heparin procedures. Did you guys really mean 30 microcuries of I-131 in case of Heparin procedures? Okay, here's what I would like you to do.

For your quality assurance program in your hospital or clinic, please say in your quality assurance program what you do for Heparin procedures; whether or not you use a written directive signed by the authorized user physician; under what conditions would you not have that.

Whatever you do, I'll take it. I want to find out if whatever you do works. Indeed, it may work for Heparin, because, as we're all aware, the probable consequence to a patient is much less severe than if you're talking about sodium iodine or I-131.

So that's one of the things that has come up about the number two objective in previous workshops. I just thought I'd give you the benefit of that.

Anybody else have any comments or questions about number two? Yes, Joe.

MR. HELLMAN: Actually, I like the way it's worded. The question I do have is have these come out in the Federal Register to supplement 35.35 now that you're re-revising them?

MR. TELFORD: No. The Federal Register was, I think, the identical words to the words that you received in the letter.

MR. HELLMAN: Yes.

MR. TELFORD: Let me note that the public comment period closed April 12. If people, in the public comments, say they don't understand number two, we probably have an insight into why not. But the reason that we're going to so much trouble in the pilot program with the volunteers is this is what we really meant. And it's the volunteers that are actually going to have a program that they try out. So if you can try it out against the real intentions, then fine.

MR. HELLMAN: Okay.

MR. TELFORD: It would be some trouble to change the Federal Register notice, not an insurmountable amount, but I would wonder what good it would do at this point. Secondly, our words have to go through a lot of review in the staff proposal, including through our Office of General Counsel, and I can just see the lawyer that I work with now arguing that the words that we have are just fine, you know

the meanings there.

But I'd like to go one step further and hit the real intent; to list it A, B, C, D, so the volunteers really understand the things we're after and not after. Yes?

MR. HUEN: I've got a question. Most of the time when the patient is being treated for teletherapy, the prescription is written down on the patient's chart prior to the patient being treated.

Occasionally, just after talking to the patient, you want to treat this patient. Is there anytime that is allowed for the physician to jot that on the chart before the patient is treated?

MR. TELFORD: We envision such conditions in the reg guide and we tried to address that. Basically, in teletherapy, we're saying the original prescription might be the patient gets 5,000 rads in 20 daily fractions. Maybe the patient has received ten of those daily fractions, but the authorized user physician has now decided that maybe the patient doesn't need ten more at 250 per day.

So there is provision made, at least an attempt at a provision made in the reg guide to say the authorized user physician can modify this prescription.

What we're really trying to achieve here is just so that the directive is written, it's signed by the authorized user physician. There are other objectives which

attempt and request, in fact, that those instructions be made clear to the technologist or the therapist or whomever needs to know, but at least this is what I want to do.

So all this says is write it down. So the direct answer to your question, yes, modifications are possible. So if you want to make a point of that in your QA program, then just put in a provision, a line item that says here's what we do.

Number three is all about diagnostics and it covers all radiopharmaceuticals, all that we regulate, including technetium, etcetera. But number three says ensure that the prior to medical use, that a diagnostic referral is made for any diagnostic radiopharmaceutical procedure.

Now, in parentheses we say or prescription because you always have the option to go to a prescription. The diagnostic referral, if you refer to the definitions section of your handout, you can see that the diagnostic referral is dated and signed by a physician, not necessarily an authorized user physician.

Now, the way that we envision that this works is that maybe it's an outpatient to your hospital. Maybe it's a general practitioner physician has referred a patient to you and has requested a liver scan for this patient.

We're attempting to put the authorized user

physician in control. The way we do that is we envision a written referral coming in signed by this general practitioner physician.

Whatever is described or requested on the referral then needs to match with the diagnostic clinical procedures manual, which I'll get to in number four. But the point is the authorized user physician approves of the clinical procedures manual, so that the authorized user physician is in control of the procedure that happens to the patient.

So even if this referral that comes in from this general practitioner physician says, oh, use three millicuries for this liver scan. The technologist, even if a bell doesn't go off automatically, goes to the clinical procedures manual and says let's see here, liver scan, technetium, that must not be right, maybe I should ask a question and maybe I should do what's in the manual.

Now, we want the technologist following exactly what's in the manual and we want the authorized user physician to approve of what's in the manual. So we're trying to incorporate business about as it happens today, but, yet, keep the authorized user physician in charge.

So number three applies to all diagnostics. And we make note of the fact here that if you're doing a diagnostic procedure that happens to require more than 30 microcuries of I-125 or I-131, you go back to number two and

have a prescription.

Now, we're making a special case out of I-131. There is this problem of micro-to-milli switch. Like the lady in Arizona that got switched from 100 micros to 100 millicuries. So if we can get every technologist and every person in the department to think, oh, iodine is a special case, if it's very much iodine, maybe more than 30 microcuries, go to a prescription; sort of treat it with more attention than you might normally do in the diagnostic case.

So we're trying to prevent the big ones from happening there. So number three is all about diagnostics. Now, number four is trying to achieve an understanding of the directions by the responsible individuals. So it just says -- and you may have to read number four twice because it says ensure prior to medical use that either, A, the referral and the diagnostic clinical procedure manual is understood by the responsible individuals.

Now read it once for the diagnostic cases, because the way we envision is that the referral and the manual goes together. In passing here, let me notice that we have interjected this word "diagnostic" in front of clinical procedures manual.

If you refer to the definition in your handout, that word is missing. The reason that we put diagnostic in

there is because in previous workshops, people came and said what, you want me to have a manual for treatment, for therapy?

And we said, no, no, no, no, no. We mean diagnostic. So that's why it's there. So if you read number four again, it said ensure prior to medical use that the prescription is understood by the responsible individual. So that's for the therapy cases.

You kind of have to read it twice, and that's the reason we put the A and the B in there. Now, all we're asking is or all the objective says here is that we want the people that do the work; it could be the therapist that's doing the calculation, it could be the technologist, it could be anybody involved, including nurses that identify patients; whatever their job is, all people that have responsibility for treating these patients, they understand these written instructions that come from two and three; they understand them before they go on.

Now, we're half way through these objectives. Any comments or questions? Yes, Beth.

MS. RIEDLINGER: Since the Agreement states are involved and since a few of the misadministrations that you indicated today were mix-ups between I-123 and I-131, could the objective be changed to just say iodine?

MR. HELLMAN: Or is that assuming regulating 123?

MR. TELFORD: I mean, we like -- let's assume for a minute that we said radioactive iodine here, but our authority would only go to 125 and 131. We can kind of imply or contemplate that they're supposed to pay attention if it's 131, but we have no regulatory authority.

On the other hand, your basis of this question was as it affects Agreement states. So Agreement states, you see, could have the authority to rewrite this and put 123 in there.

MS. RIEDLINGER: Well, it also affects misadministrations and if it's a cross between accelerator-produced material and NRC regulated material, then we do get involved. And the objective is to prevent misadministration.

MR. WIEDEMAN: Also, the licensee has the option of when they prepare their procedures manual to use the wording iodine or all iodinated radiopharmaceuticals that will have a diagnostic referral or a prescription, and that would cover it. It's just the NRC, we can't.

MT. TSE: The 1987 proposed regulation did use the word iodine. Many public comments were received that said that there are two reasons; one is the NRC does not regulate I-123. Therefore, if you put -- did you extend your authority into I-123, and we said no. The second reason is a more technical reason.

I-131, one millicurie will give a large, large dose to the thyroid. I-123 millicurie would not give a large dose to the thyroid. Therefore, there is no reason for I-123, more than 30 microcuries, you have to get a prescription from the authorized user, because a dose to the thyroid is very low.

MS. RIEDLINGER: But if they're confused and that is the reason misadministration occurs, then we are concerned.

MR. TSE: Right. The confusion is that if their technologist, for whatever reason, believes that he's going to use 30 microcurie of I-125 or I-131, regardless of what kind of confusion he's coming from, if he wants to use that, he follows this objective, he cannot do it unless he talks with the physician, his nuclear physician. He has to have a piece of paper signed by the authorized user to say you're going to administer like one millicurie of I-131.

Now, that particular kind of procedure probably would not be necessary for I-123 because it's a low dose to the thyroid.

MR. TELFORD: We can agree with your intent. The post-trial period workshop, we will be discussing ways to improve these. What we're trying to do so far is within each nuclear medicine department, each time a technologist is handling I-131, whether or not that's the

radiopharmaceutical they should be handling, is we want the mindset to be that every time they pick up I-131, they say, oh, what's the prescription say, what does my written directive say.

If we could do that, then at least that's an attempt at the same thing. But let us take that problem as a take-home assignment and work on it at the post-test workshop.

MS. MARCIANO: Just one more comment. Why even mention 30 microcuries when our concern, again, is iodine? Why not just say when handling these --

MR. TELFORD: Any amount? That's a good suggestion. Except that we did publish this restrictive rule and I believe that's what we said, wasn't it, Tony?

MR. TSE: Correct. In the 1987 proposed rule, we did say iodine, period. But the public comments suggested that you're only interested in the larger doses. If it's a 20 -- 10 microcurie or 15 microcurie which the nuclear medicine group used a lot, it may not be necessary to go through all this trouble to have the authorized user to write a specific prescription.

So, therefore, we try to limit it to the cases which could cause big problems.

MR. WIEDEMAN: There are a lot of thyroid clinics that routinely use 10 to 15 microcuries of I-131 for thyroid

uptakes, and they didn't want that much management oversight of prescriptions for 20-30 patients a day that they're doing thyroid uptakes on, because this was just seeming like an overkill.

Once you start getting beyond 30 microcuries, then you're no longer in the thyroid uptake range for I-131.

MR. TELFORD: Yes.

MR. TSE: May I ask a question? On this particular item, I-131, the participants in the other workshop have suggested that to limit further -- that means the way we said here, all chemical forms, is included. But the other participants suggest that, for example, I-131 with Heparin gives a much less dose than sodium iodine. Therefore, they suggest -- and they use a lot of Heparin. And they suggest whether we should limit further for that objective only to those I-131 30 microcurie sodium iodine.

I want to ask the participants here, nuclear medicine group, whether you have any suggestions on the Heparin item or not.

MS. MARCIANO: I think if we follow along the same lines as the people that are doing the thyroid studies with small amounts of I-131, then the same would hold true for the Heparin. We're going to try to establish something that doesn't encompass people that are doing routine tests that are not endangering patients from misadministrations, that

would be great.

MR. TSE: How about you?

MS. SULLOWAY: We do not do those studies.

MR. TELFORD: Can you use that, Joe?

MR. HELLMAN: I'm not sure what our people in nuclear medicine do.

MR. TELFORD: Okay. Let's press on to the last four objectives. Number five just says to ensure that the medical use is in accordance with -- I'll read this twice -- either, A, the diagnostic referral and the manual, or ensure that the medical use is in accordance with, B, the prescription.

So having once written down what was to be done, and it was written from either the referral and the manual or it was written in the prescription, if we just follow that, if we make sure that the administered dose or dosage is in accordance with one or the other of those, then that's the objective. If we could get that to happen, we would be one step ahead.

Number six says let's go after the problem of verifying the patient identity. Let's have something in everybody's quality assurance program that ensures that prior to use, medical use, that the patient's identity is verified. Now, the patient's identity is either part of the diagnostic referral or is part of the prescription. You can

tell by looking at the definition page in your handout that a name, it's a referral for a patient or a prescription for a patient. So the person's identity is there.

Now, recall the assurance program, of course, has to go beyond that. It would have to say what you would actually do to identify the patient. There are various little tricks that you can use and I'm sure that you're aware of most of them; that you might want to ask the patient's name. If it's an inpatient, you would want your technologist to look at their arm band ID.

You might want to ask the person their address or if they know what they're in here for, or their Social Security number, or their mother's maiden name, or many other things that you might ask them. But some subset of those would probably be helpful in identifying a patient.

So all number six says is we think it's a good idea if you verify that patient's identity and leave it up to the individual hospital or clinic as to how they do that. Whatever works for you, because in various parts of the country, you may have -- this may be a problem. In other parts of the country, it may not. It depends on your practice.

Number seven says that we would like the unintended deviations identified and evaluated. Now, the intent of number seven says if we look at the referral and

the manual for a moment, we have a liver scan and a certain amount of technetium was supposed to be used, for example.

The manual would say how much is to be given, in what chemical form, and in what route. So you look for deviations from that written directive. If it was administered as described in the manual, great. You just say delivered as prescribed, speaking generally.

On the other hand, if there was some unintended deviation; it could have been in chemical form, it could have been in route of administration, or it could have been in dose; and number seven says we think it's a good idea if you record that.

The purpose is that at the end of the year when the audit happens, then the person doing the audit can go look up these and investigate them a little bit and find out how many of these occurred were truly kind of noise level stuff; how many were a little bit beyond noise and how many were kind of stuff we ought to pay attention to. Because if we have a lot of those, the licensee management might want to ask the question did we get lucky, are those small just by a matter of chance, is this telling us something that we have a lot of small mistakes and there may be something we need to add to our quality assurance program so that we can prevent misadministrations or any kind of large mistakes in medical use.

MR. WIEDEMAN: John, I've got a couple of examples of the deviation. Let's say, for instance, you have a small child and you could not get -- your procedures manual says you'll give an intravenous injection of so many millicuries per kilogram of body weight, intravenously.

However, after making numerous attempts to get it intravenously, let's say you gave it intra-arterially. That's a deviation from your procedures manual. Or you gave it subcutaneously, which occasionally happens.

Another deviation would be if you have a patient, let's assume, that has a non-functional liver or kidney and the procedures manual says that we'll normally give technetium sulfur colloid, a range of five to 15 millicuries.

Well, because the patients liver or kidney is non-functional, your physician may decide that we're going to double the dose, go beyond what the procedures manual says. So that should be documented that this patient received a double dose because of whatever the medical decision was.

MR. TELFORD: You also have to read number seven as a therapy procedure, what we're calling a prescription, this written directive signed by the authorized user physician. So number seven would likewise say that any unintended deviation from what was prescribed is identified and evaluated.

And this might be a case of teletherapy where 200 rads was the daily fraction that was supposed to be given for 20 days. But on the 11th day, they gave 180 or on the 12th day they gave 220.

While these variations may be important or they may not be, all this says is it's a good idea to record these so that this can be part of the feedback in the licensee management, to allow them to decide that the program is sufficient or not.

If they have very, very few of these and they don't mean much, okay. Then let the licensee management have that ability to make that determination. Their program doesn't need fixing, it's okay. But on the other hand, if they see a whole lot of these in teletherapy and if they discover, for instance, that one technologist just has a really bad habit of never getting on the mark, never giving 200 and always being off -- almost always being off the mark, well, it may be time for some training, a little extra training, some sort of remedial work with that one technologist.

So these are just indicators that allow licensee management to be involved, to have control, fix a problem if it exists.

Number eight is kind of an obvious statement that just says make sure that brachytherapy and teletherapy is in

accordance with the prescription. This is the written directive for therapy.

So the theme is to have the authorized user physician in charge, to make the medical decision that, indeed, that's therapy that this patient should have for teletherapy or brachytherapy, and this is the objective that would get the medical technologist, but more specifically the medical physicist to be in accordance with this.

Now, the reg guide talks about the things that you would do before implant on brachytherapy, and then what you do after implant, because we recognize that, indeed, there may be some difficulties in the operating room.

You may think you can get 27 seeds in there, but if it turns out that you can only get 19 in there, we want to allow that to be altered, but by the nuclear medicine physician.

So that's the eight objectives. Let me pause for questions and comments.

MR. HUEN: I'd like to ask a question on number five. Ensure that the medical use is in accordance with and so forth. Who is going to do that? It's like checking the physician -- supposedly the physician would say, okay, I want to prescribe 5,000 rads to the lung. Who is going to say if that is right or wrong?

MR. TELFORD: None of us.

MR. HUEN: None of us either.

MR. TELFORD: No, no. That's not what this is all about. The authorized user physician says 5,000. That's medical judgment.

MR. HUEN: Right.

MR. TELFORD: That's completely outside of this objective. All this says is let's make sure that the 5,000 gets delivered.

MR. HUEN: Okay.

MR. TELFORD: If the 5,000 gets delivered in the number of fractions that the nuclear medicine physician has prescribed. That's the whole objective, to put the authorized user physician in charge. If they prescribe 5,000, that's their job. That's what they're supposed to do.

If this is nuclear medicine -- radiopharmaceutical therapy, if they say this person needs ten millicuries of I-131, fine. We just want ten to be given, not 15.

MR. HUEN: I misunderstood you. I thought who is going to decide whether it should be 5,000 or 6,000.

MR. TELFORD: Well, I'm glad you asked that because I don't want you going away from here thinking that. I want you going away from here saying, okay, this is what happens after the nuclear medicine physician issues the written order as to what should happen.

Now, let me back up to number three, because in other workshops, places that do a lot of diagnostics. We say diagnostic referral. You'll note in the definition that we say written.

What I'm claiming to you is that that's the ideal case is to have referrals written, signed by a physician. A lot of people have told us, oh, we don't get them written. Some of ours come up over the phone. Some people have said we get a referral over the phone and we send them a letter saying did you really intend this, this is what we're going to do. But they do it after the fact, followup.

Other folks would say we make sure that the person receiving this verbal directive knows what they're doing. They know when something is not appropriate.

So what I want to say to you is in your quality assurance program, that each of these proposed objectives, you describe in your program what your hospital or clinic does. If all these are not written, then you say under what conditions they would be otherwise.

So I don't want to upset anybody's way of doing business, but all I would ask you to do is document what you're currently doing.

MR. MONTGOMERY: John?

MR. TELFORD: Yes.

MR. MONTGOMERY: Just a comment. Having inspected

a number of medical licensees, and I recently looked into a facility that I inspected that had four diagnostic misadministrations recently, and just trying to -- even though they aren't officially under this program like this, I looked into it anyway.

One of the interesting things about this is all of these are -- most of these objectives are based on some kind of check or balance system, which is on -- the whole rule is heavily weighted towards checking -- someone checking someone else's work or other ways of verification.

In this particular institution, all four of these misadministrations were caused by an error made by the referring physician. The error was he had stamped the wrong patient's name on the referral form. The more I think about this, I see this is an error made at the very beginning of this entire process.

I see that as a very -- probably one of the most difficult to detect and deal with, and I know the institutions have a lot of trouble with it.

In addition, the referring physicians that made the errors were residents who, in every case, had -- we all know about residents and how many long hours they tend to work and the heavy patient load and a lot of paperwork and their fatigue at the end of their shift, and they try to process all this paper, and they make these stamping errors.

Simple, straightforward stamping errors.

The only way some -- they made a lot more than four errors, but most of them are caught by the technologist. Maybe it's a male and it's supposed to be a female. That kind of obvious thing. But in some cases, it wasn't obvious and they went ahead and administered the dose, and it was a misadministration.

So just a comment that there may be a little loophole there, at least something -- if you have an error occur right at the front end, something that maybe we need to look at, too.

MR. TELFORD: I agree. That's a potential problem and we've heard it in other workshops. When patients get sent to the nuclear medicine department, it's supposed to be a 51-year-old female and a 51-year-old male shows up, and they say, whoops, got a problem here.

MR. WIEDEMAN: On that situation where they stamped the wrong patient's name on the requisition, most of the hospitals that I've seen that come back with a corrective action, will state that from now on when the patient is brought to the nuclear medicine department, the patient's chart is brought down with the patient.

The technologist will then review the physician's orders and compare that with the prescription or the diagnostic referral. And it's in their procedures manual

that if they cannot find where this brain scan was ordered, then that referring physician is contacted to find out if he really wanted the brain scan, and that type of thing.

So there is a way of detecting that. Outpatients, it's a little different. They don't have a chart to review.

MS. MARCIANO: I sort of have a comment with number seven. It's really the only one that I see our institution may be having some problem with, and I'd be interested in how other workshops have commented on this particular one. Because I think for all the others, we have mechanisms in place as kind of a check and balance to ensure that the outcome is correct.

On this one, it seems that when there are these deviations, considerable thought has gone into it as far as recognizing maybe the dosage needs to be increased because of the patient's particular disease or whatever, and that maybe the thought process that people wouldn't be -- this is something we have to document, but rather to go ahead and treat that individual.

MR. TELFORD: Let me see if I understand this. What you're describing to me is that we have a patient, Patient A. A prescription was written, but now after looking at more evidence, maybe more lab tests or something, the physician says, oh, I need to change this dose a little bit.

What this is after is identifying unintended deviations. What you're describing to me is an intentional deviation that is directed, in fact, by the authorized user physician. If the note of that was made in the patient's chart or if the prescription, the written directive was -- ideally, to modify the written directive so that then the technologist knows what to do, then no unintended deviation would occur.

It's just when the authorized user physician says give this patient 50 microcuries and the technologist, for some reason, gives 75 or switches from microcuries to millicuries. That's the unintended deviation. If the prescribed dose or doses gets delivered to the patient such that the direction from the nuclear medicine physician was followed, that's exactly what we want to happen.

We don't want to infringe on what the nuclear medicine physician prescribes. We want that person in charge. We want their directives to be followed. We're not after those guys. We're after the delivery of this byproduct material, if you will.

So this is part of the paper trail that says, okay, for this list of cases last year, we had these unintended deviations. Then management can go back during the audit and say, okay, now what was the cause here, who were the people involved, what's needed here. Are you with

me?

MS. MARCIANO: Okay.

MR. TELFORD: Anybody else? Yes.

MS. RIEDLINGER: I have a comment and then some questions. The comment is that some technologists I was talking to were in a small nuclear medicine program and they were not really terribly overworked, and they told me that their approach was when the patient came in, they would say hi, what's your name, what are you in the hospital for or why are you here today, what's your medical condition, and what has your doctor prescribed.

Then they'll look on the prescription and if it doesn't match, they start making phone calls. They said that frequently they would have problems and they would track down, but at that time, there was no requirement for a written prescription and they frequently had problems.

So that might be one approach to solving -- identifying on the outpatient basis if it seemed to make sense.

Then, the other question I have -- do you have a comment?

MR. TELFORD: I thought you were going to talk about number two, which is all about therapy.

MS. RIEDLINGER: No.

MR. TELFORD: I'll put up whatever you want to ask

questions about.

MS. RIEDLINGER: Number seven.

MR. TELFORD: Number seven.

MS. RIEDLINGER: Unintended deviation. The documentation and review of that, I'm a little uncertain. What I think you've intended is that the radiation safety officer or the committee or the outside audit, annual audit, would identify and review these unintended deviations, and then they would be written up, presented to the committee, and documented there. Is that correct?

MR. TELFORD: You used one word that I have to correct. You said outside audit. Scratch outside. We never, ever said outside. We just said audit. It can be somebody from within the department.

Remember my example of Dr. Brickner has 12 technologists. One of those does the audit once a month.

MS. RIEDLINGER: Okay.

MR. TELFORD: So all we're trying to do is we're trying to prevent me from auditing myself. If I did the work, I'm blind to my mistakes. If I do the audit, I say I know I did that right, I just don't -- even if I'm looking at it, I'm still blind to those mistakes. I don't see my mistakes.

More ideally it's Joe that comes in and does my audit. I mean, he may be my colleague and he may doing

exactly the same thing. So please don't give anybody the impression this is outside.

Also, we're saying just make a record of this. We're not saying what organization -- we're not saying the RSO has to look at these. We're not saying the radiation safety committee has to look at these. We're saying at the end of the year, licensee management has to look at the results of this audit or designate somebody to look at it, somebody qualified.

I mean, it could be that the licensee comes down to be the President of the hospital and this guy says, look, I want this authorized user physician to look at the results and make a recommendation to me.

We're just giving the responsibility to the licensee. The spirit here is performance-based rule. We let the hospital decide how to do it, how to fix its own problem. So we're not in any way saying the RSO has to do it, we're not saying the radiation safety committee has to do it.

Those may be perfectly acceptable ways, I'm not saying they're not, but we're letting the licensee figure out how they do their evaluation with this unintended deviations.

MR. WIEDEMAN: I'm just going to throw in one more example, maybe an unintended versus an intended deviation.

The procedures manual says that we're going to give, say, 100 microcuries of I-131 for thyroid scan. So you are in a remote area geographically. You order the 100 microcuries from Mallenckrodt Nuclear. It's supposed to arrive on Monday morning, but it shows up on Monday morning and you go through your typical QC-QA procedures, you check it in the dose calibrator, it's 90 microcuries by the time it got to you.

Well, if the technologist went ahead and delivered that dose to the patient, that's an unintended deviation. However, if the technology went to the authorized user and said, now, Doctor, you wrote the prescription of 100 microcuries, we only have 90 microcuries because by the time it got to us. If that physician evaluates that and says no, I think 90 microcuries is more than adequate for this patient, then that is an intended.

Therefore, we're putting the burden back on the user physician rather than leaving it up to a technologist to make that medical decision.

MS. RIEDLINGER: Then does that put the technologist in the position of having to identify the unintended deviation?

MR. WIEDEMAN: Well, if the technologist went ahead and gave the 90 microcuries, did not check with the authorized user, then that's an unintended deviation and

would have to be identified and described why he did this or what happened, where he fell through or where he didn't follow up with the physician.

MR. FRAZEE: But you would not expect the technologist to do that. Why would you deliberately invite an unintended deviation. My question -- granted, yes. My question in this particular objective is, to me it seems that this is obvious that this is an ongoing thing. It's done more frequently than, say, the annual audit, although, in point of fact, the annual audit could be doing the same thing.

But your intention is that this is a daily, a weekly, a monthly -- this is a frequent --

MR. TELFORD: The actual recording of these?

MR. FRAZEE: Well, as identified and evaluated.

MR. TELFORD: Yes.

MR. FRAZEE: Therefore, this technician who went ahead and gave the 90 without checking with the physician is going to do his -- is he going to identify the unintended deviation or is someone else coming in?

MR. WIEDEMAN: Well, you do periodic audits as a way to catch it. If he didn't catch it, the authorized user didn't catch it, then during your periodic audits, the outside auditor may catch that.

MR. FRAZEE: Okay, but that's the period audit.

What I'm trying to find out is is that acceptable, that the periodic audit does it, or is this particular meant to be there as the double-check.

There is that second person that's right there over your shoulder watching what's going on; maybe not instantaneously, but the double-check. So you identify unintended deviations which, in fact, may be misadministrations and, therefore, reportable.

MR. TELFORD: Double-checks may be an outgrowth of number five; that the hospital is trying some procedure of double-checking or whatever to make sure that medical use is in accordance with either the referral and the manual or a prescription.

This one is just to make a record of if there was an unintended deviation, just make a record of it. The evaluation maybe is -- the connotation may be a little too strong here. We're not visualizing that the technolog. t would do any analysis of this, but it's more as Darrel described.

If you will, the technologist has his or her choice. They can say, okay, I'll give the 90 microcuries even though the manual says give 100. But if they do, then they say -- they write down they gave 90, and whether or not it was in accordance with the manual.

Their burden then would be to say I gave 90. My

evaluation is that it decayed before I got it and that's the end of their job.

But on the other hand, as Darrel points out, if they don't want to do that record, all they have to do is say back to the physician that the referral and the manual say give 100, but I've only got 90.

So if somebody in charge had said, okay, 90 is okay, exercising medical judgement, then you have no unintended deviation. This is really a recording device, that you just identify the unintended deviations.

MR. TSE: Maybe I would suggest that let the participants say what do they do in case if the physician says 100 microcuries, and it turns out the technologist only has 90. What do you do in those cases?

MS. SULLOWAY: I would have to go to my physician in charge.

MR. TSE: You would have to go to the physician in charge.

MS. SULLOWAY: Yes.

MR. TSE: How about your case?

MS. MARCIANO: Same thing.

MR. TSE: Okay.

MR. TELFORD: Anybody else?

MR. HELLMAN: I'm not associated with nuclear medicine. I don't know what they do.

MR. TELFORD: And both of you are therapy guys.

MR. WIEDEMAN: I can give another real-life example. We had a small community hospital up in Wisconsin. They had an old rectrolinear scanner and it was -- for some reason, this hospital had an operations manual that described the dose range for the particular scans and the chemical-physical form.

Now, the technologists, on their own, had decided that any patient over 65 might move while they're being scanned and that would just destroy their scan. So they, on their own, would automatically double-dose every patient.

So if you were going to get normally 20 millicuries, they would give them 40-45 millicuries. They would enter into the log that they gave the patient 20 millicuries, even though they really gave 40.

Now, they've been doing this for three or four years, two technologists. Finally, one of them went on vacation and they brought in an outside technologist, and they told the outside technologist, part-timer, now whenever you get anybody over 65, you give them a double-dose, but you enter the routine dose down on the books.

Well, this technologist said, hey, this does not sound right. So she ended up calling us and said can I really do that. Well, needless to say we, had an inspector the next day.

MS. MARCIANO: And they never hired her again.

MR. WIEDEMAN: The interesting thing was the hospital was issued an order to immediately suspend their operations until we could fully investigate it, and this was a case where the hospital came back and sued the technologists for their actions.

Now, that was definitely an unintended deviation. The physician, we asked him, did you ever review the technologists' work, and he said every single month I would go over the logs and I would look at the doses that should have been given and they were all in accordance with the procedures that I have established.

But there's definitely an unintended deviation. I wouldn't expect those technologists to identify it and to spell it out, but at least maybe management audit maybe have caught that, maybe if they had noticed that they keep ordering double the amount of material that they've been using, it may have been caught that way.

MS. MARCIANO: But it wouldn't be caught by what's described here, because we're, again, dependent on people entering in exactly what they're giving and what they're doing.

MR. WIEDEMAN: Exactly. There is always someone who can figure out a way of getting around the rules.

MR. HORNOR: Your inspector should have caught it.

Where was he?

MS. RIEDLINGER: My question was if you're the inspector, I'm not really clear on what's expected. I mean, if you are looking at the overall program, quality assurance program that the hospital chooses to put in place, and you want to evaluate whether or not it's working, you want to look at the evaluation of the unintended deviations, where do you find them?

MR. TELFORD: Well, I can appreciate your point of view as an inspector. Recall that I began by saying we're going to have the QA Team that's going to develop criteria for program review. That QA Team is going to go through 18 programs with a fine-toothed comb, asking the question does this program meet the proposed 35.35.

So on their own, they will have developed what we might call a standard review plan for looking at programs. Similarly, they will have developed the criteria for the site evaluation, what you might think of or I might think of as the inspection manual, inspection module for this particular one.

So that the QA Team, in fact, beginning next week, will have a meeting all week to finalize both those sets of criteria. So that by the time of the post-trial period workshop, we will be their confessing to everybody what the criteria were that we used for both the program evaluation

and the site evaluation, or what you would recognize as becoming licensing criteria and inspection criteria come final rule time.

So we're working on that and we'll have exactly what you as an inspector would use. I might note that that probably never happens. During the rule development, it probably never happens that so much work goes into developing the standard review plan and inspection module.

So I think we are greatly ahead of the game here.

MS. RIEDLINGER: Well, two things I would hope that they would really look at would be to ask the hospital how they will identify the unintended deviations and who will evaluate them and where the record of the evaluation will be maintained.

MR. TELFORD: Those are good questions. We will note them. You mentioned the word record. Let me say we're right here. I'll have an opportunity to say something about records so far as volunteers.

The objective here is for the volunteers to modify their program or structure a program to meet the proposed 35.35, and to try it out for 60 days. The only -- there are some records that we would like you to keep so that we can do an evaluation. Some of those records will be discussed on the evaluation form that we'll go through this afternoon.

But basically let me tell you that you keep the

prescriptions, the referrals, your manual, and the administered dose or doses. Part of the discussion this afternoon on the reg guide, you will come to find out that -- for instance, on a prescription.

You keep the prescription. Now, that prescription could be on a separate form or it could be in the patient's chart. Keep it in whatever form you currently do. If those charts go to central records and if our QA Team shows up to evaluate your site, we say, fine, can we see some of these records. We understand you have to go to the central files and pull those out, and that's fine. We're not asking -- my point is we're not asking for any special copies. We're not asking for any special format. We're not asking for any extra records to be kept. Just the records you've got now.

But I'm requesting that we be able to look at those prescriptions or those referrals for those patients that you treat during the 60 days, so that we can do this identification and evaluation ourselves for those 18 sites.

So let me repeat. It's prescriptions, referrals, manual, and the administered dose or doses. So that you would have your choice for writing down how you write that down. For teletherapy, for instance, if you're giving 20 fractions of 200 rads each, my understanding is most places say, okay, the prescribed is 200 for each 20 fractions.

So each day they put down the actual administered

fractions. It might be 205, it might 195, it might be 206, maybe 201. Just write it down in a column. You don't have to -- for your records, you don't have to have three columns, for instance. You don't have to say prescribed is 200, administered is 205, and the delta is five. You don't need to do all that.

If you just wrote down those first two, 200 and 205, that's enough. Anybody can look at that and say, okay, the unintended is five; big deal. But that's what we'll do when we come -- if we come to your site.

On the other hand, if it's a referral, you can say the manual said give ten millicuries. You can either say we gave ten or whatever you gave, or you can say what was supposed to have been given, we gave what was prescribed.

So you can do two out of three. You don't have to do all three. You don't have to have a delta column. So those are the only records that we would ask you to keep.

Yes, Terry?

MR. FRAZEE: Obviously, you'd have to keep a record of an audit, but it doesn't count in this case, because we're only doing a two-month period for a single audit. But what about a record of the unintended doses, or at least having checked for unintended deviations?

MR. TELFORD: Well, you're asking about --

MR. FRAZEE: If you identify an unintended

deviation, that means there must be a record of that?

MR. TELFORD: Well, this could be the patient's chart; that the authorized user physician put in the patient's chart, put the prescription in there. And likewise in the chart, you may record what was given.

MR. FRAZEE: Did you say patient's chart?

MR. TELFORD: Yes.

MR. FRAZEE: The prescription and referral? There it is. Separate form or the patient's chart. Okay.

MR. TELFORD: Yes. It could be the patient's chart as long as -- if you look at the definition of overcalling a prescription, it's a written directive. It's made, date and signed by the authorized user physician. For teletherapy, it contains certain information. For brachytherapy, certain other information. For radiopharmaceutical therapy, certain other information.

As you might suspect, the radiopharmaceutical, the dose and the route of administration for radiopharmaceutical therapy. So if that appears in the chart, all I'm saying to the volunteers is they should record what was given.

Now, this is -- so don't put too much emphasis on the word "evaluate." In number seven here --

MR. FRAZEE: Or even identify. It has to be identified, yet I would think the purpose of identifying it is so that you could, at some point in time, evaluate the

whole program; i.e., the audit.

MR. TELFORD: Right.

MR. FRAZEE: And be able to give an accounting of your program. If it's gone away with the patient chart, does that mean that at the time of the audit, that you've got to go pull all the patients' charts to identify or to find those unintended deviations?

MR. TELFORD: I'd suspect --

MR. FRAZEE: I'm saying that maybe number five here in your list of required records should be a list of unintended deviations.

MR. TELFORD: We're trying to make it easy on our volunteers.

MR. FRAZEE: Okay.

MR. TELFORD: Let me make two comments. If this rule were final, I would suspect that the licensees, the licensee management would say, okay, we'll do an audit. And if they had treated a thousand patients last year, they would go do a sampling of those thousand patients and pull up a sample of those thousand records. And they would say, okay, how many unintended deviations did we have.

The evaluation would really be done at the audit time, would be done by the licensee management or their designee, and then they would have to make a finding that their program is still effective.

So it would not be 100 percent census of all those records, but now we're talking about the pilot program. The volunteers would like not to have to do a lot of extra work. I'm convinced that their current records are sufficient, that our QA team can just come to those 18 sites and do their own little sample of those records of those patients that were treated during this time period.

Darrel?

MR. WIEDEMAN: Almost every nuclear medicine department will have what we call a utilization log where it will list the patient's name, the type of study that was prescribed, and the dose that was given. And then as the QA Audit Team, we would go in and look and say, well, you gave this patient ten millicuries; we look at your manual, your manual says ten millicuries, one cross checks with the other.

But if all of a sudden I see that they gave 40 millicuries and that goes beyond what your manual range is, then I would expect to see something written up somewhere, either in the patient's chart of another deviation log or whatever you want to call it, to explain why that patient received 40 when it went beyond your procedures manual.

MR. TELFORD: Let me ask the volunteers. My description of these records, do you understand it and is it doable?

MS. MARCIANO: I guess I'm still not clear on this unintended deviation. Does that include misadministrations? What you described, Darrel, was a misadministration with the bone scan.

MR. WIEDEMAN: Uh-huh. Well, not really. It depends. Did the physician approve the 40 millicuries for the bone scan?

MS. MARCIANO: No.

MR. WIEDEMAN: That would be a misadministration. Then if the physician had prescribed -- if you went to him and said, well, this guy or this patient has some kind of a problem. I don't know what the problem is. And we've given him, say, the previous dose of ten millicuries, it was ineffective, we didn't get a good uptake of the bone, and he said, well, let's go ahead and give 40 millicuries, that's not an unintended; that's an intended.

It's really basically misadministrations or errors in how that patient got the dose.

MS. MARCIANO: But it's an umbrella. It's everything other than what was prescribed. Is that correct?

MR. WIEDEMAN: Yeah.

MR. TELFORD: Yes. Joe.

MR. HELLMAN: Now, I'm looking at the therapy point. At first I didn't think this affected me, but now it could potentially. Physician orders therapy 300 times ten.

Say that I do a math error and I forget the attenuation factor, so I'm five percent off for one treatment.

I record -- I catch it in my weekly chart check and instead of saying you gave 300, the guy got 300 or 310 or whatever. It's not a reportable misadministration, even under these new rules, and I wouldn't do anything more than just line through the fact that they got 305 and made an adjustment to account for that later.

MR. TELFORD: I think you're saying you would make a record in your delivery that you were supposed to give 300, but you gave 310.

MR. HELLMAN: Right, 310. That's it.

MR. TELFORD: That's it.

MR. HELLMAN: Do I need to do anything more than that?

MR. TELFORD: Not now, no.

MR. HELLMAN: Where I hear the difference now is I wouldn't then keep a lot of where this mistake was, and now I hear you might be asking for that.

MR. TELFORD: No, you would not. That's what's Darrel saying, you don't keep an extra log. But if it's your practice to, say, in radiopharmaceutical therapy, to keep a record of what was actually delivered, then it might appear there. That might be useful as a tool for this recordkeeping.

MR. HUEN: You asked the question is it doable. I can envision my institution, when we come to this annual audit, there may be two problems. Number one is the mechanical problem because everybody's got a hand on it, and it would be kind of difficult to get an impartial audit; dosimitries, technologies, everybody's got his hand on the calculations. So who is going to look at that. That's number one.

Number two, when -- somebody is going to look at the charts, that means there will be more time involved. The management may not be willing to pay for the time. So these are the two things I can -- the first may still be -- somehow maybe two people can review or we take turns or this sort of thing. That might be overcome, but the second problem might be a little bit more --

MR. TELFORD: Well, the first case is about audits, but the second case is, if I understand this correctly, is about calculation --

MR. HUEN: No.

MR. TELFORD: -- of the therapy dose as a routine matter.

MR. HUEN: No. The first one is about checking to see if there's any deviation. Who is an impartial person to do this? As I say, all the physicists, all the dosimetrists, everybody's got a hand on it, so there's

nobody from the outside to look at that.

The second point is that management may not be willing to pay the extra dollars for the -- for whoever it is to do this extra work. So those are the two things I can see perhaps may be an obstacle.

MR. TELFORD: For the audit, you don't have to -- you do not have to do an audit as part of pilot programs. That's part of the proposed rule. So as part of the next workshop, we can talk about how to improve on the audit requirement.

Part of what you're saying about checking the dose, rechecking the dose calculation is an overcheck. We have some suggested things in the reg guide, but this is more like number five or number eight; that either the treatment planning is in accordance or the actual delivered dose is in accordance with the prescribed dose here.

All we're really saying is the objectives are to have it in accordance with or to have the treatment planning in accordance with. How you do it is up to you. We would very much like to find out how you minimize the impact on your facilities.

So that if it turns out that it's a check of the calculations if it's done by the same guy, the same physicist. But the person did it once the usual way, did it the second way with a different method to find out of the

two agreed, roughly; enough to satisfy themselves that they got the calculation correct.

Or if there are two such physicists, then they could exchange and do a calculation to check the other one. That's what is envisioned. So I'm merely listing objectives, that those things ought to be part of your QA program. How you do it, that's what we'd like to see you do to minimize the impact on your or your facilities.

MR. HUEN: I don't think I'm driving the point across.

MR. TELFORD: Okay.

MR. HUEN: I'm referring to the annual audit.

MR. TELFORD: All right.

MR. HUEN: And you gave me an example of Dr. Brickner who sent his 12 people around so they rotated and so forth.

MR. TELFORD: Right.

MR. HUEN: But we do not have 12 people to rotate around. So the only people we can get are the people within the same group.

MR. TELFORD: Okay.

MR. MONTGOMERY: John, I think his question is similar to one I had. In the whole audit process -- as we all know, conducting a meaningful audit is not an easy task and if you really do it right, it takes a lot of skill and a

lot of planning.

Am I hearing you right that this is going to get a lot more attention in the future about how to conduct this? You mentioned earlier that the audit right now was defined fairly loosely, that it didn't have to be an independent audit, but we simply do not want somebody auditing themselves directly.

I can see a lot of problems with an audit. One of them, obviously, is particularly in the military, which we inspect a lot in our region here. If you have an officer being audited by an enlisted man, you've obviously got a conflict there. It's something I wouldn't want to see. I would think that would be very wise.

Even a technologist auditing a physician obviously might be a conflict. This could go on and on and on with this. I think it's something that needs to be addressed here eventually.

MR. TELFORD: I agree that what you say are potential problems, but it also seems to that even if we're talking about a military hospital, that this audit, whoever is the commander there designates the person to do the audit. It may be a person, it may be a team of [redacted]. But their job is to search through the records on a [redacted] basis to find out what those unintended deviations have been, just to identify those cases.

It may not be the enlisted man who is checking on the officer or the technologist who is checking on the physician. I think that's sort of a misdirected point of view. I think the commander there should have the ability to say this team of people or this person shall go through and search those records and find out what the mistakes were last year.

And then the people that are qualified to look into that -- maybe it's a teletherapy case and maybe it's a calculational error. Then obviously you get somebody qualified to look into that, that says, okay, here's the simple mistake. The guy used the wrong factor.

Well, all that goes into the audit report. So that obviously the licensee management or the commander there has to conduct the audit in sort of an effective way. But the point of view here is to let this be a performance-based rule; to say to the licensee, we think you ought to have an audit.

The end product will be that you have a determination that your program is effective. We'd like to give them a free hand to exercise their responsibility in however manner they think they can get the job done so that they can minimize the impact.

Now, true, you look into details, then there's a lot of opportunity to make a lot of silly mistakes. But

that's the price we pay for having a performance-based rule. No two ways about it.

Let me turn the focus back over to this side. We're all here to make sure that the folks sitting over here understand the intentions of these objectives. So we've got objectives one to four and objectives five to eight.

Two questions to each of you. Do you understand them sufficiently well that you can develop a QA program to meet the proposed objectives or modify your existing one? So do you understand the intentions sufficiently well so that you can do that or do you have questions about it? Start with Joe.

MR. HELLMAN: I understand them. The only one I have a little bit of heartburn is with seven and the ultimate documentation, the audit we're getting to. The other thing I'm trying to figure out is where am I going to implement this, at what level. Am I going to set up a QA program for my clinic and have nuclear medicine set up a program for theirs, or should I have the overall institution write one that sort of encompasses it. Just the application, I'm trying to figure out how -- what's the best way to do it, or what -- or is there any guidance from you all, or are you going to leave it to us and say just do it?

MR. TELFORD: Well, certainly, on your latter choice there, whether you have it for therapy independently

and nuclear medicine independently or only have one overall, that's your choice completely.

The only thing that I wanted to get to was your question about the keeping of the -- the recording of the records. What this is after is you have the prescription someplace. All it says is write down the delivered dose someplace.

So we would like to not cause you any more problems than is absolutely necessary. So do you write down the delivered dose somewhere?

MR. HELLMAN: We do at our place. What nuclear does, I have no idea.

MR. TELFORD: So that's what we would ask of the nuclear medicine department, is that they record someplace the dosage given.

MR. HELLMAN: The only real problem I see with this is perhaps the ultimate followup on the audit, and that's to be addressed later. I'm just not sure how that's going to work.

MR. TELFORD: Well --

MR. HELLMAN: See, I'm not going to pull all 3,000 of my charts at the end of the year, or ask someone to do it, to walk through them one by one to see where these were.

MR. TELFORD: Right.

MR. HELLMAN: So it's a matter of trying to figure

out what do you want so I can either -- so I may, in fact, start an audit log of cases that I want to look at. I'm not sure exactly what I'm going to do yet. I've got to give it some thought.

MR. TELFORD: Let us all take that as kind of a take-home problem and work on that at the next workshop, noting the fact that an audit is not part of the pilot program.

MR. HELLMAN: Yes.

MR. TELFORD: Yes?

MR. KAPLAN: I just wanted to make one point that relates to what Joe said. You didn't mention this morning when you went over the schedule that by May 7, we would like to have a copy of your QA plan, if not earlier. You may have already brought it with you.

MR. TELFORD: We'll talk about that later.

MR. KAPLAN: But we'd also like to know what part of your institution, what parts, if not all, then which departments will be participating.

MR. HELLMAN: I have the authority to say that I can't make that decision.

[Laughter.]

MR. TELFORD: We'll just ask you which parts are. So you said you understood the objectives. Number seven may give you a slight problem in asking nuclear medicine to

write these -- to record these dosages, if they're not currently doing so. Is there anything else that bothers you?

MR. HELLMAN: Eight seems a little vague to me, exactly what you -- I think I know what you mean by that, but the wording of it seems a little vague. But within my department, I think I'm fine.

MR. TELFORD: In the case of your department where you're doing therapy, teletherapy, then all this says is your preplan and all your -- calculate the isotopes. It's in accordance with the prescription in that the nuclear medicine physician -- I'm sorry -- the authorized user physician is directing what should be done and makes those choices.

MR. HELLMAN: In accordance with. The question is how much deviation do I want to write in; i.e., say he writes in 11 by 15 field that changes to 11 by 16. Traditionally, we allow a centimeter of deviation within a recalculation.

MR. TELFORD: Put that in your program. Great. Just say that's what we do. Darrel?

MR. WIEDEMAN: I was just going to say the comments from the other participants in the workshop, most of them said that if you look at the wording, ensure that brachytherapy and teletherapy treatment plans are in

accordance with the prescription, you use some sort of general statements that each prescription will be reviewed, that's prepared by the dosimetrist will be reviewed by the therapist or the physicist.

We will also ensure that it's being planned properly by doing a weekly chart check and go over the mathematics, and the technologist will ensure this by reviewing that each little blank in the treatment plan is filled out, general statements like that.

MR. HELLMAN: My problem is I've got a lot of these things scattered all over a bunch of different clinic SOPs. My one QA SOP has some of this, but also some general procedures manual for this, for that, and so on. Pulling this together is going to be interesting.

MR. TELFORD: Allow me to explain later today why that's not a problem. Let's go to the next person.

MS. MARCIANO: I can pretty much echo what Joe has just stated.

MR. TELFORD: Okay.

MS. MARCIANO: I am still having problems with number seven because the standard of practice at my institution covers everything, except this, and it really comes down to the audit portion.

MR. TELFORD: Okay.

MS. MARCIANO: We are documenting prescribed dose.

We're documenting how much is given to the patient, but it's placed in a record that's been filed again. They do 10,000 procedures a year and I'm having problems committing to auditing that vast amount of information.

MR. TELFORD: Okay. The pilot program --

MS. MARCIANO: And I know the pilot program -- and I'm looking a little further.

MR. TELFORD: Sure, sure. At the next workshop, we will talk about audits.

MS. MARCIANO: The other thing I'd mention is that we are implementing computer programs in our hot lab where we'll be entering all the doses, and it will be recording what our dose calibrator is reading prior to injecting patients. So I can see that in the future this won't be a problem, but --

MR. TELFORD: It might be automatic.

MS. MARCIANO: It's in there.

MR. TELFORD: Yes.

MS. MARCIANO: Now I have a question for you, and it has to do with number eight. Am I supposed to take information back to the people doing the therapeutic procedures?

MR. TELFORD: Yes.

MS. MARCIANO: Because I can't speak -- I can only speak for nuclear medicine.

MR. TELFORD: Is that all your questions? So I take it you understand these sufficiently well.

MR. HUEN: I believe I understand the objectives and, in fact, my institution is doing practically everything already. The only uncertainty I have is in the audit part. I think perhaps there might be some mild objections from the physicians when it comes to that point.

MR. TELFORD: To the audit.

MR. HUEN: Yes.

MR. TELFORD: Okay.

MR. HUEN: Because it might involve external costs and so forth that are not anticipated.

MS. SULLOWAY: I believe I understand all the objectives and our department, nuclear medicine, has a quality assurance program that seems to pretty well match what you want. We document doses and whatever else you want.

MR. TELFORD: Great. That brings us to lunch. Does anybody object to breaking for lunch? Let's go off the record.

[Whereupon, at 12:15 p.m., the meeting was recessed for lunch, to reconvene this same day at 1:35 p.m.]

AFTERNOON SESSION

[1:35 p.m.]

MR. TELFORD: Back on the record. This afternoon, we would like to go over any special aspects this pilot program might present for doing this 60-day trial within the Agreement states. We want to discuss the evaluation forms and we would like to go through the regulatory guide, and finally to review the schedule of future activities.

This first item of conducting the 60-day trial within an Agreement state is usually done by Lloyd Bolling who is from the Headquarters Office of State Programs. His presence was requested to be in Washington today, so that's where he is.

There were just three or four items that he would mention, that I'll attempt to do so now. First of all, if you're an Agreement state licensee and you have a condition that's on your license that would either be in addition to something you have to do to meet objectives like we've been talking about today, or even in conflict with them, naturally you follow what your license condition says.

So just note that in your quality assurance program and follow your license conditions. Anybody who is an Agreement state licensee think of anything that might be of potential conflict or additional requirement from the state?

[No response.]

MR. TELFORD: Okay, none. The other thing to note is that this proposed rule does not cover the NORM material and it does not cover linear accelerators. I think Jack wants to make one particular statement and will bring up a point that we're considering that we want to inform you about for Agreement states.

MR. HORNOR: Yes. He said the rule was a matter of compatibility and I talked to him about it, and we're going to consider from this point on that it will probably be a Division 2 or Division 3 matter of compatibility. Because as a Division 1 matter of compatibility, you wouldn't be able to incorporate all the NORM material and accelerators, and you need to do that.

So we've got that in hand, but I would also encourage you to have your radius control program directors mention that at the upcoming meeting to our Headquarters people.

Thank you.

MR. TELFORD: I'd like to also note that at previous workshops, particularly the Dallas workshop which is fresh in my memory from just last Wednesday, there was a concern voiced that some Agreement states may attempt to use the regulatory guide as a prescriptive rule.

So I'd like to say that we will be taking great

pains to get the information across to the states that because this is a performance-based rule, we would like the guide not to be used as a prescriptive rule.

And one of the things that Dr. Tse will be talking about this afternoon is getting alternatives into the guide so that it's clear to everyone that any one of the alternatives ought to be acceptable for meeting that objective of the rule.

The other thing that I would like to note is that the NRC will be providing training for the Agreement state regulators in the use of this rule when it becomes final.

Any questions or comments, especially maybe from the State of California at this point?

MR. BUNN: No. All of this is good news as far as California is concerned, especially the Division 2 matter of compatibility. It allows us to have regulations in place covering items that aren't covered by NRC. So we're glad to hear that.

MR. TELFORD: Okay. The next item on the agenda is the discussion of the evaluation form. This is a draft questionnaire at this point. I don't want to steal any of Ed's thunder, but keep in mind that what you're going to see is the kind of questions that we will be asking about for the proposed 35.35.

What we're not going to show you is a

questionnaire for the regulatory guide, but just use a little bit of imagination to say, okay, I'm going to get a set of questions just like this for every section of the guide so that you will have an opportunity to comment on each section of the guide, especially if you use it and especially if you would like to give us your opinion.

At this time, I'd like to introduce Dr. Ed Kaplan from Brookhaven, who is going to talk about the evaluation form.

MR. KAPLAN: By the way, let me just mention a couple other things, first of all about reimbursement. For those of you that I've spoken to, there's a xerox copy, which is the worksheet. Send to me, to my attention, your bills, original receipts, and you can fill out the xerox copy. But the multi form should only be signed, nothing else should be on there, and we'll transfer it from the worksheet to the other sheet using our standard procedures, and then you'll be reimbursed.

Also, I'd like to point out that this one date that I mentioned this moring, which is May 7, is the date that we would like to have your QA plans, your written QA plans, and it's very important to us that if you choose to use your own rather than the draft regulatory guide, which, of course, you're free to do, but if you choose to use your own, if you could please give us a one-page description

where each of the eight objectives that you saw this morning are addressed in your plan, this will help us immensely because we're going to evaluate everybody's plan.

This will help us to go through there and just skip through parts that are not relevant and get to the important points.

The evaluation process is really a two-way street, and I'm going to have to go through this over the phone with the seven institutions in Region V that couldn't be here today, but that are also participating. There will be 11 of you in Region V participating.

But on one hand, we're evaluating your QA plans and then, going out to the sites, if you happen to be chosen, there will be another evaluation of your own QA plan. But this form that we're going to talk about now is your chance to provide us with written input.

We're counting on you to provide us with a lot of input; verbally, of course, at the next set of workshops, but specifically in writing.

What we'd like to do is we'd like you -- of course, as John mentioned, there are two forms. If you choose to use your own QA plan, that's it. What we're talking about here is what you'll need. If you choose to use the draft regulatory guide, then there will be an evaluation form that will help us learn what you think of

it. But let's just talk about this for a minute.

Each objective, each of the eight objectives should be graded and I'll show you that in a minute. But we have letter grades, A through D and F. We, of course, would like an overall grade, what you think of each particular objective, but, in particular, we're interested in knowing things like are any of these objectives of any benefit to prevent any kind of mistakes.

And we'd like to know what you find the incremental costs to your institution would be to implement each and every one of these. And then we'd like to know whether or not you have enough personnel available to do the job or whether your not you need more to effectively carry these things through.

The grading scheme -- this is what the letter grades translate to. For your benefit and to prevent mistakes, it's going from -- well, this particular thing is very likely to prevent mistakes and it's very important -- something that would be totally worthless. Similarly, down over here is it costly, is it not costly, do we have enough personnel or will we never have enough people to do this.

Then in terms of the overall grade, do you need it or not. Now, let me point out to you the bottom part of this form which is very important to us, because if you choose something on the order of a D or an F, so you don't

think these particular objectives are too important, please, down over here, tell us why.

Don't just give us a grade, but tell us what you really think of it. That's where the guts of the evaluation, from our perspective, will actually be. So we'll know what you really experienced during the course of the 60-day period.

So that's the first part of the evaluation and it's an evaluation of the objectives. Now, we also would like an additional amount of information here.

First of all, this question over here. I hope you can see it. Are any of the objectives currently covered in all or part by a voluntary requirement in your own QA plan. You may have a part, for example, the joint commission, they have something that you've adopted. And if you have it, let us know. So do this now for each of the objectives.

So if there's any particular objective that you can think of that's already in your work plan for some reason, let us know.

Also, our thrust is to get the optimal set of objectives. So what we'd like you to do, again, repeating this for each of the eight objectives, which -- after you've gone through the 60-day period, do you think that each of these objectives is worth keeping in this whole program. And if it is worth keeping, would you keep it the way it is

or would you modify it, how would you do that.

Or if you think it's just not worthwhile, would you throw it out. So let us know. This is important to us. Do this for each of the eight objectives.

Now, it may turn out that you have some other objectives that you're shooting for in your existing QA plan that we don't know about. If you do have such an objective, please let us know because that will be very useful.

As you can see, we've learned a lot over the course of these four workshops and we've actually made changes to the wording, for example, of some of the objectives. So this is a good opportunity -- this is perhaps a unique opportunity for you to be in on the proposed reg before it becomes final, and it's something that doesn't usually happen.

So we'd like you to take advantage of that. Then what we'd like to know to complete the picture is how many patients you processed in each of these categories during the 60-day period. So if you can keep some kind of running score of the number of patients that have passed through your system, please let us know.

Now, down here, if you detect any mistakes, this is not as opposed to misadministrations, did you actually catch any mistakes during this 60-day period. One question that came up in Dallas had to do with the size of this

program. After all, we only have on the order of 70 participants that we expect to catch in a 60-day period any misadministrations.

Of course, the sample size is too small to reasonably expect to catch misadministrations, and that's not what the -- we knew that from the start. But what we're really interested in, you may actually have caught pre-misadministration-type mistakes during the 60-day period, and it would be extraordinarily valuable to us to know which of these mistakes you caught, if any.

So if you can provide us with that information, I think that would be the frosting on the cake, as far as we're concerned. It would help us a great deal. So you'll be getting these draft -- this is a draft form.

You'll be getting a final version of this shortly and if by May -- well, by May 7 we'll know whether or not you choose to use the draft regulatory guide or whether you want to use your own program.

So if you use your own program, of course, what you'll get from us will be a form like this. But if you choose to use the draft regulatory guide, let us know and then we'll send you an evaluation form for the draft regulatory guide, which Anthony is going to talk about right after I'm through here.

Unless there are any questions about this -- we

tried to make it as self-explanatory as possible. We, of course, are going over in the office all of your QA plans. So there will be that level of review on our part.

I think that's about it. Just bear in mind that we're listening, that everything you say will become part of an overall compendium of what you think is worthwhile or worthless here.

We're really depending on you to tell us what you think and what your experiences are. So if you feel very good about something or violently against something, don't hesitate to let us know. I think the only one here in the room who stands to be insulted is John, right?

MR. TELFORD: Everybody else just feel free to tell me they're no good.

MR. KAPLAN: Right.

MR. TELFORD: Yes, Joe.

MR. HELLMAN: Do you have any objection to getting two of those filled out, one for nuclear medicine and one for --

MR. KAPLAN: Good point, good point. If you're going to involve more than the department that you're representing here today, yourself personally, we'd like to get all of them. So that if you are going to send one in for nuclear med and then another one for teletherapy, we'll take it. We definitely want it.

MR. HELLMAN: Well, let me ask this. I've heard what to me sounds like two different things. I'm here representing radiation therapy. Could nuclear medicine elect to not participate or -- I mean, I've heard -- I've gotten the impression that's it not really voluntary. Either the whole place does it or none.

MR. KAPLAN: That's a good question. We told you -- we did a proportional stratified random sampling and that's how we actually chose you. We wanted representation from rural versus urban, small, public or private. And when we had our categories filled out and we knew exactly what the distribution was regionally, we went in and did our selections, and then we pulled an institution.

So in your case, for example, we pulled the institution knowing that you do more than just nuclear medicine, and it's our hope that you can get the entire institution participating. So the optimal situation would be yes, you'd be the focal point for this pilot program for your institution. I know that might be hard to get the rest of your --

MR. MONTGOMERY: Joe, do you have a commanding officer that's over all the radiology programs that could help to tie this together or do you have to deal with two separate commands there?

MR. HELLMAN: I can arrange it. It's just a

matter going back to brief the chief of nuclear medicine and let him know what he's expected to do, gently. I've heard from Ed, sort of like when your section participates, it's almost like the other section doesn't have to and I just wanted to clarify that.

MR. KAPLAN: We would like all of them to. Any other questions?

[No response.]

MR. TELFORD: Okay. Next on the afternoon agenda, Dr. Anthony Tse will go over the guide and make sure that you have an insight into the intent of the kind of guidance we are trying to provide. There will be two things following this. One will be a review of the schedule of the future activities, just to give you the overview of the schedule one last time.

The last thing will be concluding remarks that will give some individual air time to each of the volunteers to say whatever they would like to say at the end of the day.

Dr. Tse?

MR. TSE: Thank you. As John mentioned this morning, this rule is a performance-based rule, so we proposed a regulatory guide to explain what we think the program should include, except for guidance. You are not necessarily required to do this, but if you would like to,

that is fine. If you have a basis for using ACR or JCAHO, kind of guidance to prepare your QA program, that also will be fine.

Now, this copy of the draft guide we sent to you earlier, so I think you've had a chance to read this. So I'm going to go through relatively quickly, following each individual topic, and I will close for anybody who has questions or suggestions or comments for those sections.

Page 1 is the introduction portion and is to say what I've said. This is a draft regulatory guide. This is a proposed rule and this guide is for your guidance, and we will ask for public comment.

Page 2, on top, would indicate that after we receive the comments from the public comments, and also from this pilot program, we will modify the guide. As John indicated, our thinking is that if the participants come up with good alternatives, we may want to put these alternatives in this guide as an acceptable alternative.

Therefore, whoever reviews, licensing reviewers would know these alternatives are acceptable ones to meet the objectives of the regulation when it becomes final.

The next section is B, which is discussion. At the end of Page 2, we just give a brief discussion of the number of misadministrations and so on. And toward the end of the page, we say that there are some misadministrations,

as John indicated this morning.

Many of this misadministrations mainly involve so-called human errors. And then the guide under regulation, so-called basic quality assurance program, is designed trying to prevent those human errors, misadministrations due to those human errors. As John mentioned, there's a comprehensive QA at a later date, not within this topic right now.

Toward the middle of Page 3, we indicated that this mainly relates to human errors. There is more quality assurance requirements already in Part 35, which is for NRC licensees, which has other kinds of requirements already, QA requirements already specified in the regulation.

The ones we will talk about are the additional ones. So far, does anyone have any questions or comments?

[No response.]

MR. TSE: Section C is a regulatory position, which we already emphasized several times, just guidance. Then let's go to Page 4. Now, the way this guide is organized is the first section is the responsibility authority and audit for this QA program.

We already had quite a bit of discussion this morning. Essentially, 1.1 and 1.2 is saying that the licensee should have a written program to indicate who has the responsibility, who has the authority, and so on. Those

are the elements of the QA program. And also 1.2 is to say that you have to have some audit within 12 months.

Anybody have a problem on Section 1, which is the general QA elements?

[No response.]

MR. TSE: Now, the others are more towards directly into the nuclear medicine, teletherapy, brachytherapy. The way it's organized, Section 2 are the general statements which apply to all cases. Then the next section, three, will be -- I'll talk about it later, but would be specific additional elements for radiopharmaceutical therapy and iodine greater than 30 microcuries, because that's more serious than the diagnostic cases.

Then the following section would be teletherapy, specific to teletherapy, additional teletherapy. I'm sorry. The next section is for brachytherapy and the last section is for teletherapy. That's how it's organized. So for nuclear medicine, if you do not have iodine, you do not have therapy, only Section 2 applies.

So let's go to Section 2. 2.1 is essentially to say that it should be legible. Trying to avoid the problems that people cannot read or mistakenly read, make it legible so it will be easy for them to read.

Second, 2.2, is that if it's unclear or you cannot

read, then you really should check before you go ahead. And 2.3 is that if you find any discrepancy, in case the referring physician says have a lung scan by using I-131, you know whoever the technologist saw this iodine, he or she would know there's a problem, discrepancy, then you should check before you go ahead.

2.4 is just to reiterate that the person who administers the dose should check whether the patient is correct, whether the dose is correct, and so on.

That's [illegible] diagnostics, for general elements for all procedures. Does anyone have any questions?

[No response]

MR. TSE: No. Okay. Now number three will be specific additional elements for radiopharmaceutical therapy and I-131 and 125 greater than 30 microcuries. Here, 3.1 says that the authorized user must be the review person to review the patient. If a referring physician sends a patient to the hospital and says do the therapy procedures, this element will say that the hospital's authorized user -- the authorized user means the person who is knowledgeable, nuclear physician, should look at first before giving the therapy dose to the patient.

Then, 3.2, he should write a prescription first or, as John said, maybe the word prescription may or may not be the right one, so we might want to consider changing to a

different words. But in nuclear medicine cases, I think prescription may be the correct word. Is that right? A doctor writes a prescription that says how many millicuries of I-131, give it to certain patient.

MS. MARCIANO: That's correct.

MR. TSE: So in this case it would be okay. Then, here is permit the change; 3.3 is permit the physician to change his prescription in case he determines that for some reason it should be changed. 3.4, to reemphasize that the patient should be checked for his identity. We did not say how you should check it, but the individual institution will come up with some good way of checking it.

Then 3.5, after you give the dose, somebody should write down what the dose was given to the patient, and you need to look at the administered dose versus the dose the physician wants to see whether there is any discrepancy.

That's Section 3. It's additional specific elements for -- well, we finished Section 3. Anybody have any questions or comments, especially with your group, you're doing therapy, I mean radiopharmaceutical therapy.

MS. MARCIANO: No.

MR. TSE: How about you, you do not?

MR. HELLMAN: I don't know.

MR. TSE: Anybody else have questions?

[No response.]

MR. TSE: Okay. Number 4 is for brachytherapy. Now, those you will be interested in and Albert will be interested in. Albert, you work in brachytherapy?

MR. HUEN: Yes.

MR. TSE: Again, 4.1 and 4.2 are the same as before. The radiation oncologist, which is the authorized user, should review the patient first, and then he should write down what he wants. Now, here the word prescription, based on the previous workshop, may not be the appropriate item, may not be an appropriate word, perhaps like written directive or preplanning, to say how many seeds the physician would like, and, therefore, you can order how many seeds of what activity and so on, and then he can choose to use number of seeds when he goes to the operating room.

Is that the procedure your group is doing?

MR. HELLMAN: It's about that.

MR. TSE: It's about that. How about Albert?

MR. HUEN: [Nods head affirmatively.]

MR. TSE: So the idea is that the physician should write down what sources, what kind of source, how many millicuries, how may seeds so that the people can give the correct sources.

4.3 is to say that whoever gives the sources to the -- or whoever picks up the sources should check, verify that those are the sources. Now, as you saw this morning,

some hospitals mix up the sources because they put two different kinds of sources in one drawer, so they're mixed up.

So we did not really say how you should do it, we just gave a couple examples, but each one of you have certain ways of identifying those sources, and in your QA program you should say how you intend to make sure the sources are the correct ones.

4.4, again, says that the physician can change a prescription after he -- for whatever reason he had, he wants to change the prescription, he can. So the initial prescription will not be tied down. If you modify under the doctor's judgment, that is permitted.

MR. WIEDEMAN: However, Tony, don't we -- we would probably prefer that if they detect an error in the dose calculations, they don't go back and write a new prescription to cover that error.

MR. TSE: That's not a practice medicine judgement. That I think you understand.

MR. HELLMAN: I get the impression that what is being alluded would be, say, initially, based on the preplan, you went to 40 rad per hour line. After implanted, look at the pictures, maybe the 50 rad per hour line may be better. Do you need to prescribe --

MR. WIEDEMAN: Write a new prescription.

MR. HELLMAN: That's my question. Do I need to prescribe before the implant and then go back and modify it, or can I just settle for one after they've seen what's inside?

MR. TSE: The prescription, the word prescription definition, it says in the definition sheet for brachytherapy --

MR. WIEDEMAN: Using your same example, if you wanted to go to 40 rad line, the doctor wrote his prescription. After evaluating the patient and the placement of the sources, you decided to go to the 50. That would be appropriate for the physician to rewrite the prescription saying that data -- saying I've gone to the 50, but you wouldn't want him to go back and rewrite the prescription at the end of the treatment plan and say, oh, we didn't go to the 40, we went to the 50, and the physician say no problem, I'll just write a whole new prescription. That's not the intent.

MR. HELLMAN: Right.

MR. TSE: So there's an alternative there how the physician -- the physician will have different ways of writing these prescriptions at the beginning. He may indicate number of seeds, he may indicate doses.

Any questions?

MR. HUEN: I think there's a lot of room for

flexibility here, because when you look at an x-ray, the difference between the 40 rad line and the 50 rad line is maybe a couple of millimeters or so. I mean, it's our judgment call.

MR. TSE: Right. But the prescription did not say you have -- which line. You don't know. But the physician should know how many seeds, what curies, what isotope he wants, and that -- or maybe he might know permanent implant, he might know I want to deliver it to how many rads to somewhere, total dose, and if he knows those things, he should write them down so the correct information will be transmitted to the physicist and so on.

MR. HUEN: I think a lot of it is not done that way because you usually decide how much to put in after the applicator is in place, because sometimes you just can't get the applicator to where you want to, and then you would have to adjust it afterwards.

So they usually say, okay, I want so many milligrams, so many hours. So that would give them more flexibility to --

MR. TSE: Yes. That's one of the permitted ways of doing things. To answer your question, 4.6 is to permit that the physician could change his prescription to reflect the actual loading of the sources, because we realize you cannot really load the sources exactly like the one you put

in the computer -- precise location, you can't do that. He should be permitted. That's not a misadministration if he -- except -- if it's a difficulty of the procedure implant as a result, it may not match the computer planning.

Then he can revise his prescription to reflect the actual loading. 4.5 is to take a radiograph to obtain -- radiograph to see where the seeds are, and then you could make the calculation.

From the earlier meetings, we realized that in many cases we won't use that, and which you use a dummy source of templates --

MR. HELLMAN: Right, prior.

MR. TSE: Or use the appliances, and you radiograph that and understand that, we were trying to work into. But if you write something in your program, please indicate what the way you're going to use them. We can use your suggestions as a guidance how we can work on this.

Please.

MR. WIEDEMAN: You just said it.

MR. TSE: Okay. 4.6 essentially reflects the flexibility provided to the surgeon, that he should not worry about -- he or she should not worry about the implant. And the time when you implant, you just do the best you can, whether it will match exactly the computer program is not a big problem. You can update afterwards.

4.7, after implant, somebody should write down the dose delivered and so on. The next page -- so far, any problems? How about Albert? Anybody else?

[No response.]

MR. TSE: Next page, Page 7 is a dose calculation check. Albert may have some problem? Do you have a problem? This dose calculation check, either you -- before the 50 percent dose is delivered, if it's 48 hours, it would be 24 hours, somebody should check the calculation with the calculation arithmetic is correct.

And if a computer program, if you use a computer program, whether the input are put in correctly.

MR. HUEN: There is some problem there.

MR. TSE: Okay.

MR. HUEN: Supposing the implant is done on a certain day and there's no physicist around, so no dosimetries around to calculate it.

MR. TSE: What would you do?

MR. HUEN: Well, we go by the milligram hours. Perhaps we have done such and such a case, this may be the second implant. The last implant, we did so many millig-am hours, so let's go by the milligram hours. I'm not saying that the physicist is not there all the time, it's just occasionally two people are not there the same day. We try not to work that way, but it happens. And just go without

calculating it and calculate afterwards when the physicist or the dosimetry comes back.

MR. TSE: Joe?

MR. HELLMAN: I was thinking something similar where we do an I-125 permanent implant. The nomagram or even the iridium, no backup physicist or where it's done in my absence. Granted, the dosimetrist could do the calculation, the doctor could just look at the sources, but that doesn't mean that the source data was entered correctly. This is vague. We can interpret it any way we want.

MR. TSE: We would ask that most -- simple arithmetic error which we're asking, not the very elaborate. For example, in the 1987 rule, we say that another person could do it, but you could use -- here it becomes a guide now. It's not a regulation. So if you don't have another person, maybe you want to do it yourself. Maybe you want to compare it with the previous ones you have done. But I'm sure that -- I think I'm sure that you will always try and make sure that the calculation is correct one way or another.

MR. HELLMAN: Oh, yeah. It's always done afterwards.

MR. TSE: When you say afterwards, meaning the whole implant is over?

MR. HELLMAN: Right.

MR. HUEN: Because the implant may only last a day, two days. And then the physicist is not there that particular day and then you don't have any recourse. So you just have to take it from experience after so many milligram hours.

MR. TSE: Maybe dose --

MR. HUEN: But eventually you calculate it.

MR. TSE: Maybe you ought to write down what you think should be done and, in your judgement, the best way to handle your situation so we can look at that.

MR. WIEDEMAN: Or another way, Al, is have the physician fill out a prescription giving a range of milligram hours; you know, intracavitary treatment for carcinoma, 3000 centigrade to 5000 centigrade for a two-day period. That would give you a very wide latitude.

MR. TSE: Okay. 4.9, toward the end of Page 4.9, is an example towards this calculation check, to say that if it's emergency, you don't have to worry about the calculation check and do the implant first, and then you check later. But it's within two working days.

MR. HUEN: That happens a lot.

MR. TSE: Emergency?

MR. HUEN: No. In the case, for instance, in the high dose rate implant, the patient got tubes all over his

nose, you just don't have time to do separate calculations. You want to deliver the dose now so that he can get out and pull the tubes out and so forth. So it's pretty hectic in that case. But you usually do those things before the two days -- in the same day, but it may not be before you administer the treatment.

MR. TSE: So maybe the high intensity --

MR. HUEN: Yea.

MR. TSE: How about you?

MR. HELLMAN: Section 4 is fine.

MR. TSE: Okay.

MR. KAPLAN: One thing. In 4.8, the preference there is, though, for somebody who did not make the original calculation to do the check. That's the preference, if at all possible.z

MR. TSE: Then they say if they do not have that person, then what should they do.

MR. KAPLAN: The description as to what you should do under that circumstance.

MR. HELLMAN: What exactly is being looked for under 4.8? My interpretation does not say that it has to be totally recalculated from scratch by another. All I see here is that if I do the calculations, then another person should come and just look at the computer printout; i.e., the strength of milligrams of cesium or the number of seeds

in milligrams of the iridium, for example. That's all I see as being required.

MR. TSE: It's relatively simple kind of check, not from scratch. That's correct. If you read this, it's arithmetic errors. Somebody with a calculator could do. Correct transfer of data from charts. If I'm checking on yours, I need to try and find the proper weight factor for that weight, what's the number, and whether you used that correctly, etcetera.

MR. HELLMAN: The only thing this is not going to catch is going to be the basic isotope data entering the computer incorrectly. So you get you iridium in and I make the multiplicative factors incorrectly. So everything looks like it's .5 milligram seeds of iridium, but the math I did actually came up with .3.

That will never be caught because the computer will still be saying that's .5

MR. TSE: Let me try and understand. You said somebody -- you put in the number into the computer as input that says .5 milligram.

MR. HELLMAN: I call it .5, but the multiplicative factor I use to enter that is only that of a .3. In other words, I made the mistake of --

MR. TSE: In the computer program itself?

MR. HELLMAN: Right. There is nothing in the

computer which is going to pick out --

MR. WIEDEMAN: No, it's input.

MR. TSE: Then it will be input.

MR. HELLMAN: I'm saying it will never be caught by this procedure.

MR. TSE: No.

MR. HELLMAN: Checking the output, it will say .5. My physician or whomever will never know --

MR. TSE: Wait a minute. We're supposed to check the input on 4.8.2. If the physician prescribes .3, you put in .5, I'm supposed to check against yours. I look at 4.8.2 to check correct input. So what did you input? Then I check with the prescription, it says .3, and the input in the computer is on .5, I say, Joe, why do you put .5 in here.

MR. WIEDEMAN: I think I know what he's talking about. See if I got it straight. Your physician says I want to implant this patient with a five milligram radio-equivalent.

MR. TSE: Okay.

MR. WIEDEMAN: You input the computer for five milligrams. However, you loaded ten milligrams into the applicator.

MR HELLMAN: No.

MR. WIEDEMAN: No?

MR. HELLMAN: I'm talking about the basic computer data. When you define the source, define initially, you can make a mathematical conversion error. You can call it one thing, but you have to do a multiplicative factor against milligrams for what it calculates off of. And it does not compare the two to see if they agree.

MR. TSE: I understand your point.

MR. HELLMAN: My physician will never catch this.

MR. TSE: It's a computer software problem.

MR. HELLMAN: Yes. It's my mistake that I entered.

MR. TSE: Way back, when you purchase a computer, you enter some number and that number you did not check, is a wrong number.

MR. HELLMAN: Right.

MR. TSE: Subsequently, everybody uses the computer, that number will not show up as input because you already input it way back.

MR. HELLMAN: Well, even if I just find an iridium source and I put it in, if I put it in incorrectly, that could very easily happen, this will never catch that. I don't think I can train my physician or whatever to look at all the raw data coming out and know exactly what to be looking for.

MR. WIEDEMAN: It's where the mathematics are

correct, but the input is wrong.

MR. HELLMAN: That's correct. That's all I'm saying.

MR. MONTGOMERY: That's the danger of errors made very early in the process, like I said before. Those errors are the toughest to pick out in a lot of ways.

MR. TSE: The other way you could do it -- there's another way you could do it, is to do a hand calculation and you will find your error.

MR. HELLMAN: That's not so easy for brachytherapy.

MR. TSE: But if you make a one point calculation, simplify the computer calculation, and then have a hand calculation. That's the idea, is that somebody checks the input of the computer.

MR. KAPLAN: I'm just curious, Joe, how would you, what would you write in a regulatory guide to catch that?

MR. HELLMAN: That's the main reason I'm not going to adopt the regulatory guide, because I'm not going to be bound by this. I think it's asking too much -- the interpretation here is so -- can be what you want to make it or what I want to make it, that I'm going to write my own to give my physicians a reasonable amount of leeway, but still leave the ultimate responsibility to myself. If I made the mistake, I don't think it reasonable that my physician is

going to catch it, the type of error I just described.

And my dosimetrist certainly won't catch it. Short of having another person coming in and double-checking your figures sometime, which is a very costly sort of thing, I think those sort of errors are probably not going to go away.

MR. WIEDEMAN: Couldn't the dosimetrist and the medical physicist cross-check each other? Usually that's the way it's done.

MR. HELLMAN: I don't have a dosimetrist right now. So it's just myself and my physician. Sometimes if you have a homegrown dosimetrist, they don't know -- I mean, they just know the way that you've always done it or the way it's always been done in the past.

I don't think it's quite so easy as you're saying for smaller institutions with only one physicist or a travelling physicist.

MR. HUEN: If it's small errors, then it's very difficult to catch. If it's a big error; for instance, if I say everybody can get 500 rads, only take two days, and you take five days or something. Then that's obvious.

MR. HELLMAN: Yes.

MR. HUEN: But if it's a very small margin of five percent error, then it's going to --

MR. HELLMAN: Especially for brachy. I just don't

think you're going to pick it up.

MR. TSE: But that's a small error. You really do not -- like the kind of misadministration we see.

MR. HELLMAN: I think even at 20 percent error, you might not even catch it.

MR. WIEDEMAN: You know, we had a case where a physician ordered a Manchester applicator with a 10/5/5 milligram and the physicist loaded a 5/10/10. If you look at the computer data, that was just 100 percent correct. They went back, they rechecked it mathematically by longhand, with a calculator, everything was correct, but the wrong source.

Unfortunately, this wouldn't get caught with this procedure.

MR. HELLMAN: With this, it would.

MR. WIEDEMAN: But later on, it will say that there will be some kind of a redundant system where you can verify back and forth; you know, did you put the right source in. So it will get caught that way.

MR. TSE: Well, it should be able to catch the 4.3.

MR. WIEDEMAN: Right.

MR. TSE: But sometimes even when you check this, it at least minimizes the chance --

MR. WIEDEMAN: Of course, and there can be two

people standing there and still the wrong source is there.

MR. TSE: Any more questions about brachytherapy?

MR. HELLMAN: 4.3 doesn't say anyone has to double-check the loading.

MR. TSE: No. Just verify. Okay. Section 5 is for teletherapy. 5.1 is the physician -- the oncologist should personally review the patient. Section 5.2 shall have a written description which is similar to brachytherapy, except have a little more information because teletherapy is more complicated.

Any questions?

MR. HELLMAN: No.

MR. TSE: Okay. 5.3 -- yes.

MR. HUEN: Excuse me. There is a question -- not a question, a comment.

MR. TSE: Yes.

MR. HUEN: On 5.2.

MR. TSE: Right.

MR. HUEN: It says a prescription and approve a treatment plan that includes the treatment modality. The treatment plan may not always precede the treatment.

MR. TSE: There's some cases, somebody is supposed to send a patient to have Linac treatment, and it turned out to be Cobalt-60 treatment, things like that.

MR. HUEN: That's not what I'm referring to.

MR. TSE: You said treatment modality.

MR. HUEN: Well, plans, to me, implies a computer treatment plan. Is that what you meant?

MR. TSE: No. The treatment plan is what you -- I'm not sure whether somebody may not use computer plan, but what kind of source you want to use, what location you want to treat, what kind of rads you need, and so on, how many fractions. It's not that computer calculation does --

MR. HUEN: I thought you mentioned --

MR. TSE: No. Do you have any better word, suggestions to avoid that confusion? If you do, please let us know. It's essential that the written directive -- maybe that's better. Yes?

MR. WIEDEMAN: And a very clear treatment plan. To give you an example, we had a case where the physician wanted to treat a hip and he wanted to use Cobalt-60 on the anterior at a certain size, and he wanted to use the Linac for the posterior at a certain size.

I know it sounds crazy, but that's what was prescribed. But it wasn't clear the way he wrote it of which machine was which and he spelled it out Cobalt-60 anterior is 10 by 10; posterior; and the technologist got it mixed up when they entered that into the treatment chart, and gave him the posterior by Cobalt and the anterior by accelerator.

MR. TSE: Item No. 5.3, to say that the physician could change a prescription. The prescription is not fixed. If the physician sees some necessary judgment, wants to reduce or increase the dose, he could do so. 5.4, after the fraction is given, somebody should write down the administered dose. I think most people already do things like that.

5.5 is a weekly check. You check the total dose within that week or any errors. 5.6 is a calculation check. That's the same, essentially similar to the brachytherapy, but 25 percent total dose, because they generally have a large number of doses, a large number of fractions. But somebody suggested that high dose treatment sometimes has only three fractions. Then you may want to propose something different, if you're going to use similar elements.

Any problems so far?

MR. HUEN: I don't know if that's redundant or not.

MR. TSE: Excuse me?

MR. HUEN: I don't know if 5.6 is redundant.

MR. TSE: Redundant to which one?

MR. HUEN: 5.5 because --

MR. TSE: 5.5 is the weekly sum of the fraction. 5.6 is the calculation of the fractional dose given by

computer, how many minutes you need to give it to the patient. Not for each -- for the calculation, initially you might want to do the calculation to see how many minutes the patient will need. So that's the calculation.

5.5 is that if Monday you give the patient 200, Wednesday 300, and so on, you add the sum of the individual fractions.

MR. HUEN: I couldn't tell the difference. Back when -- every week I checked this chart, and 5.6 tells me before 25 percent of the dose is given, I have to check it again?

MR. TSE: No, that's check the dose calculation.

MR. HELLMAN: Use the computer plan, if you did one.

MR. TSE: Right.

MR. WIEDEMAN: Your 5.5, I assume that your technologist would do this each and every day as they enter the fractionated dose on the patient's chart. That's just basically what that is. Someone is doing a weekly check to make sure that we gave the daily accumulated fractionated doses, where the 25 percent would probably be done by the physicist or the dosimetrist, go back and recheck the calculations for arithmetic errors.

MR. TSE: Not just the sum, not just the sum of the fractionated dose. It's how you derived that fraction,

your computer planning.

MR. HUEN: I thought that the physicist would do the 5.5 and the 5.6 at the same time.

MR. HELLMAN: In my place, the first time I did a weekly chart test, yes, that's true. But the second week, I do not go back and look at the whole computer plan all over again. I only look at it one time myself.

MR. HUEN: Right.

MR. HELLMAN: The same comment about 5.6 is what I had about 4.8, however. Again, if somewhere in there you enter your dose profiles incorrectly or something else, you will never pick that up.

MR. TSE: If you don't check that particular item. But when you input that, somebody should check your input.

MR. HELLMAN: Hopefully. But, again, if it's yourself and if you don't have an independent person other than yourself, you still may not catch that. What you do looks fine.

MR. TSE: But how would you do it, handle those cases? Suppose nobody is there, nobody meaning no physicist, and you make a completed calculation, do you worry about should I check it or should I not check it? If I do, how should I do it?

MR. HELLMAN: Well, I always do a hand calculation or a secondary check and my techs do a third check.

MR. TSE: Okay. Maybe that's the solution.

MR. HELLMAN: So we're covered.

MR. TSE: You can suggest to us that we might be able to use that.

MR. WIEDEMAN: I do know what the intent was on this one. There was a facility in Cleveland that had some -- it's a major hospital and they did all of the treatment computer planning. However, they had two machines. They had one machine at the hospital and then they had a satellite facility 20 miles away.

One machine had 5,000 curies, another machine had 9,000. The patient was prescribed to have treatments at the hospital and later on, after the second or third treatment, said, well, I just live a couple of blocks from your satellite facility. Go ahead and go on over to the satellite and we'll transfer your records.

Unfortunately, they didn't go back and recalculate the dose for treatment at the other one, at the other machine. Unfortunately, erythema developed in a very short period of time. When that happened, the physician decided to go back and check. They had a very large misadministration and a $1.5 million lawsuit. It was just because -- if they would have checked somewhere along the lines, oh, my goodness, we got the wrong input into the computer.

MR. HELLMAN: I understand the intent. I'm just being devil's advocate here. There's some things you're not going to catch easily.

MR. WIEDEMAN: Right.

MR. HELLMAN: But this will probably help.

MR. WIEDEMAN: We had also another case where the patient was going to receive hemibody from head to the waste, a very large dose, 1,200 rads hemibody and was supposed to be fractionated into 400 rads per day for three days. This calculation gave a little close to 2,000 rads in three days and they have a procedure for when you do that type of a calculation, it's to be rechecked mathematically by someone other than who did the original calculations. Well, the physicist did it on a Friday afternoon, knew that on Monday morning somebody is going to check that chart.

Monday morning when he got there, they had already treated the patient. So he started then doing other duties. But they also have a weekly chart check. They do that on Thursday. Well, the patient was treated on Monday, Tuesday, Wednesday, and on Thursday the patient's chart was up in billing.

So they didn't catch this till 30 days later when the chart came down. The dosimetrist happened to take one look at the calculations and said, wait a minute, six minutes of therapy on that machine, something is wrong. He

immediately just recalculated and said, oh, we made an error. Unfortunately, the patient died.

But that's the intent here of having someone recheck the calculation.

MR. HELLMAN: The patient would have died anyway from doing hemibody.

MR. WIEDEMAN: That's what the doctor said.

MR. HORNOR: Just speeded it up a bit.

MR. WIEDEMAN: I know what you're saying.

MR. TSE: Okay. 5.7 is to check -- an independent check of certain full calibration measurements. After change of source, we need to conduct a full calibration measurement, and those full calibration measurements should be independently checked to make sure they are correct.

You could do one of either ways. If a second physicist or second set of instrument, or you can use a TLD service if it's within the five percent margin accuracy, then you could use that to check it if you do not have an independent physicist.

MR. HELLMAN: What sort of feedback have you had about this?

MR. TSE: I think that the question is that whether or not there should be a person and not a TLD, what do we call accredited TLD service. That is the feedback.

MR. WIEDEMAN: If I remember right, there was very

little discussion on this because it's already a requirement in Part 35. It's a monthly spot check. The only thing that's different is have it done by someone independent who --

MR. HELLMAN: Yes. The independent --

MR. WIEDEMAN: The biggest problem was having an independent party do it, especially in a one-man operation. It's pretty hard to have someone independently verify that.

MR. HELLMAN: For myself it's not a problem because I'm not going to replace my source again. But I just -- I can see maybe some Army facilities, fewer and fewer. I may have some heartburn about that.

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

MR. HELLMAN: Because it's cheaper.

MR. TSE: Not just that you don't need an independent second person to do it. Some people just do not have an independent person.

MR. HELLMAN: That helps.

MR. HUEN: We have problems by a margin bigger than five percent, and I'm referring to the high dose rate implant with the iridium source. We change the source every three months. We compare our --

MR. HELLMAN: Brachytherapy or --

MR. HUEN: Brachytherapy.

MR. TSE: This is only applied to teletherapy.

MR. HUEN: I would think it's the same kind of thing because we're thinking about Cobalt source.

MR. TSE: We are thinking about the big Cobalt therapy machine.

MR. HUEN: Right. The Cobalt source and the iridium source, we use about nine curie iridium source.

MR. TSE: For brachytherapy?

MR. HUEN: For brachytherapy. Not millicuries.

MR. TSE: Yes, but for brachytherapy, you do not have to follow this. We do not say you have to have --

MR. HUEN: This is very, very similar in a sense. The manufacturer tells you, okay, this is so many millicuries source, I'll give you 10 curie source, and we measure maybe nine curies. So there's a ten percent difference there.

MR. HELLMAN: What do you do?

MR. HUEN: I talk to other people who use the same kind of sources and sometimes they differ by five percent, seven percent. That means the manufacturer may not be that accurate after all. Do we trust ourselves or do we trust the manufacturer?

MR. TSE: First of all, this particular section of five to 10 curies are Cobalt-60 sources. I think there would not be that much difference in calibration.

MR. HUEN: So 10,000 curie of Cobalt-60 sources

are quite accurate in measurement.

MR. TSE: In brachytherapy sources, this doesn't say you have to measure. You use the sources given by the manufacturer. Suppose there's ten millicurie. Unless you have certain confidence that's absolutely wrong, then, of course, you want to check with the manufacturer what's happening, how come my dosimetry measurement is different. But you are not too sure yet because your dosimetry might be off.

That's the so-called discrepancy. If you find the discrepancy, you really should not go ahead and give the dose first. You should check to resolve the discrepancy. You'll find out maybe your instrumentation calibration is off or maybe you find out they are wrong, but generally I'm not sure if that's case.

Currently, those sources, which are M.D. Anderson Memorial Hospital, they measure those incoming sources. They find very, very little deviation. About ten years or five years ago, they had quite a few. Therefore, they checked with the source manufacturers and they improved.

Do you find any --

MR. HUEN: We're not talking about the same kind of thing. You're talking about maybe cesium sources. I'm talking about millicurie. I'm talking about iridium sources. But we do run into some kind of discrepancy.

MR. TSE: You need to resolve the discrepancy. Anyone have discussion?

[No response.]

MR. TSE: All right. 5.8, annual calibration should include transmission factors for being modified. Currently, the regulation did not say that. We think that should be measured annually. Do you measure annually?

MR. HELLMAN: Yes.

MR. TSE: What about you? It would be a good idea or what?

MR. HUEN: Well, I don't see how you could change, because we measure the output, we measure the energy of the thing every month.

MR. TSE: Okay. Wedge.

MR. HUEN: Without the wedge, we measure the energy every month.

MR. TSE: Right.

MR. HUEN: But what can change is -- the wedge can never change.

MR. TSE: The wedge factor may change if the wedge is being dropped and maybe moved a little bit. If it's slightly moved a little bit, and you put a wedge not in a precise location, it may change. Of course, annual measurement is just some check. If you check it, if something is wrong, you will know. If you don't check at

that time, in several years you might still now know.

MR. HELLMAN: I did have that problem with my Cobalt, Theratron-80 with plastic trays. The wedges dropped. They remounted on another plastic tray, but did not mount exactly in the same place. So it not only changed the attenuation, but changed the profile as well.

MR. TSE: 5.9 says that if certain field sizes or treatment distances you have not measured in your annual measurement, but you're going to use that, if those are --

MR. HELLMAN: Extended distance.

MR. TSE: Yes. That should be also measured. Now, it's very unusual people use that, but sometimes they do. Do you think -- do you do that?

MR. HELLMAN: We haven't done anything on that, but AAPM came out recommending that for hemibody in the last couple years. But I haven't had a case since.

MR. TSE: How about you?

MR. HUEN: Yes.

MR. HELLMAN: Good idea.

MR. TSE: Okay. 5.10, the intention is to avoid -- you have a computer program you purchase new or when your sources change and so on, your computer program calculates certain minutes of distribution. Are they correct? So the way to do it -- of course, you can check on software, but that's a difficult way to check. But the way to do it is

you make a calculation under certain conditions. You put the dosimeter under similar conditions and you verify they are close enough you are happy with it, and it's good.

But if they are not the same, you know you have a problem, so you could check. That's the intention of this particular item.

Under 1, 2, 3, we also try to check the machines and so on at different angles, but they may be too complex. Some other people in the workshop say its too complex and so on. If you want to check those -- first of all, do you check them or you don't? They are computer calculation versus the actual measurement.

MR. HELLMAN: A year ago, I bought a new computer and brought it online and did this sort of thing independently to some degree. I didn't get the agreement I was looking for. I understand its intent. I think it's too complex for what you're asking for, especially since the AAPm does not require any QA even yet. I think AAPM's a little bit remiss for not requiring or having a protocol or anything else for checking it, but I'm not sure this is the best way to go.

Ed McCullough at Mayo has a fairly good protocol and so do some others that are in draft stages by the AAPM. I prefer to get input from them before you put it in this rule. I will definitely not include this. That's my

feeling about it.

MR. TSE: The other workshop participants also say that, the same agreement.

MR. HELLMAN: But it's well intended. I understand where you're trying to come from and it's necessary, because the AAPM hasn't made that step.

MR. HUEN: When you have a new computer, what I do is I would generate some isotopes on the computer and then compare that and see if it makes sense, and the same thing with the wedges and so forth.

MR. TSE: And after change of source, maybe you need to make a simple calculation, too, of the new source strength. That's to avoid --

MR. HUEN: The source strength doesn't change the characteristic of the --

MR. HELLMAN: Not the does, but it would change the times. I'm sure we do that. You change the strength. At least I would. I assume you do that.

MR. TSE: You'd make sure your procedure has been modified such that these two -- one measurement, one calculation matches.

5.11 is in terms of -- in case of an emergency. You just go back to your treatment first without having to worry too much about the check, then you can check later. D is just implementation.

Any other general questions with regard to the reg guide? Beth, do you have any?

[No response.]

MR. TELFORD: We've come to a place on the agenda where maybe, if no one objects, we can take a ten minute break and come back and go into the review of the schedule, and then include any remarks, and then call it a day. So if no one objects, let's take a ten minute break.

[Brief recess.]

MR. TELFORD: Back on the record. The final two items today will be the review of the schedule of future activities and concluding remarks by our volunteers. For the schedule of future activities, let me remind you of the dates. May 7 is the first date we're to be concerned with, and that's the date by which we would request a copy of your quality assurance program be sent to Ed.

Now, this morning I told Joe that I could relieve his worries about his quality assurance program. What we would like to see is a copy of any manual that's -- whatever section of a manual you use or whatever copy of procedures you use, just copy them, put them in a pile, and that's your quality assurance program.

What Ed was saying when he talked about the evaluation forms was that we would be most appreciative if you would give us a one-page outline that says, for example,

objective two is covered in Section X and Section Y of what I sent you. Objective three is covered in Section T and Q of what I sent you, etcetera.

So that when we review all of these 70 programs, we would be -- it would expedite our review. So we don't want you to write it in any particular format, any particular style. We want to make it easy on you. Just send us a copy, give us a roadmap and we'll be happy.

So that's by May 7, please. Now, the other reason for May 7 is that if your site is one of the ones chosen for the 18 site visits, then the QA Team will need to review these 18 programs and they only have a couple of weeks to go through those before they have to start their site visits, because they have to accomplish these 18 site visits within the 60 days.

Scheduling-wise, that's pretty tight. So they would be most appreciative of they could get those by May 7 so they can get their work done. I want to say of the 18, 12 will be NRC licensees and six will be Agreement state licensees. Most assuredly, one will be in the State of California because it's a state with a goodly number of Agreement state licensees. That's May 7.

May 14, we will say that's the start of the 60-day clock when you should have your modified QA problem in place that meets the objectives of 35.35. So that's the start of

your 60-day trial, is May 14. The end of the 60-day trial will be July 13.

So from July 13 to July 31, you have to fill out the evaluation forms which we will send you. Now, I hope from Ed's discussion, you got the impression that not only do we want a grade for each of the objectives, we would like to know what you would do if you don't like any of these objectives. If you want to throw them out, that's great. If you want to modify them, that's great. If you want to retain them, that's great. If you want to add to them, that's great.

We want to hear what you, in essence, propose is the optimal set and we hope to get 70 of these and that will be of great benefit to the staff in writing the final rule and in justifying.

So I would like to highly recommend that you give us your suggestions. That's by the end of July, the evaluation be complete.

Now, the second set of workshops, post-test workshops will be in the month of August. It will be a two-day workshop and this workshop will be back here in San Francisco, in which time we will discuss your experience, your evaluation and your suggestions for the objectives, the guide, and the reporting and recordkeeping requirements.

Before you leave, we want to make sure you have a

copy of the Federal Register Notice so that you for certain have those reporting and recordkeeping requirements, because we really want to hear your suggestions for how to make those better.

So that's August and we will try to avoid any conflicts with any society meetings in August and we will notify you as to when these meetings will be, such that if you can't make one date or one workshop, we'll give you the opportunity to attend another workshop.

It may be a little further away, you may have to fly through a lot of miles, but we really want you at a workshop.

MR. HELLMAN: Where are they?

MR. TELFORD: New York City, Chicago, Atlanta, Dallas, San Francisco. One strategy here is to have it in your back yard so it's easy for you. But if it turns out that we tell you that the August workshop might be on the 18th and 19th, and you say, gee, I'm all booked up those days, we'll give you the opportunity to come to another one. Maybe you've got a favorite place you want to go.

Our intention is to get you into a workshop so that you can make your views know. So that's the schedule. Does anybody have any questions and is everybody straight on schedule? Tony?

MR. TSE: Joe needs to go back --

MR. TELFORD: We are now up to the topic concluding remarks. So I didn't hear any questions, no comment on schedule.

MS. MARCIANO: That will be a two-day workshop versus a single day.

MR. TELFORD: Yes. We want to give everybody plenty of air time. We want to listen very carefully to what you have to say because it will be -- on the one hand, the Quality Assurance Team will be saying to you, here's the inside view of the criteria we used for program evaluation, here's what we think about the program evaluation, 18 programs. Here's the criteria we use for site evaluations, here's the result of those 18.

On the other hand, the volunteers get to say here's our experience, we try and propose 35.35. Here's our evaluation, here's our suggestions to try and make it better. So there's a lot of dialogue going on in this workshop that we anticipate.

Anything else?

[No response.]

MR. TELFORD: Okay. Concluding remarks. Let's let each of the volunteers and, as a matter of fact, everybody else at the table say any concluding remarks about their impressions so far or anything else you'd like to say.

MR. HELLMAN: I really don't have much to say

other than I think it's been well done and I appreciate the NRC's willingness to give us more input into what's a very difficult rule to implement and one that's very emotional for many of the licensees.

MR. TELFORD: Okay.

MS. MARCIANO: I think I have a lot of things to kind of absorb, and also to go back and look through some of the policies that I feel are in place and I think some of them may not actually be in quite the format that's been outlined here. But I do feel confident that what we're doing in practice is what is intended by these eight proposals that have been made.

MR. TELFORD: Anything else?

MS. MARCIANO: No. I don't think so at this time.

MR. TELFORD: Okay.

MR. HUEN: I really don't have a whole heck of a lot to add to it. I think it's a good opportunity for us to give our input so that we can't say later on we didn't say anything. In the past, I guess a lot of us didn't really do a lot of inputting when the opportunity arose, and now it's a very good opportunity. So I'm really looking forward to this to see how it works out later on.

MR. TELFORD: Good.

MS. SULLOWAY: I just want to thank you for inviting me. It was quite interesting. It's almost

overwhelming being from a very small department. I think we pretty well meet the quality assurance that you set up, so I don't think it will be too hard.

MR. TELFORD: Okay.

MR. TSE: I want to thank everybody for coming to help us out, the Agreement state personnel and the Region V staff, all the participants. We will see you next time. We've got a lot more to discuss, including misadministration requirements. Thank you.

MR. KAPLAN: I'd like to thank you again. It was only through your participation that we're going to be able to pull this off and, as Albert said, this is one opportunity get input in before something is finalized. Please, it will make our life easier, that one-page road map can be very important, because I know you're going to xerox various portions of various parts of things that exist, and pointing us in the right direction is going to make it much easier for us, and it will help us get NRR evaluation input back to you. That's it.

MR. HORNOR: John, I like what you're doing in implementing new rules. I wish you would do this in more of your new rules. Thank you for inviting me.

MR. WIEDEMAN: I just wanted to say that I review most misadministration rules or misadministration reports that come into the Region III Office. We get about 20 a

month. And I look at these and I say, well, would the new rule catch this, would it have caught that, and I would say probably 95 percent of the time the new rule would have caught these misadministrations.

One of the biggest problems is, like I said before, was ambiguous terminology that we use in the medical field, and there are things that you may want to incorporate in your procedures manual to watch out for.

There's little things like iodine scans, whole body scans, thyroid scans, cancer scans or CA scans, metastatic surveys, metastatic scans, lung/bone scans. To you it means one thing; to the other technologists, it may mean something else, and to a physician it means even something else.

So the same thing with your therapy. In your procedures manual, if you outline what the standard doses are for hyperthyroid, for CA, the use of P32 for polycythemia, what your dosage ranges are, you'll have less problems.

I'm looking forward to working with you to try and get a good QC/QA program.

MR. MONTGOMERY: I guess as kind of representing the inspection end of NRC locally, this was real informative to me. I appreciate being here and listening to all of you. As inspectors, we've got a lot to learn, I think, in terms

of how we're going to inspect this and techniques to use and we're on a learning curve here, too. So appreciate the opportunity.

MR. FRAZEE: This business of actually having a shakedown cruise for a regulation before it becomes a hard and fast rule, I find to be really an exciting time. It's a great opportunity for licensees to have that input and, on the same token, I'm a little bit surprised that we didn't have more participation from our Region. I understand that we're sort of unique in that arena and we had more that didn't attend than did attend.

I hope that either through independent conversations, we can make sure that they are, indeed, going to participate in this. It's a real good opportunity really work the bugs out of this rule.

We have 48 Agreement state licensees and 24 NRC licensees who are participating, yet did I hear you correctly that sort of the reverse is true? Is there some good reason for that and for the actual on-site visits?

MR. TELFORD: I'll explain in a minute.

MS. RIEDLINGER: I have nothing to add.

MR. TELFORD: Well, I want to thank everyone for coming and thank everybody for your participation. I'm looking forward to the next workshop, hope that will be the big payoff. I think we can conclude this meeting. Thank

you.

[Whereupon, at 3:30 p.m., the meeting was adjourned.]

REPORTER'S CERTIFICATE

This is to certify that the attached proceedings before the United States Nuclear Regulatory Commission

in the matter of:

NAME OF PROCEEDING: Pilot Program Workshop

DOCKET NUMBER:

PLACE OF PROCEEDING: San Francisco, CA

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.

Roni Borlek

Roni Borlek
Official Reporter
Ann Riley & Associates, Ltd.

PILOT PROGRAM OBJECTIVES

1. TO UNDERSTAND HOW LICENSEES DEVELOP THEIR SPECIFIC QA PROGRAM FOR THEIR INSTITUTIONS WHICH MEETS THE PERFORMANCE OBJECTIVES OF § 35.35.

2. TO UNDERSTAND HOW LICENSEES CONDUCT THEIR "35.35 QA PROGRAM" IN ACTUAL PRACTICE.

3. TO DETERMINE IF THE PERFORMANCE OBJECTIVES OF PROPOSED § 35.35 HAVE THE EFFECT OF PREVENTING OR CATCHING MISTAKES WHICH COULD LEAD TO MISADMINISTRATIONS, IF NOT CORRECTED.

4. TO DETERMINE IF PROPOSED § 35.35, IF PROPERLY IMPLEMENTED, CAN PROVIDE HIGH CONFIDENCE THAT ERRORS IN MEDICAL USE CAN BE PREVENTED. IF NOT, DETERMINE WHAT SET OF OBJECTIVES WOULD PROVIDE HIGH CONFIDENCE.

PILOT PROGRAM OUTLINE

1. INVITATIONS TO VOLUNTEERS DURING JANUARY AND FEBRUARY 1990. INVITATION PERIOD CLOSED MARCH 9,1990.

2. VOLUNTEERS: REVIEW PROPOSED § 35.35 AND DETERMINE THAT THEIR QA PROGRAM MEETS PROPOSED § 35.35 OR MODIFY THEIR QA PROGRAM TO MEET PROPOSED § 35.35 DURING APRIL 1990.

3. PRE-TEST WORKSHOPS ON MARCH 29, APRIL 4,6,18, AND 20, 1990. VOLUNTEERS BRING COPIES OF THEIR QA PROGRAM TO THE WORKSHOP.

4. VOLUNTEERS DEVELOP WRITTEN INSTRUCTIONS OR TRAIN PERSONNEL, IF REQUIRED, DURING APRIL TO PREPARE FOR QA PROGRAM 60-DAY TRIAL.

5. VOLUNTEERS CONDUCT 60-DAY TRIAL, DURING THE PERIOD MAY 14 TO JULY 13, 1990, OF THEIR "35.35 QA PROGRAM" AND RETAIN SPECIFIC RECORDS; THE NRC QA TEAM WILL VISIT 18 VOLUNTEERS FOR ONE DAY AT EACH SITE.

6. POST-TEST WORKSHOPS WILL BE DURING AUGUST 1990. VOLUNTEERS BRING COPIES OF THEIR EVAULATIONS. VOLUNTEERS WILL DISCUSS THEIR "35.35" EXPERIENCE, EVALUATIONS, AND SUGGESTIONS FOR IMPROVEMENTS TO PROPOSED § 35.35, THE REGULATORY GUIDE, AND THE RECORDKEEPING AND REPORTING REQUIREMENTS. THE NRC QA TEAM WILL DISCUSS: (A) THE CRITERIA USED TO EVALUATE THE 18 QA PROGRAMS, (B) THE RESULTS FROM THE EVAULUATION OF 18 QA PROGRAMS, (C) THE CRITERIA USED FOR 18 SITE VISIT EVAULUATIONS, AND (D) THE FINDINGS FROM THE 18 SITE VISITS.

WHAT THE PARTICIPANTS CAN EXPECT

1. TO UNDERSTAND THE CRITERIA THAT WERE USED TO EVALUATE THE "35.35. QA PROGRAMS."

2. TO LEARN THE RESULTS OF THE EVALUATION OF THEIR PROGRAM.

3. TO UNDERSTAND THE CRITERIA THAT WAS USED TO EVALUATE THE IMPLEMENTATION OF THE QA PROGRAMS DURING THE 18 SITE VISITS.

4. TO LEARN THE RESULTS FROM THE 18 SITE VISITS.

5. TO HAVE THE NRC QA TEAM LISTEN CAREFULLY TO THEIR EVALUATION OF THE PROPOSED RULEMAKING.

6. TO HAVE THE NRC QA TEAM LISTEN CAREFULLY TO THE SUGGESTIONS AND COMMENTS OF THE PARTICIPANTS ON HOW TO IMPROVE THE PROPOSED RULEMAKING.

WHAT IS EXPECTED OF THE PARTICIPANTS

1. DEVELOP A QA PROGRAM TO MEET PROPOSED § 35.35.

2. ATTEND A PRE-TEST WORKSHOP.

3. PROVIDE WRITTEN INSTRUCTIONS AND TRAIN PERSONNEL, AS NECESSARY, TO PREPARE FOR THE 60-DAY TRIAL.

4. CONDUCT A 60-DAY TRIAL OF THEIR "35.35 QA PROGRAM."

5. EVALUATE THE PROPOSED RULEMAKING AND PROVIDE SUGGESTIONS FOR IMPROVEMENT.

6. ATTEND A POST-TEST WORKSHOP.

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