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NUCLEAR REGULATORY COMMISSION

NRC QUALITY ASSURANCE WORKSHOP

Regency Ballroom C

Holiday Inn

Irving, Texas

Thursday, September 13, 1990

PROCEEDINGS

[9:08 a.m.]

MR. TELFORD: Good morning. My name is John Telford. I'm from the Rulemaking Section of the Division of Regulatory Applications, Headquarters NRC. I want to welcome you to the post-trial period workshop.

I'm going to take just a few minutes of your time and go through the first few items on the agenda for Thursday, and then I will review for you the makeup of our agenda for the next two days.

We will start with a self-introduction of volunteers and I will tell you in a minute what I would like you to say about yourselves.

We've broken these two days into four chunks of time. We've got some information, what I'll call the feedback session, where we told you in the pre-trial period workshop that we would confess to you that the criteria we used for program evaluation and the criteria we used for site evaluation. So if you were one of the 18 sites, you probably have our feel for what that was all about because when our QA Team arrived, you know the kinds of questions they asked. For the other folks, we thought that would be good information for you, a kind of foreshadow to the future.

We have program evaluations. We have checklists

of how the QA Team or the contractor viewed your program if you were one site visits, and the same kind of feedback for your evaluation on-site. This is no-fault, so we'll say this was great, or this needed more information, or something like that. I will pass those out just before noontime and you'll have ample opportunity to ask about anything you want to know there. So that's the feedback session.

The next chunk of time is to go through the proposed 35.35, the quality assurance rule itself. We'll go through that piece-by-piece. The next chunk of time is to through the regulatory guide piece-by-piece. Then we'll go through the reporting requirements, proposed reporting requirements for the diagnostic misadministrations, and, secondly, the therapy reporting and recordkeeping requirements for events and misadministrations.

Let's go back to the self-introduction. What I would like you to say about yourselves is your name, the hospital or clinic that you represent, its size, and its location; size would be in terms of number of beds or, if you only have outpatients in your clinic, then just say so; its location, and, lastly, how the various departments, like teletherapy, brachytherapy, radiopharmaceutical therapy and radiopharmaceutical diagnostics, which of those were involved in the 60-day trial at your hospital or clinic.

Let's start over here with Ray.

MR. FOSTER: My name is Ray Foster. I'm with Desert Hospital in Palm Springs. It's a 350-bed hospital, and the objectives were for nuclear medicine, both diagnostic and therapeutic.

MR. HAMMOND: My name is Bruce Hammond. I'm with Massey Health Care Services in Ft. Worth, Texas. We're a mobile nuclear medicine service and our scope was diagnostic nuclear medicine.

MR. JANICE: Emory Janice from Memorial Medical Center, Corpus Christi. We have 500 beds and involved diagnostic and radiotherapy.

MR. BELLEZZA: David Belleza, College of Medicine in Houston. Our patients are mostly outpatients, and we have teletherapy and brachytherapy.

MS. KELTY: Nellie Kelty from Baltimore, Maryland. I'm with a private radiology group and we do diagnostic medical services.

MR. SHAFFER: Mark Shaffer from VA Medical Center in Houston. It's an 1150-bed hospital. We deal with nuclear medicine, brachytherapy, and teletherapy.

MS. WALKER: Brandy Walker, Dallas, Texas VA Hospital. We have about 600 beds and our trial was in nuclear medicine.

MR. FELDMEIER: I'm John Feldmeier from San

Antonio, representing the Cancer Therapy Research Center there. It's a freestanding outpatient facility and we have teletherapy and brachytherapy there.

MR. MOK: I'm Ed Mok. I'm from San Antonio, Texas and we are a freestanding center, and we are participating in the brachytherapy and radiation therapy.

MR. KAPLAN: Ed Kaplan from Brookhaven National Laboratory. Thank you for being here.

MR. TSE: My name is Anthony Tse. I'm from the NRC Headquarters in Washington. I'm the Project Manager of this project.

MR. KLINE: My name is Ed Kline and I'm at the Atlanta NRC Office and a member of the QA Team.

MR. NELSON: I'm Kevin Nelson. I'm from Brookhaven National Laboratory.

MR. DADARI: I'm David Dadari, Northwest Texas Hospital in Amarillo, Texas; 350-bed hospital, inpatient, outpatient; nuclear medicine, diagnostic therapy, and emergencies and acute care.

MS. WOOD: My name is Pat Wood and I'm from American Center in South Arkansas. It's about a 350-bed combined hospital. We surveyed nuclear medicine therapy, brachytherapy and teletherapy.

MR. BRAHMAVAR: My name is Suresh Brahmavar, Bay State Medical Center; 950-bed hospital in Springfield,

Massachusetts. Our objectives were nuclear medicine, brachytherapy and teletherapy under the broad NRC license.

MS. LaFRANCE: I'm Terry LaFrance from Bay State Medical Center in Springfield.

MR. HIDALGO-SALVATIERRA: Oscar Hidalgo-Salvatierra. I'm a physicist with Mary Burke Perkins Counseling Center in Baton Rouge, Louisiana. It's an outpatient freestanding facility. We treat about 110 patients a day, using only linear accelerators and they're all brachytherapy. So we participated in brachytherapy.

MS. ROY: I'm Terry Roy from Branerton, Florida. I'm in charge of the Nuclear Medicine Department in a freestanding cardiac center, where we do only nuclear medicine. We treat probably 90 to 100 a month.

MR. BENNETT: I'm Doug Bennett from Duluth, Minnesota. I'm a Radiation Physics Consultant representing Miller Medical Center in Duluth. It's 150-bed hospital and we're participating in nuclear medicine, therapeutic radiology, brachytherapy.

MS. GOODWIN: I'm Sue Goodwin, West Georgia Medical Center, a 350-bed hospital southwest of Atlanta, about 75 miles from Atlanta. We participated in nuclear medicine, both diagnostic and therapeutic, and brachytherapy. We have two linear accelerators.

MR. WOOD: I'm David Wood with Bureau of Radiation

Control in Austin, Texas.

MR. TELFORD: Let's move to the next item on the agenda, which is the recap and scope of this workshop. Recall that we told you at the pre-trial period workshop [illegible] after you understood the rule and go back and modify your program and try it out for 60 days, at this workshop we would listen to you.

That's what I told you. What you will come to discover is that we will go through each part of this piece-by-piece and we will ask you what you recommend to do with it. Very openly we will say would you like to delete this, modify it, or continue it; and, if so, why or how.

We'll be listening to you this entire time. We will have very little to say, except by way of explanation or clarifying intent, whatever helps to facilitate your discussion.

Here's what I call the groundrules. Groundrules are that the volunteers talk and we listen. If we have any observers, which there are supposed to be some from the Advisory Committee on the Medical Use of Isotopes or from state programs, they have to remain silent. They cannot make any comments or ask any questions until we're done, which is after through listening to you, all of you.

There's quite a few of you here. I'm glad to see that. At this point on the agenda, 5:30 on the second day,

the NRC staff will make themselves available to discuss with those folks as long as they would like.

Now, just for your benefit, the Commission has asked the NRC staff to provide a proposed rule for them in March of 1991. What we have assembled for you today is three out of the five technical types that are from the NRC staff, which will be writing that draft-final rule.

So we're here to listen to you. We're not here to take votes. We're not here to establish a consensus. We're individuals and we will listen to your suggestions and your rationale. So it's logic that will carry the day.

I just wanted to convince you that we have the right people here so that, indeed, that we have brought to each workshop so that we can get your suggestions firsthand as well as having a transcript.

The next thing we're going to do is we're going to give you some feedback from the results of the program reviews and the criteria we used to go through that. What we are calling the QA Team were three very experienced inspectors, and the person who is the Project Manager whose name is Dr. Anthony Tse, were the four people that went to the sites.

Two of those folks are here; Ed Kline is one of the experienced inspectors. What you're going to hear in the next few minutes are going to be the work that they did

to take the next two steps.

If this were a final rule, then you would want to know what are the kind of criteria you would use to license. The next step after that would be what are the kind of criteria you would use to inspect. Of course, we didn't use those words before. We didn't say license and we didn't say inspection. So we're going to talk about program review and site evaluations.

But I think it would help you to understand that if all of this comes to pass, what we're doing is drafting that information now.

With that, I will turn it over to Mr. Ed Kline.

MR. KLINE: I'd like to welcome everybody here, also, to the workshop. I had the pleasure of meeting some of you during site visits. My name is Ed Kline and I'm part of the Pilot Team that was evaluating the programs on-site, and the programs that you submitted to us prior to us visiting the facilities.

What I would like to do is talk about the QA Team activities; what the Team was looking for when they went to visit your facility; what sort of things we looked at in your program prior to visiting your facility; and some of the information regarding the results.

I would like to talk about the background behind the QA Team activities, the evaluation criteria that we

developed, the program evaluations that were performed, and then the site visits.

To give you a quick background on the QA Team and how it came about or how this evolved, part of the rulemaking process required that a pilot program be developed and tested as a proposed rule. The pilot program was conducted between May 14 and July 13.

The purpose was to assist in determining the effectiveness of this proposed rule, Part 35.35, and to aid in the determining of the impact on the medical community and on current medical practice.

Certain evaluation criteria was formulated and this evaluation criteria was developed to quantitatively and qualitatively determine whether or not the eight objectives -- and I'll have four of the objectives over here on this slide -- whether or not they could be met.

Included in those eight objectives were the criteria and also any regulatory guide that was used as a basis for some people's programs. Also, the evaluation criteria served as standard guidelines for evaluating the programs when we were there on-site to visit you, and these guidelines will be used for future NRC development guidelines and program reviews for the licensing process.

The review criteria that were used was further divided up into a program evaluation criteria and site

evaluation criteria. The program evaluation criteria was based on the Team's experience in the inspection field and also the Team's private sector experience in the medical community.

The checklists were developed from the evaluation criteria for the program. They were used to review quality assurance packages that you submitted to the NRC prior to your participation with the on-site visits.

The site evaluation criteria evolved from the program evaluation criteria, and this also was a checklist that was used during the site visits where we looked at the different parts of your program and evaluated them, and compared them to the eight objectives.

The facility site visits comprised 18 licensees randomly selected from the list of volunteers. You're part of that 18, of which 11 were NRC licensees and seven agreement state licensees. And of these 18, we reviewed 15 diagnostic nuclear medicine departments, 12 therapeutic radiological or radiopharmaceutical uses within the nuclear medicine department, five facilities which have brachytherapy applications, and eight teletherapy facilities.

Here is a map showing the five NRC regions. On the map you will see some circles and X's which represent the sites of the 18 volunteers. We had quite a diverse

spectrum across the United States. Within this cut, we had volunteers from Washington, California, Texas, Iowa, Illinois, Michigan, Indiana, New York, Pennsylvania, New Jersey, Georgia, Maryland, Virginia and Florida. These were the sites that the Team went to visit and the programs that were evaluated.

At each site, we looked at either one of the four or a combination or all of these for medical use programs. We defined them as diagnostic nuclear medicine, which was further subdivided into less than 30 microcuries of Iodine-131 and Iodine-125. The second category, radiopharmaceutical therapy, included greater than 30 microcuries of Iodine-131 and Iodine-125.

We'll talk later about No. 2 in regard to Iodine-131 and ido-hippurate studies. Category 3 was brachytherapy. We looked at brachytherapy programs that you were volunteering, that aspect of your program was reviewed, and teletherapy.

The medical uses evaluated during the 18 site visits are further divided into NRC agreement state programs, hospitals, and P/P stands for private practice. The largest number of facilities were the diagnostic arena in the hospitals, and then you had radiopharmaceutical therapy, brachytherapy and teletherapy.

The majority of these hospitals were in the NRC

regions or jurisdictions and we also looked at agreement state hospitals and private practice.

The first medical use category was diagnostic nuclear medicine, including Iodine-125 and Iodine-131 procedures, less than 30 microcuries. All my slides are an aggregate of what the Team looked at and reviewed as part of the evaluation criteria in regard to your program that you submitted, and also the site evaluations we performed when we went to visit your facilities.

I'd like to talk about what we looked for in your program that you submitted and how what you stated in your program compared with what you actually performed on-site. The first objective -- if you look at the objectives, medical use indicators and you correlate that over to the proposed 35.35 objectives, A-1 would be ensure that medical use is indicated for the patient's medical condition.

The proposed objective will be on your right on the screen and on the left will be the criteria that we used to evaluate this objective. Authorized user reviews case or a procedure ordered by a physician. Under A, authorized user reviews case, we looked for any indication in your program that you submitted that there was a peer review by an individual on-site that was an authorized user, by definition on your NRC or state agreement license.

Also, you could have a physician working under the

supervision of an authorized user, which would satisfy that requirement also. Or we looked for, B, procedures ordered by a physician. In particular, if it is a diagnostic referral, we look for a mechanism by which you have a system where you can describe those in your program and how you received, whether it be written, oral or phone call regarding ordering of diagnostic procedures, or a number of different methods that people use that seem to be current industry standard or practice regarding diagnostic referrals.

The second item we looked at in your program and site evaluation was whether or not a prescription had been made. A prescription has a certain definition defined in 35.2 that has to meet certain requirements. In general, it's a written order or directive, dated and signed by an authorized user or a physician under the supervision of an authorized user.

We looked in the program to see if you had an example of what a prescription looks like or documentation as to how you would prescribe the prescription, and then on-site we actually looked at some cases that some of you presented showing what sort of prescription had been written up for a diagnostic procedure.

Item 3 says diagnostic referral made. We have prescription or referral which will give you latitude to

either do one or the other. The Georgia people were using a diagnostic referral and that's found in the 35.2 definition.

For diagnostic referral, we looked for written request dated and signed by the physician that included the patient's name, the diagnostic clinical procedure, and the clinical indication. Again, these are found in the definition. We looked for examples to be submitted, a method by which that was performed at your site, and also we reviewed some actual cases before we went and visited your facility.

Instructions understood by a responsible individual. That particular objective is addressed in No. 4 over here and if you committed to the regulatory guide, 2.1 or 2.2 addressed that objective. In the program that you submitted, you could refer to the above statement or you could commit to regulatory guide 2.1 and 2.2, or personnel could be instructed on the importance of accurate and clear records and requests, and personnel are instructed to clarify their records and requests.

We looked for any of these three definitions of what we felt met Objective 4. So there could be a number of different ways you could address it. Again looking at the programs that were submitted, it appeared that some people would address it in their program and, as we'll talk about later, some people felt that this sort of thing is inherent

in the training process, and individuals which have any sort of common sense or special training would know that if an instruction is not understood, you can raise the question to either the referring physician or the authorized user.

Regulatory guide 2.1 talks about records being legible and written clearly and precisely to minimize misunderstanding, which you could commit to, and also 2.2 of the regulatory guide, all workers will request clarification from an authorized user if any element of the prescription is ambiguous or unclear.

We felt it was important that people look at what they're doing and question if it's hard to decipher handwriting or ambiguous or possibly erroneous information. Just stop and look at it and ask the question, what is this, an eight or a six, what does this mean, is this a particular study, what if there's a certain slang that's used which sometimes the industry generates, what more precisely do you mean by this particular study procedure, talk about the problem.

Objective No. 5, medical use in accordance with instructions. You could confirm the above. You could commit to regulatory guide 2.4. When I talk about medical use in accordance with instructions, the instructions refer to a prescription or a diagnostic referral and clinical procedures manual.

Committing to regulatory guide 2.4, that section basically says that before medical use, we need to verify that your medical use is in accordance with a prescription of diagnostic referral. Or A-3, personnel instructed to match medical use or diagnostic referral and clinical procedures manual, and personnel confirming patient identity, radiopharmaceutical and dosage prior to administration.

Again, we looked at the program that was submitted to see if the criteria was met, and, based on your program, we looked at how it was instituted at your facility.

Part of our evaluation on-site involved dialogue regarding your understanding of the QA program. The key features, referral systems, clinical procedures manual, telephone referrals for diagnostic studies, exceptions due to emergency conditions regarding writing a referral or prescription, patient identification and what was your understanding of your objectives regarding patient identification, and clarity of records and requests.

No. 6, patient identity verified. Let me change the objective over here so that you can follow these. Patient identity verified. We felt that in order to properly identify a patient, there needed to be a redundant patient identification system. Though this is not verbatim called out in the regulatory guide, nor is it point-on-point

addressed in your proposed objective as Part 35.35, we felt that it was necessary that some second mechanism be incorporated to identify the proper patients receiving the pharmaceutical treatment.

There are number of different this is done. There's a lot of latitude in this area. You could use just a name to identify the person, calling them by name; an ID is used for identity; often activity cards were used, especially in the military; insurance card that has a person's name correlates when you are calling the individual; a sign-up log; birthday; appointment sheets.

We found that there were a number of different ways that people would check into a hospital. There are a number of ways that they'd be screened prior to getting into the nuclear medicine department or therapy department, which we'll talk about later. So there were a number of different ways of -- we say except emergencies, if you have an emergency condition, then it's not required that you have a redundant patient identification procedure. We feel that that could jeopardize the immediate care needed by that patient.

But there are a number of different ways that this is addressed in the program and on-site, a multitude of different ways that people were performing this redundant patient ID process, often performing it and not realizing

that it was being done.

Objective 7, unintended deviations identified and evaluated. We looked to see if, in the program, that statement was confirmed in writing or whether or not people committed to regulatory guide 2.3 and 3.5. Regulatory guide 2.3 states that workers will stop medical use on patients and seek guidance if an apparent discrepancy exists, which may result in what we call a diagnostic event which we'll talk about later in the definitions.

No. 3, you can commit to patient instructed to terminate medical use if stress is identified; pretty much what I just said in regulatory guide 2.3; and discrepancies are identified, evaluated, and corrected. This particular A-3 item drew a lot of attention because a lot of the programs did not address it verbatim in writing, but, yet, programs were performing this in the sense that it was inherent in the training, and if there's a discrepancy, we're going to identify it, evaluate it, and correct it.

Under B, record of prescribed and measured administered dose, that is already required by the Federal regulations in 35.35(c). The state agreement programs also require it in one form or another. If you had a dose log, for example, where you wrote down the prescribed, then you measured, it's self-evident that the agreement would be there, so it's not necessary that you make a record of the

agreement. It's pretty much understood and adequate for understanding that there is agreement masked between the two.

Treatment planning in accordance with prescription. This does not apply to the diagnostic care. This will be talked about in the therapy unit. The next medical use area was radiopharmaceutical therapy and diagrostic, which included Iodine-125 and Iodine-131 procedures, greater than 30 microcuries, not including idohippurate.

These objectives that we're going to look at in the therapy end, the majority are identical to that of the diagnostic objectives. There are a couple of areas that required more information, more detail, but, generally speaking, the criteria is the same, it is reviewed in the same manner. Medical use indicated, Objective No. 1. Authorized user reviews each case; since it's therapy, we felt that it's necessary that the authorized user review it or physician under the supervision of an authorized user, but not a referring physician.

The authorized user on your license, as listed on that license, or individuals under his jurisdiction and supervision we felt needed to review this particular patient's case for therapy.

Objective No. 2, a prescription made. Now we get

into more detail on what we define in a prescription versus a diagnostic referral. 35.2 at the top, prescription made, gives, by definition, what is in a prescription. Regulatory guide 3.3 addresses authorized user shall make and date a prescription, but a prescription is a written direction or order dated and signed by an authorized user or a supervised physician containing the radioisotope, the dosage, the chemical form, the route of administration, physical form for therapy only.

In the programs we looked at, people would submit or facilities would submit an example of what a prescription was. On-site we looked to see basically what a prescription contained. We'll talk about the results at the end, but this criteria, there were a couple objectives or parts of this objective that we had a little bit of difficulty with or felt that maybe in the field it could present a problem, and that would be No. 3, No. 4 and No. 5, or primarily 3 and 5, and we'll talk about this in a minute.

Item B, prescription changes written, dated and signed. We looked to see that the authorized user or the supervised physician documented the changes, dated and signed those changes, made sure that there was a mechanism by which, in your procedures, once the changes were made, the individuals were notified of the changes, and there was a logical sequence of how to revise the treatment or the

treatment process.

Item C, changes by phone permitted under unusual circumstances; that these are documented. If you have a prescription and you need to change it and there's a problem with being able to document that immediately or to adjust that prescription accordingly at the spot or the facility, then under unusual circumstances we looked for a method by which you could possibly call in that change, or orally, verbally give that change, at which time the documentation would have to be followed and would have to be indicated in some form or fashion regarding that patient's treatment.

Diagnostic referral to be made. This is not applicable since we're talking about therapeutic uses which we do not feel that a diagnostic referral would meet that objective. Objective No. 4, instructions understood by responsible individuals. Again, it's identical to the diagnostic where we confirm the above statement, commit to regulatory guide 2.1 or 2.2, or people are instructed on the importance of clear records.

As in the diagnostic area, we found that people felt that this was somewhat an obvious thing; that, of course, they would know how important clear records need to be, and if they had some ambiguous statement or something that was hard to decipher as far as the handwriting or signature, they would bring this question up to the

authorized user or responsible individual.

Medical use in accordance with instructions. Confirm the above, or regulatory guide 2.4 and 3.4. Regulatory guide 3.4 addresses before administering a radiopharmaceutical, the identity of the patient, radiopharmaceutical used, dosage shall be confirmed with the prescription; pretty much what Objective 3 says, you're expected to match the medical use of a prescription or a diagnostic referral and the clinical procedures manual.

Personnel must confirm the identity of the patient, pharmaceutical and dosage with the prescription prior to administration. There are a number of different ways this was done. It was nicely met in some of the programs, the writing and a number of redundant methods were incorporated in this particular category.

On-site it was generally a practice of most people we talked with that they were double and triple checking at times what the patient's ID was and the pharmaceutical dosage being used. As in the diagnostic, we looked in the therapy end of your current understanding of the QA program, meaning your procedures, the need for particular key procedures, clinical procedures manual, content of prescription, referral system, telephone referral. In this case, the diagnostic referrals did not apply. Exceptance due to patient's emergency condition, patient ID, and

clarity of records.

If possible, we would look at the clinical procedures manual in reference to your quality assurance procedures you submitted in your program and see if there was a nice tie-in or if there was a reference or procedures that were submitted via your clinical procedures manual.

Patient identity verified. As in diagnostic, in therapy end, we felt that a redundant patient identification procedure was even more important. Again, name, ID, signature, billing cards, birthday, a number of different ways you can check a person by a few different questions whether or not that's the person you want to treat.

No. 7, unintended deviations identified and evaluated. I didn't mention in the diagnostic end that this applies to, the majority of facilities already had somewhat of a quality assurance identification, problem identification program as part of other regulations or as part of your own awareness of quality.

Identification of problems was incorporated into this system. All the documentation of the problems, resolution of the problems, evaluation, correction, these sort of things were found to be documented as part of quality assurance programs which were often reviewed at quarterly assurance meetings and then submitted in the yearly report to the management of the hospital, the

administrator, or corporation, whatever the case might be.

Record of prescription measured, as in diagnostic, we looked for the same sort of criteria. Treatment planning in accordance with prescription. This is No. 8. This applies to the therapy end and that would be brachytherapy and teletherapy. So we're not going to talk about that since it wouldn't apply to the radiopharmaceutical end.

I think what we can do is maybe take a break five minutes early, and then come back and I'll talk about brachytherapy and teletherapy and what was reviewed in the programs and site evaluations.

Are there any questions to this point?

[No response.]

MR. KLINE: All right.

[Brief recess.]

MR. KLINE: I'd like to go on to the third medical use which we reviewed out of the participants, and that's brachytherapy. Again, Objective No. 1, medical use indicated. Authorized user reviews each case or a physician under the supervision of an authorized user reviews the particular case. Again, this is just like the radiopharmaceutical therapy. We felt that in brachytherapy, and a little further on the teletherapy end, things are done a number of different ways and in redundant fashion and there are a number of different people involved.

As a lot of you know, the brachytherapy, teletherapy medical use is -- I don't know if you'd call it more of a personal interaction, more of a one-on-one, point-on-point, participation by oncologists, physicists, dosimetrists, technologists, other associated departments, technology, oncology, surgery. So many different actors involved and so many different ways that each particular case is reviewed.

We felt that this oftentimes was nicely met. The chart rounds provided a nice basis for continuing followup on particular uses of the material on particular patients, as we'll talk about later in subsequent changes in the treatment planning process.

Objective No. 2, prescription made. Under the definition of brachytherapy, the prescription is a written directive or order dated and signed by an authorized user or physician under the supervision of an authorized user, containing the radioisotope, treatment site, total dose, treatment time, number of sources, and implied activity.

We also looked at this under prescription and how prescription changes were written, dated and signed by the responsible party; changes in the use of the material; the loading sequence; a number of different things were done at a later time due to the logistics; the medical opinion of the group which was administering the treatment.

The treatment chart addressed the majority of these elements, if not the treatment chart and associated documents that went with the treatment chart or with the patient's chart. That would describe these particular elements; the isotope, treatment site, and the total dose. This applies to intercavitary/interstitial, not topical applications, not teletherapy. This is brachytherapy, but we do break it down into both intercavitary and interstitial areas. Diagnostic referral does not apply since this is a therapy procedure.

Instructions understood by a responsible individual. That's the radiopharmaceutical diagnostic therapy. It's the same criteria that we looked at. We looked for records and prescriptions to be legible and precisely written, itemization of misunderstandings or areas that weren't clear, we looked to see if your program addressed that, submitted for a review, and whether or not there was some conscientious effort made by people on staff to make sure that criteria was met.

We also looked for some sort of identification process by which if you did find an area that appeared discrepant, that this was brought to the attention of the individual responsible and questioned, or if there was some unclear handwriting, as we talked about, or something that just didn't seem right. Again, we're not talking about

questioning the medical use, the physician's role. We're talking about the actual semantics of the handwriting, of the use, of certain records, if there's something that appears that is completely off-the-wall.

So we're not looking into questioning the physician's use of the material. I want to make that clear. There is no intent of the NRC to do that, but we found in the past that a lot of errors had resulted from unclear prescriptions, unclear directions, ambiguous, and this appears to be more of a problem than most people would speculate or believe is happening.

Objective 5, medical use in accordance with instructions, and instructions means medical use in accordance with the prescription. We looked to see if there was a procedure to verify the radionuclide and source strength of the prescription. Now, this is a procedure that would address the prior implantation and this would involve a number of different ways.

Examples we saw were color coding of the sources. We found that in the past that's been an avenue of mistake, where they say in a tandem intercavitary work, the source sequence for loading, a mistake was made by an individual loading the sources, and the improper configuration activity for a number of sources were used. So we looked for some verification that could be used. All the big manufacturers

use color coding. There is talk of standardization of the color coding eventually so the various companies will have a particular activity that equals the millicurie activity or milligram rating equivalent activity so that everybody has the same colors.

We looked for clearly marked storage spaces. If you had, let's say, a vault of some sort, if you had a mechanism, a report by which you would correlate your configuration for particular after-loading devices or sources that were in the safe that you knew which sources were out, and a lot of this is being met with your current Part 35 regulations.

Some individuals could use a radiation detection device which is a mechanism by which you can see the different source activities as you are loading or some sort of serial number check that corresponds to some sort of appropriate shielding. We don't want to sacrifice shielding. We want to definitely keep with the ALAR concept. So we don't want additional exposure in order to verify source strength, and hopefully there's a tradeoff there where you can look at the benefit returned from verifying the source that somebody would receive.

Remote after-loading devices, procedures to ensure proper input of data. We were only -- personally, I was only able to see one facility which, during the pilot

program that we talked about in the beginning, actually used a remote after-loading device. Though there were facilities we visited which did have them, we were looking to evaluate the objectives during the period of time that the program was initiated.

So we didn't -- we talked with a number of people at their facilities about their high dose rate after-loading devices, low dose rate after-loading devices, but we did not look at any case histories. Number C, the actual loading or implantation of sources or prescription changes promptly reported. We looked for any changes to be reported, dated and signed by an authorized user or an individual under the supervision of an authorized user.

In particular, what we looked for here is the initial prescription to find the loading sequence, number of seeds, activities, the site, though we realized that that could be very easily changed, whether it be in the operating room, whether it be once the patient is brought down in the department, configuration of routing or radiographs, or CT, or the mobility of physiology the person dictates that it's impossible to plant the seeds, the initial number.

Though we are fully aware that once a prescription is made, it can be changed and we would expect that people would have to change a prescription based on what they end up administering. So these changes we request be documented

so that everybody knows, logical fashion, what the initial prescription was and now what is the prescription, so there is no misunderstanding of the dose administered to that particular area or source is used.

Again, we looked at the understanding of current procedures, prescription, emergency conditions, patient ID, and unclear records. Patient identity verified. We looked for redundant patient identification processes. As in the radiopharmaceutical therapy, we felt this was important since you were dealing with a therapeutic need.

As we talked about, most patients were intercavitary or interstitial. Consequently, they have an ID bracelet which can be nicely used and matched with their chart to come down with the patient or with another mechanism, billing process. Often brachytherapy involves such a close relationship with the physicians and oncologist or surgeon or whoever is aware the patient the patient has talked with him on numerous occasions and can positively identify the person as being the correct patient.

Often in brachytherapy there will be pictures of the individual's face, moreso in teletherapy, but sometimes in brachytherapy, which can be used as some sort of additional identification mechanism, of the patient, particular implant in a particular area, and we viewed that area as part of the followup or part of the treatment.

There are a number of different ways this is being done.

No. 7, unintended deviations are identified and evaluated, identical to the radiopharmaceutical instance. Regulatory guide 4.7 under A-2 talks about after a brachytherapy dose is administered, a qualified person will make, date, and sign a written record in the patient's chart or equivalent describing the administered dose. There are adjustments in the treatment regime often, since there are sometimes combinations of teletherapy, brachytherapy dose. It's important that the total dose be summarized again so everybody knows that what they started with is what they expected at the end.

Item No. 3, personnel instructions, determine the medical use if a problem is identified. We talked about that They're well aware if there are any problems to bring them to the attention of appropriate personnel. Item No. B, record of administered dose and agreement of prescription. If the administered and prescribed dose are on the same sheet of paper and, of course, this is adequate, you can see how closely you matched the two on some sort of document; maybe a separate sheet of paper kept in the same notebook so that you could see what was given and what was intended.

Treatment planning in accordance with prescription. We looked at the method used as the basis for calculating delivered dose. We looked at the program that

was submitted and on-site and tried to see what was submitted and what was being done on-site, medical methods by which this could be done. There are a number of different modalities, radiographs.

The majority of people would do your AP and/or films and calculating it in accordance to the system, input into their computer system if they have one. Radiographs, comparable imaging, like CT possibly. There are a number of different ways that you can find where that source is; known brands, dose tables or other equivalent methods.

Item No. B, procedure for confirming dose calculations are after or prior to completion of the treatment. We looked for a method by which independent calculations were done. If you have a small facility and you don't have but maybe one dosimetrist and a parttime physicist, or only one physicist and not two physicists, if possible, we would like to have independent calculations, but we realize that logistically sometimes it's very difficult to have somebody there that knows how to do the calculations, and it's training.

We'd rather have somebody trained and know what they're doing than somebody who doesn't check somebody else's work. Therefore, if it required only one person to do the check, we would look to see if an alternative method was incorporated to calculate the dose. Now, this method

does not have to be -- often, due to the way things are done, it's very impossible or very hard, difficult to get an exact dose. You can use approximations if they're reasonable. It takes time and effort to sit down and do brachytherapy calculations for interstitial implants, use a large number of seeds.

We realize that, but we want an effort made to independently check that in some manner or mechanism which is relatively accurate or puts you in the ballpark.

Procedure for confirming dose calculations are accurate prior to completion of treatment. We looked for the individual who performed these calculations; physicist, dosimetrist, physician; and when they were performed. On the manual dose calculation, Item No. 2, we looked for a mechanism by which you could verify that there were no arithmetic errors on the dose calculation, that it was a correct transfer of data from the prescription, from the table, graph, nomagrams. A mechanism by which you could go through and confirm that the calculations, at least the implicator put in that calculation was correct.

Item No. 3, computer-generated calculations, we looked for a mechanism by which you could confirm dose, examining computer input to determine the proper input. A lot of the errors that are reported to the NRC regarding misadministrations are related to simple arithmetic or data

transfer problems, not so much the actual calculation itself when it's performed.

The simple things seem to be getting people. We also looked for your method by which you would calculate doses to a key point manually and compare that with the computer calculations. So you could pick out any point in your software or any point in your treatment plan and possibly do a quick-hand calculation to see what sort of dose you were receiving at that point.

Then when it came to Item No. 4, computer and manual calculation, we looked at verifying if you're going to combine the two, make sure your input is correct; that if you're using part of your manual calculation from your computer output -- for example, if you're using -- if you have your dose that you want to a particular organ, let's say your treatment plan is all set up and you need to calculate the timer, you want to make sure the dose calculations are right and know what your output factor is.

Software is very programmatically -- there's so many different types of software and different ways to do it, but often it requires a second calculation, how much time do you leave the machine on or how many linear accelerator -- how many monitoring units to administer.

For remote after-loading devices, as I mentioned, we've only found one facility, at least the group that I was

with, that had an after-loading device, but they did not treat any patients during the period of time that the pilot program was conducted. So we didn't review that, though we did look at some of the paperwork. But we would have looked at the method of dose calculation, verification of treatment time, verification of dose calculations, verification of patient setup.

We're curious as to the information that was transferred from the software to be used on the input console of the after-loading machine, and also time calculations, verify what the sources were, moving at the rate that they were prescribed, verification of these sources. As in brachytherapy, after-loading devices were placed properly in the configuration that was required, but we did not really test that particular part because we didn't see any people that were treated during the testing period.

On the teletherapy medical use, we looked for, again, the medical use indicated, authorized user, oncologist reviews each case, or physician under the supervision of an authorized user.

As I mentioned earlier, there were a lot of people reviewing each particular case and there were a lot of actors, often a lot of physicians and hospitals, large medical centers, chart rounds, morning rounds, whatever you

might want to call them. They review each case and monitor it. They might review the case once a week. This mechanism was fully acceptable.

Prescription made. A prescription is a written directive or order dated and signed by an authorized user or a supervised individual under that physician, which includes the total dose, number of fractions and treatment site. We also looked under the treatment plan for the treatment modality, the treatment volume for the nuclear area that had been identified for treatment, and the portal and field arrangement that was used for that particular treatment.

So we're looking at pretty much patient charts, the examples of patient charts, where we would go through the identification process of each fraction, the cumulative summations, changes in the programs which would change the prescription. And we looked for once a change in a prescription occurred, so you needed to change your treatment process by which you're administering total dose or number of fractions, that a prescription change was made in that chart by an authorized user or supervised physician under his direction.

Diagnostic referral, again, does not apply to teletherapy. Objective No. 4, instructions understood by responsible individuals, as we mentioned, confirming the above, committing to the regulatory guide would have been

acceptable, or an actual instruction in your procedures to the individuals in the training process, that if there are any ambiguous or unclear requests, please bring it to our attention.

Objective No. 5, medical use in accordance with instructions. We looked for procedures to detect error in the daily cumulative dose and any prescription changes. Current practice is or medical practice is -- includes a weekly chart check, which seems to be the most common mechanism by which people review the treatment process for that particular patient.

We looked for these chart checks to be performed weekly and to look for errors in the daily cumulative totals, addition errors, dose summations, any prescription changes, any changes with modifying devices, injection of a wedge, smaller field sizes, changes in portals, changes in fractionation dose, anything that changes the total dose or prescription.

We also looked to see if this sort of mechanism for catching any errors was deceptive. We felt pretty happy in the sense that a lot of people already were doing a lot of these weekly chart checks and doing a very nice job of it. This was already incorporated in their quality assurance program. Some people went to great lengths to identify the problem, find the root cause, document it,

tabulate, collate, trend, and try to lower the number of mistakes.

For problems they identified in the treatment and at this review process, this weekly review process often was done by a physicist; dose calculations, dose checks were done when the physician reviewed the charts; the dosimetrist, the technologist often would be involved in the weekly chart check problem, whether in the morning or possibly in the clinic where they would go through random charts.

We also looked for understanding of the current procedures in the facility, the content of prescription, exceptions to the patient's emergency condition. If it's an emergency, a prescription is not required. You want to get the patient treated as soon as possible, then you need to document shortly after what the prescription is or what was given to the patient. Patient identification process; clarity of unclear records.

The patient identification process in teletherapy, let me go to the next slide and we'll talk about that. This redundant mechanism involved, again, some other possible alternative methods that we have not already talked about. Tatoos were often used on individuals. Templates could be used and matched up with the tattoo lines; pictures, photographs, polaroids of the individual's face, and/or

treatment sites.

Throughout the treatment process, initially and later on, since we had inpatient and outpatient, the inpatient appeared to be nicely met with the ID and also with the physician contact and diagrams and the treatment chart as to what area was being treated.

The outpatients, you don't have your patient identification process with an ID bracelet, but certain people did have billing cards. When you would check into the clinic, the patient would have to sign a log or identify themselves to the receptionist. The technologist often would come out and ask for that individual by name or have them sign a waiver or document of some form or another who they were.

So this redundant process was often being performed and a lot of individuals weren't really aware that, verbatim, they had a redundant process, but they did. No. 7 objective, unintended deviations identified and evaluated. As in the other three treatment modalities, this is the same regulatory guide at 2.3 under A-2. It addresses after administering dose fraction, a qualified person shall make, date and sign a written record or equivalent describing dose administered. In other words, you're just writing into the chart what has occurred. So you're just documenting what you delivered, what dose is given, what

time is used on your machine.

Discrepancies identified if there are any problems. Again, this comes up in the chart checks. Often there is documentation in the clinic where individuals would find a problem and write it down, ongoing on a daily basis. We looked in your program to see if you had some sort of QA program intact that was already doing this, and it appeared that a lot of people were doing it in their program and were doing it on-site.

The record of agreement with administered dose and agreement with the prescription, again, is on your treatment plan or on your chart, patient chart so that you have a nice summary of total dose given or fractions given and prescribed dose. So your agreement is evident.

Objective No. 8, the treatment planning is in accordance with the prescription. We looked for procedures to confirm dose calculations are accurate prior to completion of treatment. If possible, a person under the supervision of the authorized user, a qualified individual by definition in Part 35, this is just somebody who has the background and training, if necessary, would check the dose calculations.

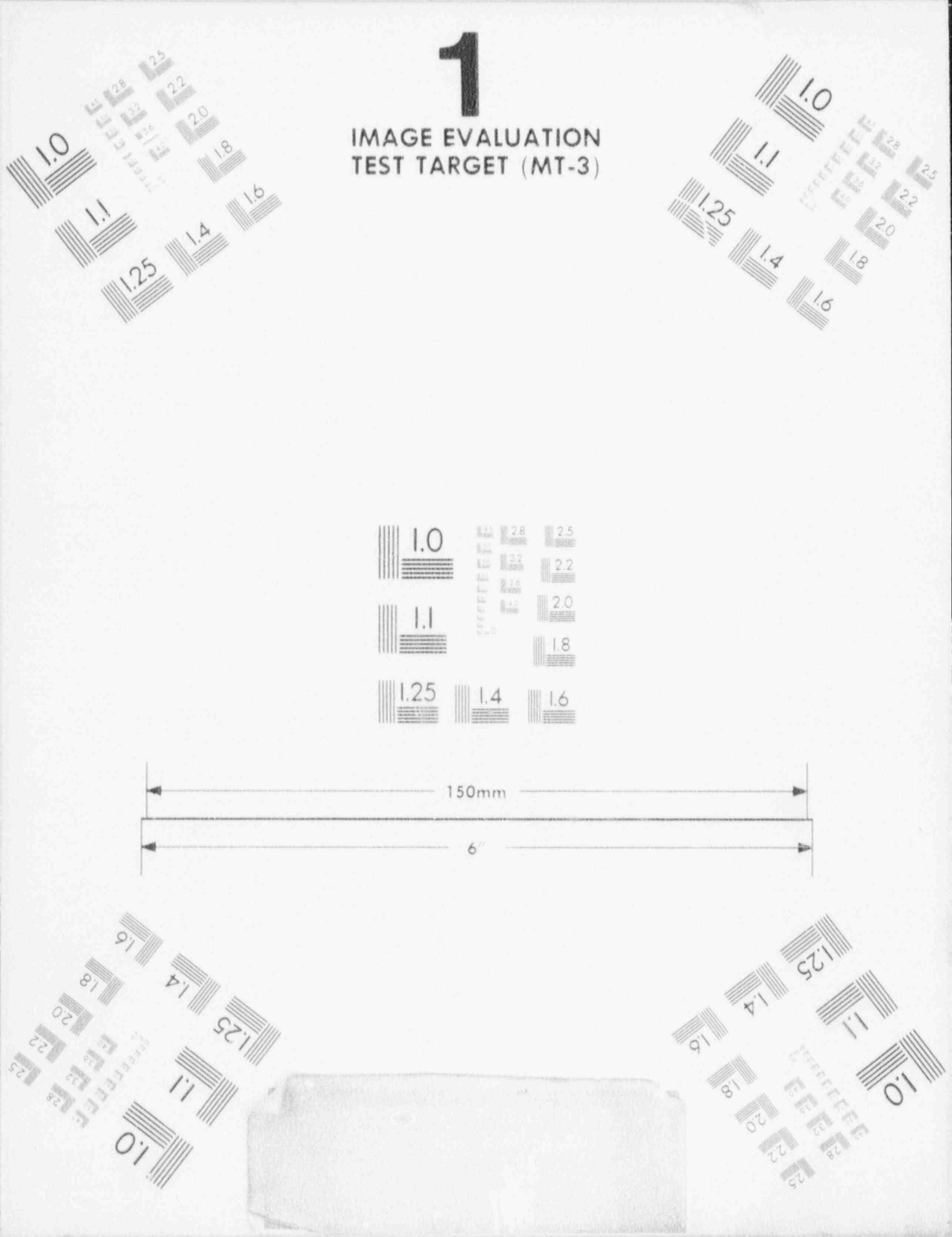
Again, the dose calculation checks do not have to be a full-blown-out three-hour calculation down to plus or minus half a percent. We're talking possibly a check that

involves a rough calculation, not too rough, but within a reasonable tolerance because we don't want you giving such a rough calculation that you would be outside your plus or minus ten percent, which we'll talk about later, which is a therapeutic misadministration.

But we want some sort of mechanism by which you can confirm that that dose is somewhat accurate. Item No. B, independent check of full calibration measurements required by Part 35.632. That section requires a check of your calibration measurements whenever you change your source, which is already a Part 35 requirement. I'm sure the agreement states have a similar set of requirements in their program.

If your spot checks on your teletherapy differ by greater than plus or minus five percent, you would want a full calibration done, but in this case you would want an independent check of those full calibration measurements. The independent check can be done a number of ways, but we realize that it's hard to find physicists, it's hard to find people that can do this sort of work.

There are TLD services which are offered which can give you a relatively reasonable estimate of your output of your machine. There are also independent physicists in the area which can come in and measure the output of your machine. We would prefer that the individual, when they do


1
IMAGE EVALUATION
TEST TARGET (MT-3)
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150mm
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this output check, would not use your same instrumentation.

If there is an error in your electrometer, you can have the same error repeated. So you would want independent equipment used during that calibration check. Full calibration includes check of the beam of modifying devices. A lot of people are doing this sort of thing in their annual calibration process.

We looked for measurements to be performed on wedges. Wedges are often dropped and the configuration changes. Though they appear to be the same year after year, sometimes people buy new wedges. Sometimes, not often, they'll get changed between machines and you have a different wedge factor.

We looked for a measurement of the wedges and trays. They're not much different than trays. There is some difference in different plastics and different properties; holes, cracks, what have you. It does influence output a little bit, but we looked for some sort of check on the full calibration process of the trays, compensating material. It could be bolus, things of this nature.

We looked to see if there was some factor that was used and there are different thicknesses of bolus people can make. We realize the different configurations and they're all patient-specific, but for a particular thickness, generally people can measure the output and get a

transmission factor that would be applicable to most cases.

Block material. Block would be in the sense of blocks that were sent with you teletherapy unit. There are different ways you could do that. You don't have to do direct beam transmission. You could do film, you could do densitometry, or some way to quantitate and qualitate how much radiation is going through that material, so long as you know what your transmission factor is for that material.

We looked to see if that had been done during the calibration process. Item No. D, procedure to measure output. We were looking for anything that falls outside your annual calibration; unique treatments, body treatment, changes in SSDs that are outside of the measured SSDs, field sizes, beam modifying devices if you're using something to interject between the beam that you have not measured before, split-beam devices not being used, or any unique situation.

You would want to measure the output to verify that what you're giving is what you think you're giving. Most facilities were doing this and appeared to be routinely done whenever there was a non-routine treatment.

Item No. E, before first use or after source change, computer program does dose calculation check against physical measurements. Acceptance testing was a very complex and also a very time-consuming process. For

software packages, we don't look into evaluating your program to see if you do a full-blown-out examination of the software and test every conceivable field size, every conceivable depth, and every conceivable configuration.

We looked just to see if you picked out a depth or a point, measured it, and then did the plan on your computer and checked to see if there was a reasonable correlation between the two doses. So there a number of ways that could be done. We just want to make sure there is some check done. How you do your acceptance testing is, of course, up to your facility and we're not into critiquing the software companies and finding out which one is more accurate than the others. We just looked for a simple check if depth dose calculation using the treatment planning system versus an actual physical measurement.

Now I want to talk quickly about the facility statistics from the site visits. We looked at five private practice facilities, which included two diagnostic, three teletherapy, and one brachytherapy program. We also looked at 13 hospitals that ranged in bed size from 150 to 1,000 beds. We reviewed 15 diagnostic nuclear medicine facilities with an average workload range of 180 to 7,500 procedures per year. We looked at small and relatively large departments.

The Team reviewed 12 radiopharmaceutical therapy

facilities with an average of three to 52 procedures per year. Often a facility with diagnostic would use therapeutic and we'd break these down accordingly. They're not separate facilities. Some of these facilities could be all inclusive in one.

The Team looked at five brachytherapy facilities with an average workload of 40 patients per year. We also looked at eight teletherapy facilities with an average workload of 30 patients per month, approximately 4,500 treatments per month.

I'd like to talk about the results and how they matched with the objectives. I guess we're looking at the bottom line here, after all this rhetoric of going over the same review criteria.

The first bargraph is an evaluation of the eight objectives in nuclear medicine with 15 facilities. The facilities meeting the objectives are over here on the Y axis. Your X is Objective Nos. 1 through 8. There's a legend, the cross-line. The QA Team looked at your program you submitted to the NRC, we evaluated it, critiqued it, and documented whether or not we felt your program met the objective as defined down here.

Then we also went on-site and reviewed your program you submitted against what you actually were doing in practice in your clinic.

Objective No. 1, 15 out of the 15 facilities appeared to have no problem with that objective. No. 2, you'll see, is a small number. It's two for Objective No. 2. A prescription is not required for diagnostic nuclear medicine. That's why the darker site audit is not there. Nobody was writing a prescription for a diagnostic referral. That's your option and discretion.

The problem with the diagnostic referral on Objective No. 2 regarding the program review, why all 15 didn't meet that objective was that the contents of the sample that was submitted in your program did not meet, verbatim, the definitions. If it did meet one of the parts of that definition in Part 35, then the entire objective is not met.

Also, written changes possibly were not addressed. If your diagnostic referral would have been changed, how did you document it. That was not addressed in the program. Objective No. 3, four or five or six, seven -- if you would look over under radiopharmaceutical therapy, you see the same legends. You see also Objective 2 had a similar problem.

The prescription definition, as in Objective No. 1, as in Objective No. over on the diagnostic end, was not being met verbatim. The different parts of the prescription in the program and on-site were not completely filled in.

And there were some good reasons why certain individuals didn't include everything on their prescription.

For example, if you did therapeutic Iodine procedures and you only had capsule form Iodine, most people felt it was a little crazy to have to list the physical form of the isotope that was used if you always used the pill form all the time. So there were certain facilities that did not document something that was very obvious to them.

Objective No. 3 appeared in the diagnostic area to be a little more closely met. No. 3 over here does not apply because the pharmaceutical therapy is greater than 30 microcuries of Iodine-131. Over here, this is less than.

The other programs or the other objectives, if you look at them, appeared to be met on-site. Those programs that were submitted do not really address them in your quality assurance package. So we found a lot of people were doing things either that they were unaware that they were doing, or they were aware they were doing it, but they just did not document they were doing it in the quality assurance package.

MR. HIDALGO-SALVATIERRA: Are we allowed questions?

MR. KLINE: Yes.

MR. HIDALGO-SALVATIERRA: Can you explain to me again the difference between the dashed and the black bars?

MR. KLINE: Sure. The dashed bar is in the legend. It's a measure of the programs that you submitted to NRC. the QA quality assurance program; it's a measure of how the Team evaluated that program and felt that it met the objectives.

MR. JANICE: Evaluated before you went out and actually went on-site, correct?

MR. KLINE: That's correct. Before we went on-site, we reviewed everybody's program as a team and we sat down with our checklist, that we talked about in the beginning, and looked at each objective and looked for a roadmap on your QA procedures you submitted or just found it reading through it, to see if what you submitted addressed Objective No. 1 in writing.

So we spent a lot of time going through each program to see if, on paper, you looked at who the authorized user was; did an authorized user or a physician under the direction, the supervision, did he review the patient prior to administration; or was there a referral that was made; whether or not you addressed those particular issues as they were all defined in Objective No. 1.

Now, this rule is what they refer to as a performance-based rule. Instead of being prescriptive, which you're very used to in the past, it was performance-based. The prescription tells you verbatim you have to do

it this way. You have to put down the isotope. You have to put down the quantity. You have to do this, you have to do that.

This is now saying tell us in a broad sense how you're going to ensure that you treat the right patient. Then we let you decide, based on your needs and your program, how that can be done. The Team's mission was to amend this broad definition and without being too confined, define what are the minimum requirements in that objective to meet that objective that you have to do in order to ensure that that is done, which gives the latitude for a lot of different mechanisms to be used, a lot of different ways that you can ensure that the proper patient is treated.

But that's the main difference and that's why we reviewed your program prior to going out. Then once we got there, we looked at it and tried to find out, well, did you meet the objective or did it appear that it was not met. But the objective could be met in a number of various ways. There is no absolute right or wrong way to do the number of things.

Did that answer your question a little bit?

MR. HIDALGO-SALVATIERRA: Does that mean that the taller the black bar is, the better they are, better than what they believe they are?

MR. KLINE: You could say it that way. The black

bar means that you did it. That means that five of these facilities for Objective No. 1, they wrote in their program how they were going to do something, and then when we went to visit, they actually did do it. So the black bar means not so much that you did it better, but you were actually performing what you were expected to do for that objective.

It means that the black is good. If you look at the two, the black is good.

MR. JANICE: In this case, the good guys wear black hats.

MR. KLINE: Objective Nos. 1 and 2 on the brachytherapy was nicely met. Objective No. 3 did not apply because that's a diagnostic referral requirement and we're talking brachytherapy. Objective No. 4, the problem there was that it was not addressed on the program review, though it was actually being done, professional training, common sense, that people felt it was not necessary to be redundant about it.

MR. JANICE: I have a problem with Objective No. 3. You say a diagnostic referral does not apply. But how does one know that that patient is actually coming to them for treatment? Is there not some type of referral that has to be made?

MR. TELFORD: That's correct, there is. We define

--

MR. JANICE: So, in essence, there was some type of referral made that you're not indicating.

MR. KLINE: Well, the referral, if you send a patient over for treatment, over to the hospital to an oncologist, at that point a prescription is made. So what we were looking for -- a diagnostic referral --

MR. JANICE: Still, you see, that leads me to believe that the oncologist routinely goes around the floors looking at the charts to do self-referrals, if he doesn't have some type of referral slip coming to him.

MR. TELFORD: This is just a matter of definition here. What you're saying is that the patient gets referred for therapy. We're just not looking for that. We're looking for a prescription for a therapy patient, whereas for a diagnostic patient we're looking for a referral. It's just a matter of the way we divide the patients and made a definition for both types. What you're saying is true.

MR. KLINE: I think we're looking at the semantics of it.

MR. FELDMEIER: I don't think it's entirely true, because there are such things as self-referrals in radiation oncology. If you have a patient that you treated for lung cancer and you're saying you continue to see on an outpatient basis and evaluate, and if you determine that

patient has some central nervous system symptoms that need evaluated and you initiate an NCT or an MRI, and you determine the patient does have metastasis, at least in our practice, we would go ahead and treat even without the medical oncologist or the neuro-oncologist or somebody doing that and determining that the patient has --

MR. JANICE: In your radioactive therapy you're going to do the same thing. If you start following the patient with metastasis, you're the one that's self-referring. He's not going to have a prescription coming from the doctor. So, in essence, that should be up here somewhere because they didn't have one.

MR. TELFORD: Prescription is a directive dated and signed by the authorized user. In Dr. Feldmeier's case, he is the authorized user. He's right. So you get a therapy patient, we're looking for what we're calling a prescription; a written directive signed by the authorized user.

MR. KLINE: Part of that process can be referral, as you talked about, but the bottom line is the authorized user or a physician under his supervision has to write a prescription, has to designate what he's going to do. We felt that there were problems with orally going down the hall, hey, let's go ahead and give 180 more today, let's give a boost. You don't encourage that because there will

be mistakes in that area.

If you look at all these objectives, in summary, it appears that a lot of people are meeting the objectives on-site versus the ones that appeared on paper were not. So people were doing more of the objectives on-site than were documented in their QA program. I guess the areas which might have been some problem areas were with patient identification, documentation that there was a redundant system in your program for meeting the prescription definition.

Are there any questions at this point?

[No response.]

MR. KLINE: John is going to later on talk about each objective and go into sections of the objectives and discuss what you feel might be more appropriate or what we can do to improve that definition of prescription, what we can do to change the content of the objective. We want that feedback.

This evaluation is a living document. It means that what we've reviewed here can change based on everybody's input. So you'll be authors to this work once it finally comes out. That means that what I have up here is not already set. What we've gone through is an evaluation program, but the final results will be based on the feedback from the group. So I don't want you to be

misled to take the regulatory guidance is the way it's got to be done or the objectives have to be done this way.

It is based on everybody's feedback and that's why we have these meetings, to get this feedback and see if we change things and make them a little better and more in line with the current medical practice that's more reasonable.

MR. TELFORD: Thank you, Ed. Let's move to the next item on the agenda to hear from the volunteers about your summary, your experience. Let me say a word about the timing. We'll go at your speed. If you want to go fast, we'll go fast. If you want to go slow, we'll go slow. So don't pay all that much attention to the timing. We have done these workshops prior to today and they all have different timing. So let's not be a slave to the clock.

I would like each person to take three to five minutes and tell us about some things. You are the folks that took this proposed rule, you actually tried it in your facility for 60 days. So we would like to hear from you about your experience, any observations that you would like to make after having done this, the extent of the work, the extent of the changes you had to make to your existing quality assurance program, the delta incremental costs for work that this caused you, basically anything that you'd like to say about the proposed rule that you would like to tell us based on your 60-day trial.

We'll start over here with Ray.

MR. FOSTER: Yes. First I have a comment, or a question, I guess, on all the eight objectives. Are you looking for a monitoring system that will cover like the JCO ten-step unit program? When we did one, we did our objectives. I tried to do it that way and it became really, really involved and extremely time-consuming. How are you documenting this? How do you want to see the documentation? The hospital or clinics will have certain policies and procedures related to what their supposed to do now to identify patients.

But how would you like that documented to improve that type of thing if you're using other than a requisition? We do it, but how do you want to see it documented?

MR. TELFORD: That's a real good question and doesn't have a short answer. We'll have an answer for each objective. So as the workshop unfolds, I think you'll get an answer for all those, but keep in mind this is supposed to be a performance-based rule. So we list these eight objectives as a good thing to do, but we have certain definitions, like prescription or referral that would define and answer to each of the questions which you could ask about each of the objectives, like what do you want me to do for having a prescription; what do you want me to do about patient ID. We'll get into all of that.

Would you like to tell me about your experience?

MR. FOSTER: On many of the objectives, we combined it. We have an existing QA program that covers a lot of the diagnostic. It only covered diagnostic nuclear medicine and I went over some of the teletherapy that we performed, but I didn't get really involved with it. We did not perform any brachytherapy.

On No. 1, with the appropriateness of the exam survey, we had that covered in our own QA program. We followed the ten-step QA program with JCH and where we had the threshold to make 100 percent. All the patient requisitions and clinical information matched up. That became involved.

And some of the other ones, like 2 and 3, were combined as into one. That's how I changed the monitoring system. I found it useful to try to combine as many of these things as I could instead of having each one separated, if you understand. In our institution, we require written and oral referrals on all radiopharmaceutical procedures. The patient just can't come in. We'd have to get an oral referral from a physician so that was documented.

All radiopharmaceutical therapy requires consent forms, where the patient had to sign the consent. So that would easily verify patient identification.

The same thing with No. 4. That was also done -- that was also defined in No. 2 and No. 3. That was covered also by the appropriateness of the exam.

MR. TELFORD: Overall, just drop back a time-step and say I did this for 60 days, I tried it. What was it like? Was it terrible?

MR. FOSTER: No, it wasn't terrible.

MR. TELFORD: What was the incremental work that this cost you as compared to your existing program? How about delta cost? What observations would you like to make in general about having suffered under this thing for 60 days?

MR. FOSTER: The cost wasn't that significant, other than my own time. It did take quite a few hours a day to collect the information. The way we monitored was each patient had a log sheet and we documented, a checkmark system to make sure we covered each area, then those were all combined, and a summary was made of that. That would be involved. That took a lot of time of the technologists. That's where we came into some problems.

Overall, the objectives that are listed are usually covered and it was not that difficult to do.

MR. TELFORD: Any other observations you'd like to make about that trial period?

MR. FOSTER: Not really.

MR. TELFORD: Okay. Thank you.

MR. HAMMOND: Like Ray, we looked only at diagnostic and our operation is kind of unique, not being a hospital or a fixed facility. It's a mobile service. So we had some unique aspects, and we verified certain things as prescriptions and those types of things. Fortunately for us, we had a pretty involved quality assurance program ongoing because of the Joint Commission requirements for client facilities.

In general, I have a problem with the use of the term "QA" for this program. It has presented some problems in some of our hospitals. Basically what we're talking about are minimal standard operating procedures. If you call it a QA program, you're going to have some nurse run down to administration that says, oh, that's mine. Then you're going to have to teach her, and unfortunately she's not here today. So I have a problem with it really being a QA program. It's more standard operating procedures.

If we're going to call it a QA program, it's kind of a mandate on the problem. Instead of coming out here and trying to correct problems after they happen or tell me how many problems did happen, that's establishment of standards, those kinds of things.

As far as resource use, I just say that our QA program is fairly involved and mostly computerized before we

began the program. So we anticipated some 300 to 500 hours per year in order to do the program, the initial evaluation involved, and the requests that we received, and the creation of additional reports and some minor programming changes in order to make the program work.

It's hard for me looking at the misadministration report that Mr. Pollack sent to me. It's hard to go to somebody, particularly my client facilities, and say you've got to start doing this, and they say, well, why is it a problem, and you say, well, in one one-hundredth of the procedures done, there is a potential problem for misadministration or some misuse in the diagnostic nuclear medicine arena.

Eight years of information that a lot of this stuff is based on. Your chances of any kind of problem are relatively insignificant, particularly in the diagnostic arena. The other problems we're going to have particulary with this is just that; is educating the small facility out there as to what they need to do, and we're doing five studies a month, how much we can do.

I had some of these comments before the meeting, kind of informally with David, where he said we have to convince people this is a guide, not a mandate; that this is not a procedure for inspection or licensing, but it's actually a guide. There should be a great deal of

interpretation as to what fit.

I like the fact that it's not a prescriptive program. It tends to be more like the Medicare and Joint Commission things we're already used to, where they say here's the standard, now you tell us how you're going to meet it, as opposed to saying here's the five steps to meet it.

I think overall it's probably a giant step forward in the way regulations are done, that we have something that's less prescriptive, that we have an opportunity to be involved before the final rules are proposed.

It's not going to be that expensive for us to do, but I think the cost is a relative item based upon where we already are.

MR. TELFORD: Is that all?

MR. HAMMOND: Yes.

MR. TELFORD: Emory?

MR. JANICE: I really don't think there was much expense involved because it was already in place. Most of what we did was already there. We did have some of the physicians involved by sending the prescription over with a patient, instead of just having the receptionist pick up the phone and order it.

But when I was asked why are you doing this, I use the gallium/thallium thing; I said fine. If you ordered

thallium/gallium, we give your patient valium, what are you going to do. That cured that. I did have one that wrote a prescription on a piece of toilet paper and said here you are. I said fine, I'll put it in the patient's chart; the Regulatory Commission comes and inspects that, we'll see ya.

He wrote an official prescription later. We actually started about three weeks before it took place by informing the receptionist what was taking place, and that kind of stuff. The radiologists were very open to writing the prescriptions on anything with Iodine because it was a good way of CMA.

If they wrote it out, then we should not misunderstand what they wrote down, and calling it in, there should not have been any mistake. The verification of treatment patients did sign. So all in all, there wasn't that much -- what is done actually is really curtail the use of anything over 30 microcuries of Iodine-131.

That's about it.

MR. TELFORD: David?

MR. BELLEZZA: My program covered brachytherapy and teletherapy. If anything, the pilot program objectives reaffirmed our own philosophy that's been going on for quite some time. The QA that we had been doing was essentially covered by the essential elements. In doing the program, we

deleted certain ones which we disagreed with.

The cost, therefore, of the program was negligible. It didn't put any extra burden on us. One thing that struck us was the review by management didn't seem to be necessary since the people that were doing the QA were people that were qualified to evaluate it and to bring management in when they really didn't understand. All they wanted to know was is everything fine.

Other than specific things of the essential elements that we'll talk about later, that's all I have.

MR. TELFORD: Nellie?

MS. KELTY: Our program was diagnostic nuclear medicine procedures. Essentially we had no problems with the program. My only concern going into was having to request all referring physicians to give us written referrals. Radiologists that we work with preferred not to request a written referral and change their diagnostic patterns at that time, and just to document how many were sending us written referrals and how many weren't.

It varied one month from 70 percent that we did receive referrals on to 50 percent in another month. Cost involved was minimal. Basically, it's second nature or inherent in the quality assurance that was already done. I guess one thing that I saw represented in the bar graphs was trying to document in writing some of the things you do

seemed tedious and on-site they were actually picked up, but getting them on the paper was difficult to do.

You just thought it was trivial. Of course, we verified the patients and then we checked the date and whatever it might be. I wasn't aware that we had changed the Iodine-131. I thought it was still all Iodine-131 greater than 30 microcuries, so that was something of concern to me; not specifically for this particular office, but for other offices where we do use Iodine, so I'm glad to see that change.

MR. SHAFFER: Our program encompassed nuclear medicine, teletherapy and brachytherapy. For the most part, it was not a lot of time, minimal cost associated with a change of our existing program. Primarily with nuclear medicine and teletherapy, our program already covered the objectives with minimal changes.

Specifically in nuclear medicine, all of the objectives were basically met with our existing program. The same with teletherapy; our existing program didn't really need to be changed.

The brachytherapy department was probably the hardest to just meet some of the objectives specifically. With a written prescription, it's difficult to get the therapist to write a specific prescription for a patient. In that sense of the word, we do write a directive that a

particular patient is going to receive X amount of seeds, but as was brought up at the last workshop, it's very difficult to tell how many microcuries or whatever a patient is going to receive. So we somewhat deleted that from our program and included what we were using, which was basically a log book from the radio room, that Mr. Jones or whatever is undertaking X amount of seeds to surgery, and when he gets back, say he did use or didn't use what was the total prescription for that patient.

Those are really the only areas we needed to change. As Mr. Kline was saying, we realized that after -- upon the site visit from them, we realized that a lot of the program that we didn't think that we had met with our QA program, we did, but we hadn't written it into the program. So subsequent to that visit, we have kind of rewritten some portions to outline things that we did do.

But all in all, we didn't have to do a whole lot to change our program.

MR. TELFORD: Brandy?

MS. WALKER: Our program was in nuclear medicine. We originally felt that we met the criteria. I don't know what you all found when you reviewed it, but we did not make any changes in our QA program. So it didn't involve any additional cost the way we were doing it.

We do have a written prescription. I don't know

where that came from. It's a stamp we fill in and after we review that, consult what form it will be in, how much will be administered, and signed, and then the tech, when she does the study, writes down what was administered and signs it.

MR. FELDMEIER: We have sort of a unique situation in that we practice in a freestanding center with about six different private practice groups, a university practice, and sometimes the whole systems works about as well as the United Nations. It never ceases to amaze me, actually, that we get the patients treated pretty well and things like quality assurance and professional staff meetings and things like that are often not too dissimilar from Saturday night wrestling on TV.

But I think taking all that into account and trying to look at how we initiated the program, and also I want to remark that as a freestanding center, we don't come under JCH regulations, as yet. I found sort of a couple problems with our program.

I think, first of all, as one of the other gentleman mentioned, this really is not -- if it's not a quality assurance program or a quality assurance program is a poor name for it, I think it at least represents only a small part of the quality assurance program.

And I think that one of the tasks that we have to

do in the days ahead is to integrate sort of the professional component of the quality assurance program into this portion, which is regulated and supervised by the NRC with the appropriate state agency for states that aren't NRC states, because I think in and of itself it really isn't a small part of the whole picture. It's an important part.

Another comment that I heard this morning that I think is maybe worth sharing with the group -- as a physician, maybe I can do it better than others and I can appreciate it, in our group, since we have so many different philosophies of practice -- is that I think one of the things that can be helpful about this is it gives the physicist, radiation safety officer, or technologist sort of tool that they can use as some leverage with the physician to require them to document things.

It's not necessarily the physicians who are practicing poorly or don't want to do things in a controlled situation that oftentimes, because they're going in 14 different directions at once, time is of such a premium, it sometimes takes a little extra leverage to force the physician to sit down and write something or document something or allow someone else to document it.

So I think that's advantageous. I think I'm getting off the point a little bit because the point is what was the incremental increase in our effort, financially or

in terms of man hours. I wanted to put some of those preliminaries in there to sort of give some perspective.

I think looking at our program, what we did is we went out and hired a second year medical student to act as quality assurance monitor for the time of the 60-day trial period. I think it's fairly obvious to me that to have a total quality assurance program, including the regulatory aspects from the NRC, that we need a fulltime quality assurance monitor. I think that's really the only way to do it.

And I think in a radiation oncology practice, that person should be preferentially a technologist at least who has had some years of experience in the clinic and has some perspective. I don't think we could go out and get an R.N. off the street who has never worked in radiation oncology, I don't think we could go out and get some sort of administrative type, I think we have to have someone with some clinical expertise.

To go on salary rate for a RTT in the community, some experience, is probably somewhere around $30,000, something like that. So I think if you're question is what's the expense, I think probably the biggest component to the expense would be the salary for such a person who could be the quality assurance monitor.

Again, I want to say that the NRC portion of this

is just part of the overall quality assurance program. I think in terms of additional man hours spent, I add myself or a chief technologist or a chief nurse, the other physicians, probably on average this would be something on the order of ten additional man hours, person hours per week.

So I think that in terms of additional expense, in terms of additional time spent, we're talking about probably one fulltime person, and among the other key players in the whole thing, probably each an hour to an hour-and-a-half per week. Once the program was set up and going, we're just attending to the documentation and having the necessary quality assurance meetings and interactions.

MR. MOK: I want to say that what he said I do agree with him. I especially want to emphasize that we need a fulltime person to monitor the quality assurance program. In the trial period, we had a second year medical student and we do learn a lot from our data collection process.

We find out, for example, that some of the second checks that have been done before the first working date and it hasn't been done for some reason, and for some reason skipped checking that second step. So I think that having a person is just to look at the charts and find out what is supposed to be done and make sure that step is done and make sure that patient is confirmed or verified.

What the program is designed to do is very valuable and I would highly recommend it. The second comment I have about the program is that we are in a very special situation. We treat both private and academic patients, like Dr. Feldmeier represents the academic portion of the patient that we see in our institution, and there are about seven or eight private physicians who see patients at our center. We have a freestanding center.

Besides that, we also do dosimetry for brachytherapy. Our center does not have any inpatients at all. All the brachytherapy is done outside of our center, except the high dose after-loading. So we tried to combine the quality assurance program into our existing quality assurance program here.

For example, some of the brachytherapy that they have done in their hospitals they send to us and we use it; it takes an afternoon or maybe even days, and they don't usually come with a prescription. The physician never comes to our center. So the brachytherapy is done by oncologists or other fields of medicine.

So we would not be able to get a prescription until the very late stage of the treatment. The computer dosimetry to have a second check before the completion of the treatment is sometimes almost impossible for us to do that.

So in terms of that, we may not be able to comply to that specific area in brachytherapy. I think that we might represent a very small group in the whole country that has this problem, but we do have a big problem.

MR. DADARI: Our program involved diagnostic nuclear medicine and therapeutic nuclear medicine. Most of these items were already in our QA programs. We didn't have too much problem to implement this program, except a few items, especially requiring the prescription from outpatients.

It's very hard for us to ask that and most outpatients are walking in for bone scan or thyroid scan, and if you just wait and find out where is the prescription or where is the doctor, talking to the doctor is very hard for us. It's very costly for us. Sometimes you have to wait two hours till you find the doctor on the golf course and ask him if he wants this or not.

We have to rely on our secretaries and the doctors' secretaries to take their order. Sometimes our patients, like Ed's and John's patients, are chemotherapy patients or cancer patients. We have rely on our common sense. A patient coming in for a bone scan, we have to -- we know the history of him, we know it's a bone scan.

That part of requiring a prescription from outpatient diagnostics is very hard for us. I believe it's

costly. The other cost probably is documenting an obvious thing, common sense, which we do generally every day. We have to document those and it takes a lot of time for us.

But some other parts we find some problems which are very routine and it involves the clarification of the orders. We do a lot of osteoporosis and sometimes patients, the doctor sends the patient in for a bone scan and he means osteoporosis scan which does not involve any injection of isotope. We find that kind of stuff -- we find that sometimes the doctor writes liver function test or liver scan, or lung scan.

Of course, most of these are inpatient and we don't want to wait on those and clarify. Basically most of our misadministrations, which we've had just one or two the last seven or eight years, were from unclear orders.

MR. TELFORD: Patricia?

MS. WOOD: We reported on all three of the different areas, but my most interaction was with nuclear medicine. There are two facilities, two hospitals who recently merged and the larger one does more nuclear medicine.

We did experience one misadministration where the tech didn't verify the order, but then the doctor wrote an order, so it was covered. So it technically wasn't a misadministration.

But overall, pretty much all the objectives were met beforehand. It wasn't anything new or anything that they aren't currently practicing in normalized standards. No change.

MR. BRAHMAVAR: All the eight objectives that covered all the four programs; nuclear medicine, radiopharmaceutical therapy, brachytherapy and teletherapy. Almost 95 percent of the objectives that were proposed in the pilot program were already in place at our institution under the broad license and two teletherapy licenses.

So we did not really change our program as it existed. But what we did when we submitted our comments, as well as the program for evaluation, we cross-referenced each of the objectives, where they could be found in our own program. So there was not any incremental work in this 60-day period.

The cost itself, there was no incremental cost because there was no incremental work that was identified. As a part of the QC program and the radiation safety program, it was centralized for the entire hospital. All radiation use is centralized under medical physics and radiation safety, and we have been very fortunate in having staffing.

If I need to categorize how much staff is allowed to do our QC and radiation safety, then my estimate is about

two FTE equivalents doing the QC and radiation safety related to these four programs.

Thank you.

MS. LaFRANCE: I work with the brachytherapy and the teletherapy. As Dr. Brahmavar has mentioned, all these programs have been instituted at our hospital and were just done routinely. So the only thing I did find confusing was on the treatment reports, getting statistics in that manner.

We normally do it based upon patients, which is much more -- it's not as lenient. That's the only thing we found a little difficult, because everybody that was involved into it interpreted it in a different fashion. So it was hard to get that.

Otherwise from that, everything was just routinely done.

MR. HIDALGO-SALVATIERRA: Our center is a freestanding facility. We participated in brachytherapy only. We treat about 100 to 110 patients a day, mostly with linear accelerators. But this program, participating in this program, it was an opportunity to also focus a little bit more on the quality assurance aspects of the linear accelerators.

We have QA program, like many institutions. They have a QA program. The problem is implementing the QA program. It's nice to say, yes, we'll do that, but when it

comes time to review it, you realize that you're not really doing it like you wished you would do it.

Our QA program is lower for the whole center. It is divided into the QA program for the linear accelerators and brachytherapy; the QA program for the clinical aspects; and, the QA program for the treatment aspects, treatment services. We have a responsible person for each one of them.

One is responsible for the QA on the linear accelerators. There is a physician responsible for the clinical part. The head supervisor of the technologists, she is responsible for the QA on the treatment services. So we all work together.

But participating in this program, we were able to make more emphasis in the things that we wanted to do, we were not able to do because some resistance on the part of the physicians. The big problem is physicists try to convince physicians. You have to have physicians working with you. If you don't have physicians willing to participate, the program will not move or, if it does move, it doesn't move properly.

The chairman of the overall QA program is a physician and he worked with us on this project. That's one of the reasons we were able to implement some of the objectives; for instance, the prescriptions. In a

freestanding facility, some of the brachytherapy don't belong to the same center. They belong to some other doctor. For instance, a liver implant or a bronchial implant.

The lung doctor, he has a patient and he wants to implant the iridium wire in 192. So he calls the physics and he says I need a iridium wire here in 192. Before about a year ago, the physicists from that institution would go to a hospital and put the iridium wire, and they was very little participation of our radiation oncologists. It was kind of done between the lung doctor and the physicist.

But now we're not doing it that way. Thanks to this program, now we are able not to do an implant of 192 unless the radiation oncologist writes a prescription. If he doesn't write a prescription, we won't go. We were trying to do that before, but it was kind of difficult. Doctors didn't care. This gave us leverage to convince them, because we had a physician also participating in the program.

Now, how did we extend it to linear accelerators? Because I wrote a memorandum saying from now on no dosimetry calculations are done without a prescription. It's not enough to say no treatment can be done without a prescription. There shouldn't be any dosimetry calculation done unless a prescription is made.

Now, if the doctor gives the dosimetrist an order, a verbal order, you have to allow the physician to do that because sometimes they just don't have time to do it. But the dosimetrist has to write a prescription in pencil and within a period of time the physician has to come and sign it and date it.

In our case, it's 24 hours. But you cannot also be too restrictive. You have to give the physician a certain amount of time, a reasonable time. We have two facilities and sometimes they are at the other facility and they cannot write a prescription at a particular moment.

We found participating in this program really gave us an opportunity to have the courage to enforce what we wanted to do before. And now we are doing it.

MR. TELFORD: Is that it?

MR. HIDALGO-SALVATIERRA: That's about it.

MR. TELFORD: Terry?

MS. ROY: I'm from a nuclear medicine facility that is freestanding. We only do cardiac work, so it was only technetium and thallium used there. The state that I'm in, Florida, we have very strict state regulations from the HRS which oversees everything else on our staff qualifications, ordering of our doses. We go with only unit doses, so we don't have a generator there.

They are very strict in recordkeeping in Florida.

So to follow along with the recordkeeping for this program was very easy. We have a computer system in our department where everything is logged in automatically every morning. Our patients are scheduled, the referring physician is in there, the reason for the testing, the prescription number of the dose, the amount, everything.

So everything is already record-kept already in the computer. So when the state comes in, the state sees this and you pass with flying colors. The program, this program is covered doubly with that.

The one thing I did find a little bit of difficulty with was getting the prescription from the physicians for ordering the tests. We normally take the prescription over the phone, the referral over the phone from the doctor's office.

I asked the offices to cooperate with us and get the doctors to write a written prescription. I'd say 80 to 85 percent of the time, I had no problems at all. They have to write prescription to send the patient to a hospital or to send them for any other procedure, such as an x-ray or anything like that. Other diagnostic centers request this. They had no problem in doing it.

If a patient forgot the written prescription when they showed up at the door, we got on the phone, called the doctor's office and had the nurse read the order from that

patient's chart. So we double checked ourselves there.

We instituted a patient ID number, being the Social Security number. We have an age group in Florida, on the west coast of Florida, it's very elderly. You ask for John Doe out in the waiting room and you're going to get three people that stand up because none of them can hear.

So the only way to check it was for them to repeat back to us their Social Security number, because we may really have three John Does out there. So that was the only way to be sure of it. We instituted that and we've had no problems with patients coming back to the department being the right patient.

The cost of the program was minimal. Like I say, we only do cardiac work. We're a small facility doing up to 100 scans a month. So the cost was minimal to us.

I found it worked very well.

MR. BENNETT: I come from a small to medium sized hospital and we were participating in both nuclear medicine and teletherapy, diagnostic pharmaceutical or therapy pharmaceutical, brachytherapy, and the teletherapy.

By and large, most of the work that we perform is teletherapy and most of that, for external beam I should say, most of that is accelerator and not Cobalt. During the trial period, we only had a minimal number of diagnostic nuclear medicine scans performed because typically we only

do about ten a month.

There were no therapeutic pharmaceuticals given during the period of time. There was no brachytherapy done during that period of time. So obviously most of what we're involved with is teletherapy.

As far as cost is concerned, I found that most of the cost involved was my time in reviewing the current procedures and making certain that they complied with what it was that you wanted them to comply with. I have to agree with Dr. Feldmeier's comments about this is really just the beginning of a process that needs to be done in quality assurance within any department.

We have extensive quality assurance programs in all four areas. We've implemented them for quite some time. We also decided that it was necessary to have somebody monitor th equality assurance program and have hired an individual to assist us in monitoring all the aspects of it. I have to agree that I think that her involvement specifically for these regulations would be in the order of two hours a week.

The only problem that I had with any of the program was going through the recommended reg guide, the guide that came with it, and some of the suggested things that were there. I didn't agree with the terminology in some cases and that's just the way that we say things. Some

things that you were saying meant something totally different to us. So I had to deal with that to some extent.

Other things were in software verification in that some of the recommended things were totally out of line with either what we were doing because the software required certain information, and I don't see any reason why I should have to verify additional information when we already do plenty of things. So all I wanted to do was to reword your reg guide so that it complied with what we already did.

Overall, I think it was something that is needed. I do think that it's already being done, as statistics are proving out or your audits are proving. I personally would like to see, being that we weren't one of the review sites or the inspection sites, how we met the written procedure aspect of it. What we said we were going to do, did it really meet what you were hoping it would do? Were we in compliance with what you were hoping to get us to write or not. So some feedback there would be good, I think, for all institutions that weren't actually reviewed.

The only problem that I have with this I have already stated at the early meeting, is that it only begins to touch on the things that we need to do and you aren't even beginning to -- because your authority, line of authority is limited to teletherapy and most of our patients are accelerator patients, it doesn't apply to that.

Certainly we are going to cause it to go over and we'll bring those patients in and we'll include it there, but there won't be anybody monitoring that because our state is a non-agreement state and they don't have the staff, personnel to review that kind of thing.

So in a way it will have some impact on that program, but all of the auditing of it will have to be done internally.

MS. GOODWIN: I found most everything that he said to be true. We did have -- most of this program was already in place and I really didn't have any trouble initiating anything since most of it was in place.

It did take a good bit of time to review the program that we had and how it met the objectives. I thought some of the terminology, I disagreed with some of the terminology, and I think that's just a matter of understanding. I think we discussed that in our previous meeting.

That was more or less discussed at that point, and I think that's been remedied in some of the things that we've sent in. Documentation and auditing of the program are probably going to be the most time-consuming parts. I think we're hearing most everybody say that.

Our state is an agreement state and very strict with what we already had to do, and most of it was already

in place. The Joint Commission is just now beginning to look at therapy. We participated in the brachytherapy and we, as I said, have linear accelerators. We let that carry over into our linear accelerator program using some of the same criteria that was in this program.

The Joint Commission is really just beginning to look at that, and I think this will be helpful to us in writing our QA program to them. But I found that it was already -- most of it was in place.

We do still have trouble getting written prescriptions from physicians, but this gave us a little leverage and we're working on that. I mean, referring physicians for diagnostic procedures. We have an inhouse radiation oncologist and that is no problem. He is very aware of QA and helps us with the program considerably.

We have two physicists. So cross-checking is not a problem.

MR. TELFORD: Thank you all very much. I draw your attention to the next item on the agenda, which is the program evaluations. We'll pass out the program evaluations at this time.

I remind you that if you get a checksheet for just a program evaluation, keep in mind that we did not go through an intricate process that we would do if this were licensing. So if we didn't find what we were looking for

there, we just checked the box need more information about something. So please don't feel bad about that. Don't take that as a derogatory remark.

It's just that's what we found and we sort of expected that. But the ones for the sites that we went to, if you're asking the questions, you'll find the answers. So as the figures showed, when we came to the pretrial workshop and we asked you to go out and build a program which met the objectives, for the vast majority of those 18 and the vast majority of the eight objectives, indeed, you were more than able to do that.

But if you have questions about these or there is a program evaluation or a site evaluation and we have folks here, Mr. Kline or Mr. Nelson or Dr. Kaplan or Dr. Tse, and please feel free to ask. Dr. Kaplan passed a form earlier about clarification of your facility, your hospital or clinic, and its participation in this program. Please fill those out and give those to Dr. Kaplan before we go to lunch, if that's at all possible.

I would suggest that we break for lunch at this time. We'll all remain here for a few minutes and answer your questions and make sure that we're available for those questions, and come back at 1:00.

Dr. Kaplan has an announcement.

MR. KAPLAN: I would just like to mention that for

those of you submitting reimbursement forms, we cannot take copies. We need originals of all your bills. You should have gotten a form like this in the mail. I do have a couple extra ones. Please; we're coming to the end of our fiscal year, so that we would like to process your requests within two weeks. Get it in to us in that time. You'll get your reimbursements rather quickly. If you don't get your requests in within two weeks, it will take a lot longer.

Thank you.

MR. TELFORD: Let's go off the record.

[Whereupon, at 11:52 a.m., the workshop was recessed for lunch, to reconvene this same day at 1:00 p.m.]

AFTERNOON SESSION

[1:02 p.m.]

MR. TELFORD: Welcome back. The first thing this afternoon, we'll go into proposed 35.35 objectives and all parts of that. We'll start with the purpose paragraph. When you see the words that I'm going to put up on the viewgraphs aren't descriptive of the actual words, the actual words you will find either in the handout that we gave you at the pretrial workshop, which I see many of you have, or we have a copy that was published in the Federal Register. So if any of you need that, stick up your hand and we'll give you a copy of all these things.

You'll need the Federal Register Notice. For instance, for the purpose paragraph, we should be looking on Page 1449 of the Federal Register Notice, about halfway back of this handout. This is the Paragraph A that says each applicable licensee shall establish a quality assurance program, but what I have on the screen are the basic ideas of the program. Detect the source and cause of errors and to provide confidence that errors will be prevented; to require each licensee to establish a written basic quality assurance program to prevent, detect and correct the cause of errors.

It's a performance-based requirement. It's not prescriptive. You had this morning that -- maybe we don't

want to call this quality assurance. We want to call it something else. So instead of calling it a basic quality assurance program, what would you like to call it? We said basic because we know that, just sort of focusing on a small subset of the quality assurance a hospital is doing in all of the areas, but we're open.

MS. WOOD: Isn't it just a quality control program?

MR. TELFORD: Quality control program.

MS. WOOD: Instead of quality assurance. It's one part, everything you do for the whole program.

MR. TELFORD: You can think of it as quality control because these are the -- at least in the objectives, those things are the good things to do of trying to ensure that the administration of the byproduct material is as prescribed. So you could think of them as quality control steps, whereas you might think of quality assurance as the paper trail that proves you've done the right steps.

MS. KELTY: I'm thinking more in terms of performance management. These criteria almost seem to be more performance. I think of quality, quality of image, quality of care given, quality of diagnostic interpretation, patient management. So is this separate from that? This is kind of the mechanics of following the prescription, making sure that what we said we would give we administered it in

the way that we said we would. It's just the mechanics versus the quality in that perspective.

MR. TELFORD: This is not about giving good pictures. It's not about the quality of care. It's about medical use and that term is defined in 35.2 of the Federal Register -- I mean the Federal Regulations, 10 CFR Part 35.2, currently says this is the administration of byproduct material. It's not for research. It's treatment or diagnostic use.

I'm trying to make sure I understand your suggestion. We're saying we're focusing on medical use, it's focusing on the steps required to actually deliver byproduct material. So it's performance assurance.

MS. KELTY: In my mind, I guess working with the Joint Commission and the quality assurance programs, it's almost the bottom line that you've got to focus on, and that is patient management, interpretation, and the steps to do that are all done properly.

To me, these objectives are almost more mechanical procedural things, not so much quality.

MR. TELFORD: Ray, do you have something?

MR. FOSTER: I was just thinking. I was looking at minimum performance standards and the medical use and application of radioisotopes. You are looking at performance standards.

MR. TELFORD: Performance standards.

MR. HAMMOND: I think the performance idea is a good one, but I hesitate to use the word standards because it goes to a regulatory item. Maybe performance objectives for medical use or some kind of thing like that. I don't particularly want to say quality or assurance in there, but these are kind of objectives or performance guidelines. If they're minimum performance guidelines, you have to meet these minimum guidelines in order to be in compliance. You can always do some other version, but at the minimum you've got to meet these guidelines.

Anything except QA, because that opens up a whole can of worms. Anything that is called QA, it necessarily has to follow through a said change. If you create it at a department head level or department level, it's got to come through that department review through the quality assurance program, to medical staff, to the governing board of the hospital. It has to by definition.

Under the definition of Medicare, everything that is quality assurance has to go that far. Some of this stuff may need to go if it relates to an undesired outcome of the patient. If it's just routine performance evaluation, it doesn't necessarily need to go that far.

MR. TELFORD: Okay. So somehow we should focus on performance standards for prevention. Anybody have any

ideas?

MS. WALKER: Performance guidelines.

MR. TELFORD: For prevention.

MR. FELDMEIER: I think the only risk, and I agree with the arguments that have been brought forth, certainly in an institution that comes into JCH guidelines, when you say quality assurance, it sets off a whole standard series of events and reports. People outside our field, outside radiation oncology, nuclear medicine, and they have different concepts. There is confusion.

If you completely divorce it from quality assurance, though, some of the arguments that we have had, I think properly a lot of this belongs to an inhouse quality assurance. It's not the sum total of things that need to come in a quality assurance program, but things here are pertinent to a quality assurance program.

I think if we call it performance standards or performance objectives or something like that, I think there should be a phrase in there that says that this obviously would be a portion of an overall quality assurance program for nuclear medicine, clinical activity or radiation oncology.

I think in our zest to distinguish this from a quality assurance program, because it's not the sum total of quality assurance program, I shouldn't completely divorce

it from that because it is an essential part of that.

MR. TELFORD: If we can call it a performance guideline and say it's part of a QA program, but this it not it.

MR. FELDMEIER: Right. It's not the whole thing.

MR. FOSTER: Am I correct to assume that all eight of these objectives are simply to prevent misadministration? They only cover basic misadministration. Would it be prevention?

MR. TELFORD: Let me hold that question till we get to those objectives, because, in part, I can say yes and, in part, I can say no. Any more thoughts or suggestions on what we call it?

MR. BELLEZZA: I would just call them minimum safety standards. The bottom line is safety.

MR. TELFORD: Yes, it is.

MS. RAY: Something to do with a misadministration.

MR. TELFORD: We're saying errors in medical use. Misadministration is an error of a specific magnitude. If we're after preventing errors in medical use, wouldn't it be nice to catch an error that was a small one before it became a misadministration?

MS. RAY: A performance safety guideline.

MR. TELFORD: Performance safety guidelines.

Okay. We're getting there.

MR. HIDALGO-SALVATIERRA: You said it. It would be nice to catch an error. You will never prevent errors. There is no QA program that would prevent errors. The purpose of the QA program is to detect them before they cause any damage or sea of damage. I don't agree with the word preventive. I think it should be something else, because you're not going to prevent them.

MR. TELFORD: Is it too strong?

MR. HIDALGO-SALVATIERRA: No. The purpose of a QA program is not to prevent the errors. It's to detect them, like you say so.

MR. TELFORD: It says provide a confidence.

MR. HIDALGO-SALVATIERRA: That the errors will be detected. You're not going to prevent them.

MR. TELFORD: Not prevent them?

MR. HIDALGO-SALVATIERRA: The errors will continue to be made all the time.

MR. TELFORD: Let's say for a moment that it said the objective is to provide high confidence that errors in medical use will be detected.

MR. HIDALGO-SALVATIERRA: Before they cause any damage to the patient.

MR. TELFORD: Then we're really saying the same thing.

MR. HIDALGO-SALVATIERRA: No.

MR. TELFORD: No?

MR. HIDALGO-SALVATIERRA: I don't think so. I don't think you can prevent them. Just an opinion.

MR. JANICE: If you're going to detect an error, you're going to prevent the error.

MR. RAY: Sort of logically, if you saw it was a mistake, you wouldn't do it.

MS. RAY: If you saw that it's a mistake, it's already been done. It's already happened if you see this as a mistake.

MR. TELFORD: This is after the fact.

MR. BENNETT: No. He's saying if you detect an error, you haven't prevented it.

MS. RAY: It has already happened.

MR. BENNETT: You've just detected that it's there. So you're back to preventing misadministrations, it sounds like to me.

MR. TELFORD: I'm just trying to grasp your thoughts.

MR. HIDALGO-SALVATIERRA: No matter what you do, errors will be made. You have to have a criteria on a certain threshold, a criteria to keep the errors within certain limits, and if they reach a certain threshold, then you have to take some actions to prevent them from

repeating.

MR. TELFORD: Are you suggesting that we sort of quantify high confidence to establish a threshold; that a certain percent of them be detected?

MR. HAMMOND: I think that Oscar is right. At first glance, it may be too strong a word because you're not going to be able to prevent it. But what you're talking about is the governing a cyclical program. You're going to have ten problems the first time, then eight, then four, then two, and one. So essentially the program will not prevent every error, but it will prevent errors if you do all the elements of it.

If you do the checking before the patient gets there and as you cycle through, you will eventually prevent errors.

MR. TELFORD: So through the iterative process of auditing and making sure that the program is still effective, you iterate year to year to constantly improve, if we're focusing on detection and we detect we've got ten problems the first year, and fix those that we think are big deals; then we discover we've got eight problems the next year. So we're constantly getting better. So in the end, we are preventing reoccurrence of errors in medical use.

MR. FELDMEIER: I think the whole fallacy of all quality assurance programs is that if you do this long

enough, you create prevention, you identify a certain number of indicators, you work on those for a while and you fix that problem. Then you have another set of indicators. So if you do this long enough, you're going to achieve perfection. Realistically, that's never going to happen.

I think what you have to say is to modify that to make it a realistic statement and still to achieve the goal that we're all shooting for. I mean, we would like to have perfection, but, realistically, a perfect human situation, we're never going to have it. We need to say something like to provide high confidence that clinically-significant errors in medical use will be minimized.

MR. HIDALGO-SALVATIERRA: Minimized, yes.

MR. FELDMEIER: I don't think you can use absolutes. You can't say prevent, you can't say errors. I think one of the fallacies of a lot of the regulations, it's fairly easy to quantify things. In a quality assurance program, you consider indicators as fairly minor little things. You consider an indicator that on the chart every patient's middle initial should be recorded. We can go back and audit 100 charts and say, well, gee, five out of the last 100 charts, the patient's middle initial wasn't recorded on the chart.

You can work on that, and then once you get that to 100 percent, in the overall management of the patient

situation, it doesn't mean anything. So I think somewhere in here in this program, a quality assurance type programs, we have to be able to distinguish between things that are easily quantifiable but relatively insignificant as far as the patient's management from things that are sometimes kind of nebulous and hard to define and hard to set standards, but really are clinically significant.

If I were going to rephrase that No. 2, I would say something like to provide a high confidence level that clinically significant errors in medical use will be minimized.

MR. TELFORD: How about detected and minimized?

MR. FELDMEIER: That's fine. You have to detect them before you can work on correcting them.

MR. TELFORD: Let me ask when do we stop in this perpetual pursuit of excellence. We iterate each year, is there a stopping point.

MS. RAY: We can only be perfect if we're God.

MS. WALKER: As long as there are humans involved, there are going to be errors. No matter what the rule says, somebody is going to mess up. None of the things in here, we were all following these and have followed these and there are still occasional errors in misadministrations.

MR. TELFORD: Do we build into our purpose statement the statement that says to achieve this threshold,

if we're this good --

MS. WALKER: Ninety-five percent or something like that.

MR. JANICE: If we get to where we are perfect, there is no need for the NRC. There will continue to be errors.

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

[Discussion off the record.]

MR. TELFORD: Back on the record.

MR. BENNETT: Why can't we go with the concept that's already been accepted as low as reasonably achievable?

MR. TELFORD: That's okay, but it's not significantly different than saying provide high confidence. I still don't know when to stop. Maybe that's what we're after.

MR. BENNETT: You're not going to get any reasonable person in this room to tell you that we will do it within one one-thousandths of one percent. I wouldn't even say that we'll do it within one percent. The definition of what's reasonable, I think, is more appropriate.

MS. WALKER: Also, if you put a threshold, aren't you going from a guideline to a strict regulation, where the

inspector is going to come and say you went outside this number?

MR. TELFORD: If we put in a threshold that says instead of provide high confidence, it says provide confidence that 99.9 percent of all errors in medical use will be detected. We can't say minimize because now we've stated what's going to happen. You would have to apply the acceptance criteria to each institution.

I'm merely asking is that what you'd like to see or would you like to see more of that qualitative statement as long as reasonably achievable, it's kind of a qualitative acceptance in some cases. Where you can't quantify, we've had certain working rules, like you could spend a thousand dollars and prevent one man rem or person rem, then spend the money.

We've had working rules like that. There was hand up over here.

MR. MOK: I don't think you can put a threshold. How could you measure the errors before you can detect them? Let's say you wanted to cut down or prevent an error less than 99 percent. How could you measure something that you couldn't detect. I don't think it's realistic to put a threshold. I think the word "minimize" would be sufficient in this case.

MR. TELFORD: So you would say provide high

confidence that errors in medical use would be detected and minimized. Logic is hard to measure.

MR. MOK: Yes. It's impossible to measure the amount of error.

MR. TELFORD: Any other comments on our purpose paragraph?

MR. FOSTER: The bottom line, we're still looking at QA. The terminology, we're talking indicators, we're talking followups. That's QA. I guess we are saying different terminology, but basically it's QA if you use the term threshold and monitoring errors. What other terminology is there?

MR. TSE: I just want to mention with respect to the term QA, basic QA, think about it this way. Suppose you never be in the program. You are someplace in an institution and then come up with a term called minimum performance standards or minimum performance guidance or minimum safety standards. What do you think that term would imply?

Would it include all those calibrations, teletherapy, or other kind of safety, proper dose to the patient, dose to the workers, etcetera. I'm thinking in terms of if you adopt those terms we just discussed, it sounds like we would avoid certain problems with the term QA, but it may create some other kind of problems.

I just wanted to throw this out and make this known to you.

MR. HAMMOND: I would agree with Tony. If you're talking about just that title where you've got the rest of the guide back here that says what the components are of those guidelines, I don't see that we're going to create any real new problems.

MR. TELFORD: Is that all the suggestions on this part?

[No response.]

MR. TELFORD: Let's go into the specific objectives. We're going to take these one at a time. Let's take the first one.

Medical use is indicated. What would you like to do with this? Would you like to delete it, modify it, or retain it?

MR. HIDALGO-SALVATIERRA: May I ask a question?

MR. TELFORD: Sure.

MR. HIDALGO-SALVATIERRA: Why does the NRC have to regulate the use for the treatment of a medical condition? Why?

MR. TELFORD: Are you focusing on the patient's medical condition?

MR. HIDALGO-SALVATIERRA: Yes.

MR. TELFORD: Let me see if I can rephrase your

question. You're asking why are we focusing on the patient's medical condition at all, implying that we shouldn't do that.

MR. HIDALGO-SALVATIERRA: No. I'm asking. Why does NRC have to regulate -- why do you have to make sure that we make and use these indicators? That's the physicians. You're in the field of the physician.

MR. TELFORD: Okay.

MR. JANICE: As I remember the first meeting, the NRC wasn't there to play doctor.

MR. TELFORD: Right. Wait a minute. You said it was a question and I'm obligated to answer. We are regulating medical use. We absolutely want to stay out of the practice of medicine as much as we can. That is the judgment of the physician.

Now, if you want to say you don't need this, you want to delete this, okay. If you want to say it's not required, it doesn't get us anything, okay. But I've tried to answer your question. What I will do here, maybe you're really asking another question.

For instance, why do we have this at all in our list of objectives. It's a good thing to do that some thought process should happen before somebody should decide, like the authorized user should decide that this patient is supposed to get a byproduct material or radiation. So this

is a logical first step if somebody decides that that should happen.

If you say you don't need it, okay.

MR. JANICE: I agree with Oscar to an extent. Regardless of what we might feel is a medical use, all we get is a diagnosis that comes from the admitting diagnosis. If the patient comes in with ingrown toenails and the doctor says he's going to get a liver can, he's going to get a liver scan regardless. There is no way you can say that that's medical use by that criteria.

MR. MOK: I agree that somebody should look at the medical use as indicated for a patient's condition. What you are trying to do is you're trying to look at this condition for the user, for the authorized user and send out the user, test for any drug use or any other disciplines.

If there's nobody else looking at it, why should they be singled out for this? The physicians ask us, nobody looks at the chemotherapist, nobody looks at the radiologist, why are we singled out as a radiation user to be looked at by NRC?

And I don't think the NRC should look at a medical use. I mean, somebody should, I agree with you, but the NRC should be looking at the safe use of radiation.

MR. TELFORD: Okay. What's the next step? What do you want me to do with that?

MR. JANICE: Take it out.

MR. TELFORD: Okay.

MS. WALKER: I don't think the NRC should be looking at it. It's the patient's physician that decides in the first place that it's necessary for the patient's condition. Maybe he's wrong. We've already looked at it. But once again, it's back to the basics; that it is medical practice and the NRC shouldn't look at it.

MR. FELDMEIER: I think a way around this and probably accomplish what you want to do is do exactly what the particular objective is saying. I think there are very valid arguments in this. I don't think the NRC should interject itself into the medical profession aspects. Nuclear medicine or radiology oncology is to say something like that. It is anticipated that the proper medical indications for the use of radioactive isotopes will be monitored by the appropriate quality assurance agency or something like that, and essentially by pointing and saying that the NRC is not going to do it and say it's within the realm of somebody else, you're reminding people that that should be done.

MR. TELFORD: Anybody else?

[No response.]

MR. TELFORD: Any volunteers? I'm waiting for somebody to tell me, when you said we could do without this,

what if we had this --

MR. JANICE: The last thing said modify it.

MR. TELFORD: That was a punt and I understand that. If we say we're punting, we're taking out of it --

MR. FELDMEIER: Not really, because I think that gets into your subsequent points. In my mind, and maybe I'm approaching this very simplistically, I've looked at the NRC's role in this and I've looked at the proposed 35.35 objectives as being a part of an overall quality assurance program.

I think it's beyond the scope of the NRC to regulate the physician, the professional medical indications, part of the overall quality assurance program. But since this is an integral part of an overall quality assurance program, by saying that those aspects are the purview of another agency, of a quality assurance program, some type of peer review, the professional staff at the institution in question.

And then by saying that once that is done and these other things follow, you're sort of putting the whole thing into perspective. Saying that once it is monitored and that there is a regulatory board that is looking at the appropriate application of this modality in an individual patient's case, once that's done, then a written prescription should follow. There should be documentation

according to the objectives that are proposed.

MR. TELFORD: Let me followup here. Part of what Dr. Walker was saying is that if you have a referral here, then maybe that's evidence that this was done, or if you have a prescription. To take the logic one step further, if you have logic, then maybe that's evidence that this was done. Therefore, this was necessary.

Which physician do we want in the loop? Don't we want the authorized user in the loop somehow?

MR. JANICE: The authorized user --

MS. WALKER: The authorized physician is the only one that can write the prescription.

MR. TELFORD: Okay. I think we'll get there.

MR. JANICE: You've already said that you owed Oscar an answer a while ago. I'm going to want an answer, too, then. What was NRC's thinking of putting No. 1 in there? Why did the NRC want it in there?

MR. TELFORD: Because it's a logical first step that the authorized user should decide this patient should get the byproduct material or the radiation.

MR. JANICE: They already have when they picked up the phone and said I want so-and-so to get this.

MR. TELFORD: That could be a non-nuclear physician making that reference. We would like the authorized user in the loop, but that's kind of a sideline

of why did we do this.

MR. JANICE: I think that the authorized user is in the loop when he signs his name on that line.

MR. TELFORD: If he does.

MR. JANICE: What do you mean if he does?

MR. TELFORD: Like in referrals, diagnostic cases. In all cases, does the authorized user sign?

MR. JANICE: When they sign the dotted line on the report, he is in the loop.

MR. TELFORD: That's after the fact. It's after the administration. I mean, I answered the question. I confess that's why we did that. We wanted this whole process to happen. We thought it was a good thing to do. These are eight good things to do.

As I told you at the pretrial workshop, I was going to be the only one that said these were any good. I'm not claiming this is good today. I'm rather asking what would you like to do with it.

MR. JANICE: From what I'm hearing, then I've got the wrong impression altogether because when I heard referrals and I heard prescriptions, the ones I'm looking at is the one that's referring the patient to us, writing a prescription as to why he wants it and what he wants.

MR. TELFORD: You're getting a written referral signed by the referring physician.

MR. JANICE: That's right.

MR. TELFORD: Let's hold that for here, because we're making a distinction between a referral and a prescription.

MR. HAMMOND: I'm going to take the other side. I'm going to say that we ought to leave it in here. It's not that the NRC is practicing medicine, in my opinion. These are proposed objectives or guidelines. It would be the practice of medicine if the NRC came back and said use these indications for a bone scan, these indications for a lung scan.

All this is saying, in very broad terms, is that one of the requirements, one of the guidelines that you're going to have to have in your program, and you write your own program, and you decide how you're going to practice medicine, is that you will have used some criteria to evaluate that whatever is ordered is for a valid condition the patient has.

I don't view it as a threat. I view it more as just a basic tenet of the program.

MR. TELFORD: It's a basic statement that says we think a thought process ought to happen by some means, use your own criteria. That's just the first step.

MR. FOSTER: Being a non-physician, I guess it's not appropriate to say this, but it seems to me that the

terminology is, again, the problem. When you're involved with medical use, you're getting involved with the medical staff personnel. Medical use; that's the treatment of patients. Maybe changing the terminology, like proper application of radioisotopes in the performance of patient procedure or whatever.

But you're looking at the application of the radioactive material, application of the isotope, rather than the medical use.

MR. TELFORD: We were stuck with this term because it's already defined in the 10 CFR. But what we're saying is what these two words really mean is the application -- administration of byproduct material or radiation, that's the definition.

Unfortunately, that's not the connotation. It's part of the diagnostic step or treatment step.

MR. HAMMOND: If semantics are a problem, if we look at what the Joint Commission says, they have almost exactly the same criteria or the same guidelines in every section of their accreditation manual. The only word that is different is indicated. Theirs says ensure that medical use is appropriate for a patient's medical condition.

MR. FELDMEIER: But the JCH is a different kind of organization. The JCH, by its charter, is looking at the quality of medical care. I don't think that's the NRC's

charter.

MR. HAMMOND: I don't think the NRC is looking at it through Objective 1, either. I think they are trying to establish some minimum guidelines, that it's going to be up to the physician, director, and the administrator of whatever facility they have to establish these guidelines, to decide what is appropriate or indicated for patients that they either treat or diagnose at their facility.

I view it the same way as the basic tenets of the Joint Commission.

MR. FELDMEIER: I think if you're going to leave that statement as is, you need to put some sort of disclaimer on it. I think you need to follow that with a second sentence. The exact professional application and indications of radioisotopes in the patient's management is beyond the scope of the NRC and will more properly be evaluated by professional quality assurance programs.

MR. TELFORD: Or it is up to the discretion of the authorized user.

MR. FELDMEIER: Yes. But I think that statement by itself --

MR. TELFORD: Does the term medical use bother you?

MR. FELDMEIER: Yes.

MR. TELFORD: If we just administration of

byproduct material or radiation --

MR. FELDMEIER: It may be better. I think indicated for the patient's medical condition.

MR. TELFORD: What is appropriate.

MR. FELDMEIER: In that sentence, I think the phrase medical use is the most troublesome.

MR. TELFORD: Okay. We could say exactly what happens is up to the authorized user. You could say that in your own words in the follow-on sentence is what you're really telling me.

MS. WALKER: I think you need to, because if an inspector comes along, this is a very nice guideline, it doesn't say you have to do this or you have to do that, but sooner or later somebody is going to come along and he is going to follow some guideline religiously and he's going to get very sticky on that point.

So I think perhaps the last thing you just said is that it's under the discretion of the authorized user is appropriate because we don't want the NRC, for example, according to what's in the packet.

There are lots of things that are perfectly safe that are indicated in the literature that aren't in the packet.

MR. TELFORD: The package insert.

MS. WALKER: To make it that restrictive is

dictating the practice of medicine.

MR. TELFORD: That's 35.300. Therapy uses, the diagnostic uses have such and such restriction. Since you brought it up, we just recently published an interim final rule which addresses that problem and fixes that problem. We do some things right.

There was a handout here --

MR. MOK: That medical use is a lot of problem. Safety use of radioactive substance and radiation, instead using the medical use, something like safety use, safe application or something like that, because medical use on a patient I don't think is under the scope of the NRC, but the safety use of radiation is.

MR. TELFORD: Okay.

MR. BENNETT: The point has already been brought up that I'm very concerned about this eventually getting drawn into the same problem with package insert; that the NRC is going ot dictate that it can only be used in certain ways. I am enough of a skeptic to believe that that could eventually come out that way.

But another problem is that one group within your organization writes the regulations and another group doesn't seem to always talk with you folks interprets your regulations and comes out and inspects us. With a very big statement like that, how is one of your people that comes to

the field going to be able to interpret whether or not the physician or authorized user is using it properly if they are not of the same background, training and qualifications?

MR. TELFORD: You really asked -- you either made two statements or asked two questions.

MR. BENNETT: I made a statement and asked a question.

MR. TELFORD: Let's go back to your first statement about the package insert. Do you mean for diagnostics or therapy?

MR. BENNETT: Any of it.

MR. TELFORD: Any of it?

MR. BENNETT: I know currently there have been a lot of protests about your package insert comments.

MR. TELFORD: It's not directly related to this, but maybe it's worth talking about. 35.200 says you must follow the manufacturer's instructions. When you're using a generator using a kit, like in diagnostics, that's what it says for diagnostics. The use is not restrictive. Part 35, only in therapy -- currently -- I can't say currently because it's going to change now.

Previously in 35.300 it says you must follow the package insert for uses and routes of administration. So I'm trying to put your comment or question into that context. Both of those have been changed very recently in

response to a petition.

I'm trying to apply that to this, to No. 1. So that if we said be sure that the administration of the byproduct material or the radiation therefrom is appropriate for the patient's medical condition, we'd follow that with a statement that says the treatment of this patient is solely up to th discretion of the authorized user.

In the context of manufacturer's instructions and package inserts, does that fix it? He says no. Okay. Tell me.

MR. BENNETT: I don't think that the comment has any role to play at all. I don't think the NRC should be or needs to be involved in this. First of all, I don't see that you have anybody that can appropriately interpret this and apply it when you go to the field. How are they going to interpret if it is indicated, if it's appropriate use.

MR. TELFORD: You moved to your second comment or question. Let's look at that. For this particular rulemaking, we've done more work toward that end than I've ever done for these rules that I've ever seen since I've been at NRC.

What we are doing is, for instance, we're already developing the criteria that we would use for licensing, the criteria that we would use for inspection. We're bringing in inspectors from Regions I, II and III and the lion's

share of all the NRC licensees are in Regions I and III.

We will have reference guidelines to those folks that are licensing, that will exactly follow the script here, and to the inspectors. We're way ahead of the game on this rulemaking. Maybe you don't -- maybe that's totally irrelevant to you, but we've already started that process. And if there were any other rulemaking, at this point I'd be saying, well, we're evaluating the public comments and we're going to write up our responses and put it in the Federal Register to go with the final rule.

Later on we would do the stuff for standard review plan for licensing or the inspection manual for our inspectors. But in this case we haven't even done the final rule yet and we've already started that.

So the answer to your question is we agree with you completely that that's very important and we've already started that. That's all I can say. I'm not here to challenge your thoughts. I'm here to understand what you want to suggest to me.

So with those two comments of mine, what would you do with No. 1?

MR. BENNETT: Drop it.

MR. TELFORD: Okay. Anybody else on No. 1?

MR. FELDMEIER: An example comes to mind. Maybe this helps me. Let's say there is an orthopedist and, as a

matter of course, every time he has someone come in with a fracture, decides that he needs to get a bone scan because sometime in his career a person sustained a fracture, after minimum trauma, and was later found out to have malignancy. So he's decided that the better part of valor is to make sure that every patient that comes in with a fracture has a bone scan to make sure that this isn't part of a metastatic process, especially these little kids who fall and break their wrists.

You know that it's not appropriate and the guy should be hammered for making that decision. I don't think NRC is the agency to do that.

MR. BENNETT: The authorized user should be reviewing those requests and they're making that decision.

MR. FELDMEIER: But if the request says a 16-year-old patient with a fracture from metastasis, how is your nuclear medicine doctor going to know that the patient doesn't have an established diagnosis malignancy?

MS. WALKER: The point is the orthopedist is practicing bad medicine and the overseers need to get after him, not the NRC.

MR. TELFORD: Okay.

MR. FELDMEIER: I really think that what we should do is say that this responsibility is beyond the purview of the NRC and more properly belongs to other peer review

agencies or financial agencies or quality assurance. I think by doing that you're saying somebody needs to do it, but it's not within the NRC's purview to do this, and we sure as heck think this is a good thing to do and think it's a necessary thing to do and somebody out there should be doing it, and I think you accomplish what you want to do.

You're saying, gee, we're controlling the safety aspects of the application of radioisotopes. We're hoping that somebody out there is looking to make sure that it's the first step in this process. When patients are selected for isotope application, whether it's diagnostic or therapeutic, that there is enough medical indication that they'll have that because there is a radiation exposure and certain potential hazards relating to exposing the patient to isotopes.

I don't think it's for the NRC to determine which cases are appropriate and which are not.

MR. TELFORD: Okay. Anybody else's final thoughts on No. 1?

MR. BENNETT: I can live with the disclaimer.

MR. TELFORD: Are we ready to go to No. 2?

MR. JANICE: Are we going to take an hour for each one?

MR. TELFORD: If you'd like. No. 2 says, in essence, let's have a prescription for therapy. We list

teletherapy, brachytherapy, radiopharmaceutical therapy, or new procedures involving greater than 30 microcuries of I-125 or I-131.

Now, let me hasten to add we're saying prescription as we defined it in the proposed rule. If we go back to the Federal Register Notice, this would be Page 1447, the bottom of the second column, prescription means as follows. A couple of key ingredients. It's dated and signed by an authorized user, not just any physician, an authorized user. After that, you find some A, B, C, D. Those are simply content that we're looking for for teletherapy, brachytherapy, radiopharmaceutical, etcetera.

So we're not yet into diagnostics. We'll pick that up in No. 3 for referrals, not in prescription. So what would you like to do with No. 2? Delete it, modify it, or retain it?

MR. FOSTER: I think just keep it. It's easy for me. I don't use Iodine-131.

MR. TELFORD: Anything you do here, you can work up a definition of prescription and find something there that needs similar action, like a deletion, modification or retention.

MR. FELDMEIER: I think it's pretty good. I think that No. 3 if you put referral or prescription, recognizing the fact that when people read regulations, they don't

necessarily read all the definitions like they should beforehand. It might be less offensive if, in parentheses next to prescription, you put or written direction.

I mean, I have no problem with it as you define it. The only problem I have is that someone reading the regulation without reading the definitions ahead of time, because prescription has such a definite connotation to the physician, that that -- you know, it's a buzz word. It's something that you have an immediate reflex to, and I think you accomplished that in three by saying diagnostic referral, parentheses or prescription, might accomplish the same thing by saying that a prescription or written direction is made for any teletherapy procedure, brachytherapy procedure, etcetera.

MR. TELFORD: Let me offer an alternative. We don't have to use the word prescription. We can say written directive.

MR. FELDMEIER: I think that would be fine.

MR. TELFORD: Then on Page 1447, we would define written directive rather than defining a prescription, that's dated and signed by an authorized user.

MR. FELDMEIER: I think it would make it a lot more palatable.

MR. TELFORD: It means the same thing, has the same effect.

MR. BRAHMAVAR: Also under prescription, you have A, B, C, and D that define what the prescription should include.

MR. TELFORD: Yes.

MR. BRAHMAVAR: I doubt it that every time a prescription or a written direction is given that the physician is going to write what isotope, what dosage, what chemical form, the route of administration. Basically they'll say do brain scan. He is not going to tell 15 millicuries and IV administration and all of that.

MR. TELFORD: Brain scan, is that diagnostic?

MR. BRAHMAVAR: That's right.

MR. TELFORD: We're not there yet. That's No. 3.

MR. BRAHMAVAR: But I'm saying the prescription, in one little word, you have added a lot of details.

MR. TELFORD: Yes.

MR. BRAHMAVAR: And that those details will not be on every prescription that is sent by a physician for every patient.

MR. JANICE: In fact, it is --

MR. TELFORD: Let me turn the question around, because like B, for radiopharmaceutical therapy, the content should include the radioisotope, the dosage, the physical form, the chemical form and route of administration. We're not asking the authorized user to write that. We're asking

the authorized user to sign his or her name, that that's what they want done.

So is that what we should be doing?

MR. BRAHMAVAR: But you're asking them to write all those details.

MR. TELFORD: No. Not write. Anybody else can write. They sign.

MR. BRAHMAVAR: That's what I'm saying. They may just sign it, but nobody's going to write it. The prescribing attending is going to sign, I-131 therapy.

MR. TELFORD: Let's not talk about what happens. Let's talk about what should happen. What is the information content that ought to be in this written directive? Do you mean to tell me that you can have a written directive and not include that information and know what to do?

MR. BRAHMAVAR: No, no. In a written directive, all they are going to say is brain scan.

MR. TELFORD: No, no, no, no. We're not talking about diagnostics. This is therapy.

MR. BRAHMAVAR: Therapy, fine. It's going to say Iodine-131 therapy. That's all they're going to say.

MR. TELFORD: Oh, yeah? They're not going to say how many millicuries or --

MR. BRAHMAVAR: Just talking about the authorized

physician, not the --

MS. WALKER: He's confusing the referring. When they request a study, it's not a prescription. It's a referral. He doesn't write the prescription. The nuclear medicine physician, the authorized user only writes the prescription. He gets that referral and says, oh, let's use ten millicuries, let's use 100 millicuries, whatever is appropriate.

MR. BRAHMAVAR: But that should be written on every patient.

MS. WALKER: We write it on every patient, but that brings another question to mind. If you have a procedure manual and it says for this you will use this amount --

MR. TELFORD: We didn't envision a clinical procedures manual for therapy. We did, however, envision one for diagnostics. As part of your -- I don't want to say quality assurance program anymore -- your performance guidelines, your safety standard guidelines or something, your program, if it had said that -- we're really talking about a standard therapy kind of procedure that you would know what to do for, say, a thyroid scan for the normal case.

It might say thyroid scans are done with ten microcuries. Then you might want to say whole body scans

are done with four millicuries. Therefore, you know what to do. You could write it once instead of every time, but then you would have to have some key phrase defined within your program that the authorized user could use that phrase, sign their name, and then the technologist would know exactly what to do.

MR. TSE: [Inaudible].

MR. TELFORD: The ten microcuries would not come under No. 2. They would come under here. I was just trying to envision how this might work.

MR. HIDALGO-SALVATIERRA: Might I?

MR. TELFORD: Yes.

MR. HIDALGO-SALVATIERRA: I have a problem with the written prescription.

MR. TELFORD: Okay.

MR. HIDALGO-SALVATIERRA: Page 1447.

MR. TELFORD: Yes.

MR. HIDALGO-SALVATIERRA: To me it's not good enough, it's not strong enough.

MR. TELFORD: Okay.

MR. HIDALGO-SALVATIERRA: And I want to give you an example of that.

MR. TELFORD: All right.

MR. HIDALGO-SALVATIERRA: If a prescription means a written direction for medical use, etcetera, by an

authorized user or a physician under the supervision of an authorized user.

MR. TELFORD: Yes.

MR. HIDALGO-SALVATIERRA: What do you mean by supervision? We have many cases -- I review many cases where there were bronchial implants with the signature of every physician that was not an authorized user or a physicist, but was not an authorized user either.

Now, there was no signature by any individual oncologist. What do you mean by supervision? In my opinion, it should be the signature or an initial by the radiation oncologist.

MR. TELFORD: By the authorized user.

MR. HIDALGO-SALVATIERRA: Right.

MR. TELFORD: Nobody else.

MR. HIDALGO-SALVATIERRA: No, no. The physician could have his signature, but when you talk about supervised by an authorized user, he's got to put his initials on that also.

MR. TELFORD: So you should have two signatures or a signature and an initial in that case.

MR. HIDALGO-SALVATIERRA: That's correct.

MR. TELFORD: Okay.

MR. HIDALGO-SALVATIERRA: It's not strong enough.

MR. TELFORD: I understand. Dr. Walker?

MS. WALKER: Under our broad license, there is only one authorized user.

MR. TELFORD: You might have more than one.

MS. WALKER: I believe we only have one. The chief of service. Then, for example, as a physician in the nuclear medicine line, I guess I'm under the supervision rather than being an exactly stated, on the license, authorized user.

MR. TELFORD: You could be on the license. As a nuclear physician, you meet the training qualifications for authorized user, then you could be on the license so you could have that signature authority.

MS. WALKER: The thing that I interpreted this to be was, of course, my residents who are rotating on the service at that time and are being instructed in nuclear medicine as opposed to pulmonary doctor.

MR. TELFORD: Let me ask this question. You just got a new resident, day one of training. Would you let them sign?

MS. WALKER: We do let them sign. They have guidelines as to what amount to use. I would say probably for the first few days on the service, we work very closely with them, sitting in the room and going over what they do. Our residents are intelligent enough that if they don't know what to do, they're not going to do it. They're not going

to just make up some figure, and if they did, the techs would say you made that up, I'm not going to do that.

At some point, you are relying on people's common sense.

MR. TELFORD: So, de facto, you're saying that early on when you're looking over their shoulder, you're not exactly initialing, but you're there.

MS. WALKER: Yes. If it's a brand new person, I'd do it myself and go over each case and show them what the standard doses are.

MR. FELDMEIER: That is how I've always interpreted that phrase, under the supervision of. If someone who is in training that particular specialty but he's not yet achieved the level to be on the license, we have a senior staff physician who hasn't taken his boards yet, so he's not eligible to be on the license or to get him on the license would take a lot of paperwork.

My residents, if they do a brachytherapy procedure, I am going to directly supervise them. If it's the least little bit out of the usual, I'm going to be there and I'm going to do it. I don't make that a pulmonologist independently doing a proctoscopy and putting an iridium wire down a catheter is under the supervision of a radiation oncologist or a radioisotope licensee.

The pulmonologist would be offended if we said

they were supervised by a radiation oncologist. I don't think that should be interpreted that way. Oscar, I think I agree with you completely that that would be very bad practice to have a pulmonologist go ahead and do a procedure like that without having a radiation oncologist right there.

I think that under the supervision of is meant to include just physicians in that discipline, who are rotating in that discipline, who are under the direct supervision of a licensee.

MR. TELFORD: That phrase is defined in Part 35, supervision. It says basically that the authorized user is still responsible, whatever happens, whatever this guy does. But Oscar was looking for some overt steps for sign-off that says you've checked it, you agreed with it. You both said that you agree that you ought to be there, making sure you stop sure of saying we would join that person by initialing it.

Is that just not required or is that not necessary or just too much work or what?

MS. WALKER: I think you're monitoring that with your trainees, and I think, once again, that's the practice of medicine and the education of a resident. The residents repeatedly make mistakes. The tech is not going to do it in the first place. We have the same techs that have been there for 20 years.

But if they make any mistakes, we're going to have to sit down and talk with them.

MR. FELDMEIER: Frequently I do encounter residents. I don't do it [illegible] percent of the time because, for one thing, they have to learn to stand on their own two feet. They have to show an increasing level of responsibility and as they progress through their training and get more and more responsibility, I think it might be somewhat restrictive to require the licensee to sign every prescription, every order.

You don't want to change your staff physician who is not on the license. I trust him to go ahead and write the orders, do the brachytherapy. I know I'm responsible because he's operating under the fact that I'm a licensee under a state license, but I would not want to actually countersign every one of his prescriptions.

MR. TELFORD: Okay.

MS. WALKER: It depends, too, on how important it is. I wouldn't let a brand new resident, I don't let any residents handle a therapy prescription, but a diagnostic prescription, sure. That's my discretion. I would hope nobody would do that.

MR. TELFORD: Maybe one way to look at these is these are minimum standards.

MS. WALKER: No. 2, as you said, would apply to a

total body scan, say five millicuries of I-131. They did fill out a prescription for those.

MR. TELFORD: Do you look at those or countersign those?

MS. WALKER: Since we instituted prescriptions, I would say we have, but only because the resident asked me.

MR. BENNETT: I need some clarification from some of the other users. That is if you have a patient that is sent to you for hypothyroidism and you're going to prescribe 15 millicuries, which would require a prescription, and there isn't an authorized user available, but a resident available, can they sign the request, have that performed, and then reviewed later by the authorized user and signed off? Is that legit?

MS. WALKER: Not in our department.

MR. TELFORD: What happens --

MR. JANICE: Someone has to make the determination they're going to give the 15 millicuries in the first place.

MS. WALKER: Each therapy is done by an attending physician, a staff physician. You talk to the patient. You make sure that it really needs to be done because the referring is sometimes a resident in medicine.

MR. TELFORD: This attending physician is a nuclear medicine physician?

MS. WALKER: Yes.

MR. TELFORD: Okay.

MS. WALKER: I don't know if Parkland let's the residents make that decision, they might. We don't. We're a fairly small department and there's always an attending there, except today.

MR. JANICE: That goes back to what I said earlier about CMA. If your resident, in talking to that patient, retreated, he could have just used 15, but what if he said 30, and signed off on it, it's going to be the user's neck that's going to hang if that patient later on comes back and says something is wrong with him.

MR. BENNETT: I know what I would like to see done, but I would like to know how we are expected to interpret this. For example, same scenario, only you've got a second staff physician, no residents involved, who is not an authorized user. The authorized user is on vacation. You either have another radiologist or radiation oncologist who says, well, my partner is authorized to do this, but he's on vacation for two weeks.

This patient has come 150 miles to receive this dose. We happen to have the dose. Gives the dose to the patient and then has his partner sign for this after the fact. Is that appropriate or inappropriate? Because if he's under the supervision, does he have to be under the supervision immediately?

MR. TELFORD: You mean like within sight? No.

MR. BENNETT: Within the building?

MR. TELFORD: No.

MR. BENNETT: Within the town?

MR. TELFORD: No.

MR. BENNETT: Within the state?

MR. JANICE: I would have thought, if that's a one-man operation, that he has already gotten his license --

MR. TELFORD: You want to say something about definition of supervision?

MR. KLINE: The definition of supervision has caused a lot of concern in the past with the NRC, and rightfully so, because it's a broad interpretation. But at the same time, it can be narrowly defined, depending on circumstances. The NRC is currently reviewing that definition and they are generating the information notice that will clearly define that definition of supervision.

There are other mechanisms. The attending physician is allowed by NRC rules to be a physician that is listed on the NRC license at another facility coming to your facility, the authorized user.

And in regard to your question on what is a reasonable distance or time of response, if you have somebody working under the supervision of an authorized user, this is why we are looking more closely at this

definition. For example, if you have a physician who is over in Europe and contend that he is supervising the physician at home here in Texas, is that distance too far apart; or if he's down the road here five miles, is that an adequate distance.

These are the questions they are addressing. It's very difficult to put limits about restricting the authority vested in a physician as to what is reasonable.

MR. TELFORD: Currently I think we'd have to say that just because this patient is not coming, this authorized user is out of town, the authorized user is still responsible for supervision of that second physician. If the second physician were so instructed, they could -- under this definition, they could sign this written directive, as long they're a nuclear physician.

We kind of got off on prescription quite a bit. Is there anything else on two?

MS. KELTY: I guess I'm confused with two and three. If I wanted to an Iodine whole body scan with two millicuries, Iodine-131, that diagnostic procedure, that then goes under three in the referral?

MR. TELFORD: No. Look at Part D. It says any radiopharmaceutical procedure. Any. Anything you think of --

MS. KELTY: So two is not exclusively therapy.

MR. TELFORD: Two is aimed at therapy, but if we said, oh, Iodine.

MR. JANICE: You've got the same thing in the other part, too.

MR. TELFORD: We've got consequences here. Even a procedure that you would think of as a scan or a diagnostic study, if it involves more than 30 microcuries, it needs a prescription.

MS. KELTY: And the Iodine-131 hippuran, this morning we heard --

MR. TELFORD: Different chemical form.

MR. JANICE: So it's excluded.

MR. TELFORD: I shouldn't be saying this. You should be telling me what to do.

MR. JANICE: That's what the Survey Team did.

MR. TELFORD: The Survey Team said they didn't want to cause anyone a problem, more or less, so they're not going to say we have a deficiency if you're not doing this.

After all that --

MS. KELTY: I guess I have problems with a prescription for that because we don't always have an authorized user on-site when we do Iodine-131 hippuran studies.

MR. TELFORD: So you're suggesting that we exempt that from No. 2 and --

MR. HAMMOND: I was just going to second that request for exemption.

MR. TELFORD: Give me a little logic here. It's got a different chemical form.

MR. HAMMOND: It's a different chemical form, it's a different use. The potential harm with the I-131 sodium iodine is obviously the thyroid. Here are 250 microcuries of I-131 hippuran is obviously more than the 30, but your chances for over-dosing somebody with ten or 15 millicuries of hippuran are remote at best.

That's going to be an unusual order for anybody to order 250 millicuries. It's not unusual to order maybe 30 of I-131, but if the chemical form is different and the numbers are so different, if you ordered that from a pharmacy or a manufacturer, they're going to question the order to begin with.

MR. TELFORD: With hippurate, the possibility of dire consequences are a lot less.

MR. DADARI: I have two comments. The first one, I don't know about other states, but in the state of Texas, the licensed users are put in different categories. We have about eight physicians licensed in our nuclear medicine department. The first four of them are diagnostic physicians. They cannot order therapy doses.

The second set, they can order up to 30

millicuries, which we can treat hyperthyroids in outpatients, and the third one, which is the highest level of our physicians, they go 30 to 300.

Regarding this gentleman's example of the patient driving 150 miles to the hospital and there is no authorized user and they want to give him therapy. First of all, the therapy dose can be ordered 24 hours ahead of time. You don't have it in stock.

The second, whenever there's an emergency for therapy, it can wait. It can wait a week. It can wait two weeks and never hurt anything. They've been waiting all their lives. So they can wait two more weeks, it's not an emergency. It will be handled if any of those physicians which are authorized use that -- if they are not in the department, we will just reschedule them again and everybody is happy so far. We've never had any problems.

Second, my point was in that same point on I-131 hippuran. Usual dose is between 300 and 400 microcuries. You have an order for 200 microcuries as a standard dose, so you have to dilute it and make it standard. If you order more, it's impossible you can get more than one millicurie. The biological half-life of Iodine-131 hippuran in the body is about 27 minutes or less in normal patients, and Iodine-131 doesn't have any chances to get in the thyroid.

If it's tagged to hippuran, it will not detach

itself from its tag. So it's directly in the blood stream, in the kidneys, and out. So I believe it should be an amendment on the end of the Iodine-131 that says Iodine form or not including hippuran, something like that should be included.

MR. TELFORD: Okay. Anything else on No. 2?

[No response.]

MR. TELFORD: Now, this is diagnostics. It talks about diagnostic referral and it says or prescription in parentheses, because, of course, if you have an authorized user sign it, it's okay. That's great. But this is envisioned to handle the outpatient or referral.

When we wrote this, we said the ideal case is to have a written referral, and it's defined on Page 1447, I hope. Yes. Diagnostic referral, center of the page. This says dated and signed by a physician. So this could be the general practitioner who sends the outpatient. This is not a nuclear physician. So it's any physician. You've got an ideal case for having a written referral.

When that patient got to the nuclear medicine department, then the technologist would compare that referral to the clinical procedures manual, which is also defined on Page 1447, the little column, clinical procedures manual. The authorized user would have approved the clinical procedures manual.

Therefore, it would be directing the technologist to follow a specific procedure for a specific referral, like liver scan. Then you kind of incorporate the way that business is done, with the exception that we ask for a written referral.

Now, what would you like to do with No. 3? Delete it, modify it, retain it?

MR. JANICE: We like that.

MR. TELFORD: You'd like to have a written referral. Okay. Surely some people are going to speak up.

MR. FOSTER: Does it always have to be written, it can't be oral? You want to get away from oral, of calling a physician's office?

MR. TELFORD: It's your call. Tell me what you want. What kind of referral system would work there? What kind of referral system would guarantee that you get -- that the technologists in your department get the right directives so they know what to do.

MR. JANICE: Again, it goes back to what I said this morning. They pick up the phone and --

MR. FOSTER: You also have to look at the procedure to make sure this is pertinent clinical information. So if we know someone is having a heart problem, we're not necessarily going to put gallium on it.

MR. TELFORD: How do you get that pertinent

information?

MR. JANICE: The referral slip.

MR. FOSTER: When they schedule. When they call to schedule a bone scan, we ask the name, the date of birth, and so on and so forth, the diagnosis, and the exam, the phone number, all that stuff.

MR. TELFORD: So the receptionist or the secretary from the referring physician calls your secretary. You schedule it. You get all this information over the phone and your person writes all this down?

MR. FOSTER: Right.

MR. TELFORD: Is it written down at the other end? Is the information written? Are they reading from written material?

MR. FOSTER: From the patient's chart, yes. I'm not disputing that it shouldn't be written. Written would be fine. I'm just looking for an alternative where we may have to -- some small offices may have problems trying to get written referrals from this doctor.

MR. TELFORD: Me, too. I'm looking for an alternative.

MR. FOSTER: I'd like to see the action open for oral.

MR. TELFORD: Okay. How do you take care of this gallium/thallium problem? Who is in the loop? Who is in

the loop here that says, no, no, no, no, not gallium, it's thallium or vice versa.

MR. JANICE: Another way you have to look at it, you're going to have 50 percent of your staff sending something written, that you know exactly what's going on. The other 50 percent or 75 percent is going to be picking up the phone.

MS. WALKER: When we met before, I think some people were saying that they got all of their referrals on a computer. Is that right?

MS. RAY: We have a phone-in system. The referrals are entered in the computer system. We put them in there.

MS. WALKER: Yourself.

MS. RAY: Yes.

MS. WALKER: Some central hospitals put them into a central computer.

MS. RAY: No. We put them in and it's either a telephone order read off of the physician's order in the other office, actual prescription slip that comes in with the patient, or from a chart within our office.

MS. WALKER: I wonder how many offices have fax machines.

MR. JANICE: I'm glad you mentioned that. What we did, we told the receptionist, we said, look, if they don't

want to send it with the patient, here's the fax number for the hospital. They can fax it into the hospital. What the hospital has done, not just because of this, but because of other reasons, the hospital has gone out and purchased fax machines and put them in the physicians' offices who use the hospital more frequently than anyone else.

So we do give them the option. You could use the hospital-printed referral slips that are given to the doctors' offices. All they do is fill it in, sign it and send it with the patient. They can put a prescription with their own office on it or they can pick up the phone or fax it. So there are three ways in which they can do it.

MR. TELFORD: You said three ways they can send a written prescription. They can fax it. What's the third?

MR. JANICE: What we did is we made out our hospital's logo with all the exams possible that they might be ordering and sent it out to the physicians' offices. They look out there say bone scan, and then give us a diagnosis at the end of it, the patient's name on the top, dated and signed by the physician, and then it comes with the patient, or they can use their own prescription pad that they have in their office.

MR. TELFORD: Both of those are written referrals.

MR. JANICE: Or they can fax it in. They are always called in on the phone, but they are also in writing.

MR. HAMMOND: Ideally, from a risk management standpoint or radiation safety standpoint, I, too, would like to see everything written. However, particularly in our instance where we're dealing with small, small rural hospitals that may do five studies a month or may do ten studies a year, they don't do enough of them to stay in practice and the common practice in a town of 1,200 people is Dr. Jim-Bob calls the hospital and tells whoever is there that that is what he wants done, and we may never see anything in writing from the physician once we actually get to the hospital.

It may not be the perfect way to do it, but --

MR. JANICE: But they still have the hospital chart.

MR. HAMMOND: There may not be anything in writing from the physician. They'll show up in admitting and talk to the next door neighbor, say Dr. Jim-Bob sent me over here to get my brain scan done. All of it has been verbal communication. Now, it may not be the perfect system, but it's the real world. It's going to happen that way. It happens that way a lot.

We certainly don't get -- in our office when things are scheduled, everything is done by telephone. These hospitals -- I bet you 90 percent of them don't have fax machines.

MR. TELFORD: What could you add to that system to make sure that the right direction was given?

MR. HAMMOND: We require that they have some pertinent clinical information. So even if it's a gallium/thallium type thing, they're ordering a gallium study and the patient is being evaluated for some kind of heart problem, obviously we're going to question that order before we place it in order to get a good exam.

MR. TELFORD: Do you have like a telephone log where you take the referral, you write down this pertinent information?

MR. HAMMOND: Yes.

MR. TELFORD: Who is responsible at your end for making sure that's the right study?

MR. HAMMOND: Ours is, like I said, really unique. The licensed nuclear physician is only involved peripherally until the exam is actually done a lot of times. The referring physician will call it in or send the patient over to the hospital, calls us, somebody at our office takes down the order, one of the people in our office, usually one of two registered techs review it, and then if they have a question, they call the licensed physician of that facility.

Ninety-nine percent of the time, they all flow through normally.

MR. TELFORD: So you have a procedure that says

that if there's a question, the technologist calls the nuclear physician before proceeding.

MR. HAMMOND: Right.

MR. TELFORD: So that your step to make sure it's done right.

MR. HAMMOND: Yes.

MR. TELFORD: All right.

MS. RAY: I have a question. On the telephone orders, most of the time I will get a written prescription from the referring physician's office. But if I don't, the patient shows up, I'll call the other doctor's office and have that nurse read us from the chart the exact order. Would that cover?

MR. TELFORD: Do you write that down?

MS. RAY: Yes. Everything is written down.

MR. TELFORD: On your end.

MS. RAY: On our end. Everything is written down on the telephone order, also.

MR. TELFORD: What if there's a question? Is there a procedure that tells you what to do?

MS. RAY: As to what the nurse is reading to us over the phone?

MR. TELFORD: Everything sounds right, except the scan is all wrong. It shouldn't be that at all.

MS. RAY: I'd speak with the referring physician,

and they've gotten to where they don't mind picking up the phone and holding it for 30 seconds; are you sure you want to do this scan for this diagnosis.

MR. TELFORD: So that's a direct communication between the technologist and the --

MS. RAY: And the referring physician.

MR. TELFORD: All right.

MR. DADARI: If I recall it correctly, her situation is a lot easier than the hospital situation. You are only involved with cardiac only, right?

MS. RAY: Right.

MR. DADARI: So if there is a big mess of either it's thallium or PYP, it cannot go any further direction, which is ideal place to work. But our situation is very different. I had a very hard time to implement that No. 3 in our pilot program. We tried to push it as far as it could go, but it didn't go anyplace. We wrote the letter, we sent all the staff doctors, about 150 of them, and explained the situation, cooperate with us for 60 days and see how this thing goes.

Basically, except one or two doctors, nobody cooperated. Our situation exactly is like Bruce's mobile situation. Doctor's office, 99 percent of the time, his secretary sitting on that end and wanting a bone scan or gallium, thallium or whatever.

MR. JANICE: Let me ask you this. What happens if it becomes law? From what I understand from the last meeting, the NRC would urge that agreement states follow this. What is going to happen if this becomes law and John Sharp sends his boys around and you don't have a prescription in that patient's folder?

MR. DADARI: He shuts us down.

MR. JANICE: What public relations are you going to do in the meanwhile?

MR. DADARI: I don't now. We tried anything. We tried -- we got a lot of bad phone calls to administration after that first letter we sent.

MR. JANICE: You're a sole institution in the city, right?

MR. DADARI: No, we are not. There are three others.

MR. JANICE: Three. What happens if they call in and you say, well, I'm sorry, we can't do it unless you have a prescription?

MR. DADARI: They take it to another hospital. It's a fact of life. It's business.

MR. JANICE: I had one physician that tried to get me that way and said that she was not going to send a prescription with her patients and stop bugging her patients to send them back. She said, well, I'll take them to

another hospital. I said fine. But if it's made state law, it's not going to make any difference what hospital you take them to. You're still going to need a prescription, a referral slip.

MR. DADARI: I can't argue you with it being a law and everybody enforcing it, but, again, it will come to the point where we will refuse valuable service sometimes because there is no prescription, and I know this patient has a stress fracture or hasn't been eating or was throwing up the last two days and needs a scan, I know it, and I have to refuse that patient. That's a refusal of medical care because of -- if they want to force that, which is fine with me, but --

MR. TELFORD: Wait a minute. Let me change the question a little bit. We're talking about a diagnostic referral. We're saying the ideal case is a written referral. What could you use in your hospital that would be as good as a written referral? What would be less trouble?

MR. DADARI: What we've been doing -- that's ideal, if you can enforce it. I'm not going to argue against that. But it's not practical. What we've been doing, we've been using our own discrimination as to clinical case or look at the patient and see is it logical to order this test. If it's not, just hold on. That might be one every 50 or one every 100 patients, might be

something like that. So we can hold on on that patient and verify one way or another. It might be something written in the doctor's office in the chart.

Sometimes there is something written --

MR. TELFORD: But you call the referring physician in that case.

MR. DADARI: Exactly. But our situation is we have two cameras and we have to do at least 12 studies a day and three or four of them are thallium, so one camera is locked up. The other camera, every one hour there is one patient. If you back off this, you're here till 9:00 and everybody is going to scream and yell at you.

So the situation is I cannot afford on each of my outpatients -- 60 percent of my patients are outpatients, 40 percent inpatient. We don't have any problem with the inpatients. If it's not written down, we won't touch the patient. Fine. But I can't enforce that with the outpatient. Sixty percent means that seven patients are coming walking in every day, one every hour --

MR. TELFORD: You've made your point. Let me ask if we can omit something here that would be as good as a written referral. Maybe you've already kind of touched on it. If you have taken an oral referral provided that you get the right information over the phone and you write it down on your end, you ask questions, if there's anything

that looks fishy, then the technologist is obligated to call either the nuclear physician or the referring physician or both.

In your mind, would that be as good as a written referral?

MR. DADARI: It's been so far.

MR. FELDMEIER: I don't practice this type medicine, so take that into account as far as my comment is concerned. If I were a nuclear physician and if I had an established practice and if I had a cantankerous old doctor send me a bunch of patients and absolutely refused to send a written referral because he didn't do that 20 years ago and doesn't see why he needs to do it now, and if I were not on-site, it seems to me if the nuclear physician is on-site, it's not a problem.

But in some places where there are multiple centers being covered perhaps by one group and you don't always have the nuclear physician there, if I were a nuclear physician and you guys were doing scans based on my name on the isotope license, I would want you to call me and say, well, you know, Joe Smith up the road sent us another one and it looks like a good case to me, and I called the office and we've checked it out.

What I would do is say go ahead and do the scan, I know Joe Smith, it sounds like a good case, I've checked it

out, asked the appropriate questions. I would have, just like many cases we do with patients in the hospital, that telephone order by the nuclear physician by his technologist saying go ahead and do the scan.

And then when the nuclear medicine physician was available, the next day or later that day, have the nuclear physician sign that prescription for that study.

MR. TELFORD: Would that work in your case?

MR. DADARI: No. As a matter of fact, I'm talking on behalf of nuclear medicine physicians. If it's puzzled and something is fishy to me, we have all the time access at least between 7 a.m. till 7 p.m., there is at least one nuclear physician. And during the other times, there is somebody on call all the time.

If anytime I'm puzzled, he's puzzled. If I don't know this is a correct order, he doesn't know either. All he does -- we've taken to him -- almost 100 percent all the time, if we are puzzled, he's the first one, but he's puzzled the same.

Nobody knows that it's the same information from him.

MR. TELFORD: What does he do? What does he or she do?

MR. DADARI: In this kind of situation, which is -- it happens probably not very often, we just page the

referring doctor, we'll page him and wait an hour, half-an-hour or ten minutes or whatever, until they call back and we question.

MR. TELFORD: That's in inpatient.

MR. DADARI: No. We're talking about outpatient. With the inpatients we don't have any problems. We can implement that anytime.

MR. TELFORD: What I've heard so far is that we agree it's an ideal case to have a written referral, but we might also agree that there's an alternative to this which is have an oral referral provided that the appropriate information comes with it, and the authorized user is consulted.

It's a verbal order from the authorized user. That's a second alternative.

MS. KELTY: I just have a comment about the diagnostic referral. They're not always absolutely perfect. We had an indication for an outpatient who had been ordered a lung scan, it was really a MCT, or a gull bladder scan which was really an ultrasound. So even though you have a diagnostic referral, sometimes this still can be a misadministration because the referring physician did not appropriate designate which modality was to be done.

MR. JANICE: That's when you go back to the other person, if you see something is out of line, that you go

back and you question it with the manual. Then that's when the nuclear medicine physician picks up the phone and calls the referring physician.

MR. FOSTER: I just had a comment that it's done for the oral part, too. If I'm not mistaken, all of these things are being checked in Objectives 4 and 5, and these other areas we're also checking the order. So we're still double-checking, we're still ensuring that we're doing the proper medical use. I've seen plenty of written orders.

MR. TELFORD: Having the alternative in here of having a verbal directive from the authorized user or nuclear physician, does that work in your case?

MR. FOSTER: It would work. What also would work is changing the definition of referral to include either written or oral. Then you wouldn't have to add a bunch of stuff in the prescription. The prescription is a written directive. Am I getting that right?

MR. TELFORD: The prescription is written, right.

MR. FOSTER: And the referral could be either one.

MR. TELFORD: That's right.

MR. FOSTER: Change the definition, and then you wouldn't have to change the objective.

MR. TELFORD: That would be one way. In other words, in the definition of referral, offer some alternatives.

MR. FOSTER: Right.

MR. BENNETT: I'd like to ask Bruce a question with your mobile service. I'm familiar with that in my part of the country, too. Frequently the mobile service will come on-site and it will be to do one or two scans per month. Do you leave the scans there to be reviewed by an authorized user at that site or do you take the scans with you and they're read by the radiologist within your organization?

MR. HAMMOND: We don't have any radiologists within our organization, so it's always the authorized user for the hospital. We can take them to his office or another hospital or we may leave them there. A lot of our interaction with the authorized user is after these things are performed. Ours is based pretty much on the clinical procedures manual, which is already reviewed, and approved in writing, that kind of thing. So it's kind of a de facto description.

MR. BENNETT: I see this very frequently and a lot of times the scans are left at the site. The radiologist is not there and even more confusing than that is he may be on vacation being covered by a local attending who is not an authorized user on the mobile services' program, and, for that matter, may not even be an authorized user anywhere. It might be a diagnostic radiologist that's just covering

for another.

Without any written documentation by an authorized user anywhere along the line presents some real dilemmas, I think.

MR. TELFORD: What is your suggestion?

MR. BENNETT: I'm concerned about the fact that I think that there are services being provided without even an authorized user ever being involved until far after the fact.

MR. HAMMOND: See, we've got a couple things. I don't think that's really true. Not in Texas it's not. I don't know what goes on where you are from, but in Texas it doesn't happen that way. The requirements are so stringent here on mobile service that you have to have interaction with the licensed nuclear physician -- well, we recently got them to move to the point where we could use a standard set of criteria that has specific indicators. When the exam is scheduled with us or with the hospital and it doesn't meet one of those indicators, we have to stop and call the nuclear physician before we can ever order an isotope.

If we get there and there's not pertinent clinical information for the technologist, he has to stop and call the physician. If everything works right, there is a requirement that no matter what the volume of the hospital is, the licensed nuclear physician has to be there a minimum

-- has to observe the operation of the mobile service at least once a week, review the records at least once, an actual physical review of the records, once every two weeks.

So there is some interaction there and we have to deliver the thing to the licensed nuclear physician in a timely manner so we don't leave them laying there.

MR. TELFORD: Doug, what would you like to see in No. 3?

MR. BENNETT: I don't have any problems with No. 3, but I have a real problems with what really happens. We have situations where there are mobile services running around, will go to an institution once a month, may never have met the radiologist to say anything about delivering anything to them, and also that the NRC does not have any handle -- it's my observation that they don't have any handle as to who are these authorized users. And most of the time the mobile services, there are so many changes, say in even a year's time, that they don't know that the radiologists have changed or that they have, for a period of time, that the radiologist wasn't covering there for two months because it just didn't work out that way and some local came in, nobody checks to see whether or not they're an authorized user or not.

MR. HAMMOND: See, I don't think Item 3 is going

to solve that because there are already mechanisms in place under Part 35 and under EPRI agreement state operations, if the licensing actions taken by the state and the NRC are strict enough, and they're holding mobile service and the hospital and the authorized user to the standards that they license.

The mobile service is going to know whether the authorized user was there. The authorized user is responsible. It's kind of like the pulmonologist doing brachytherapy. I mean, what Oscar described is not poor medical practice; it was the unauthorized use of radioactive materials by two unauthorized people; one was not a physician. I don't think that changing the -- making three so specific that I have to have a written referral every time is going to help improve the quality of care unless we're going to hold people to the standards that already exist.

We can put mandates on top of the wound, but unless we clean the wound, we're still going to have a wound.

MR. JANICE: Is it easier to change the terminology on diagnostic referral or is it easier to change this?

MR. TELFORD: Either way.

MR. JANICE: Because from what I hear, it would be

a lot easier if you changed the diagnostic referral to means a written or oral request dated and signed by a physician. I'm adding the word "oral."

MR. TELFORD: No. Written referral from the physician, but an oral directive from the authorized user.

MR. JANICE: Oral directive, then.

MR. TELFORD: If we're going to allow oral, let's get it from the authorized user, the nuclear physician.

MR. FELDMEIER: I don't think that's how the discussion has been. If you're going to have an oral order, I think it should come from the nuclear physician, but I think the people that are in the trenches in this situation disagree with that. David, do you agree with that? Would you be willing to see an oral --

MR. DADARI: It wouldn't help us. It would be helpful if it comes from referral, not from our authorized user because he knows as much as I do.

MR. JANICE: Maybe I misunderstood, but I basically understood you to say that if you don't have something in writing, you pick up the phone and you call the radiologist. That's what I understood you to say.

MR. DADARI: If anything is wrong, we do that. We would not do it on every patient. If this patient comes as bone metastasis checkup, no prescription, we'll never ask any questions. This is indicated on the chart. Bone scan

goes with bone metastasis. We will not ask that question. But if somebody comes with bone metastasis or history of cancer and they want to do a gull bladder scan, we'll question that.

Again, we will call them and question the authorized user and he'll decide. And if he cannot decide, he'll call the referral.

MR. FELDMEIER: David, I don't understand -- again, I don't do this, but in the interaction within the department with your -- you have nuclear physicians present almost all the time?

MR. DADARI: We do.

MR. FELDMEIER: I don't understand why they're prohibited to take the form back and say, hey, this patient showed up and it says needs a bone scan; we call the doctor's office; it sounds reasonable; we think the patient needs a bone scan; I fill out the form and you go ahead and sign it. This is just to have everything documented that the licensee reviewed in a situation without a written directive, reviewed the situation and has decided that it's appropriate to do this.

MR. DADARI: It would be, but we aren't able to call the doctor's office in each case

MS. WOOD: He's not saying you have to call the doctor; just take what the doctor told you and run back to

your nuclear and say can we do this, and he says yeah.

MR. FELDMEIER: For your protection, if I were a nuclear medicine technologist, I wouldn't go ahead and do it unless my doc said go ahead and do it. Since docs sometimes forget things, I would make sure that he's initialed or signed it.

MR. JANICE: I think you hit an important key when you said protection; not only protection of the patient, protection of the physician, protection also of the technologist.

MR. DADARI: I believe you're passing the buck to somebody else. You're protecting me and you're putting the nuclear physician on the loose. So what he's going to do with that referral, say bone scan, with no indication, what is he going to do. You put yourself in his place.

MR. JANICE: If you already talked to the patient --

MR. DADARI: It would not match the clinical situation.

MR. FELDMEIER: The nuclear medicine physician is, first of all, a licensed physician and, second, the licensee. I think in a situation where let's say he can't get a hold of the referring physician. He says, well, this is a confusing situation, let me call Dr. Smith down the road. The doctor is out playing golf out of town. He's

still a licensed physician. He can go out and say to the patient, well, Ms. Roberts, you're here, we can't quite figure out why, what can you tell me about your situation. And she says, well, doctor, I have breast cancer and my doctor thinks that I might have spread of the cancer into the bone.

Then the doctor, the nuclear medicine physician, I think after evaluating the situation clinically, should be the one to deter ne whether the bone scan is appropriate. I think Dr. Wal could probably speak to that a lot better.

MS. WALKER: If you're passing the buck, you're passing it to the person who needs it and deserves it and he's going to be responsible for it anyway. If you do that bone scan and it's inappropriate and the patient sues, he's going to sue the doctor, too. He may or may not sue the tech, but he's going to sue the doctor. So I would want to know -- you take a look at it and you can try to call the physician --

MR. DADARI: There's no clinical history.

MS. WALKER: Talk to the patient. It's radical, but it's done.

MR. DADARI: We do that all the time. If we can match it, the clinical history to the test, we never go to the doctor.

MS. WALKER: But why can't your doctor talk to the patient?

MR. DADARI: He cannot get anything if I can't get it. It's the same thing. He's not going to talk a different language.

MS. WALKER: If nobody can get any information and you can't get a hold of the doctor, then it shouldn't be done.

MR. DADARI: This is situation which happens not every day, but it happens. But the order says this one happens one in 100, but the other 60 percent of my patients will match. The clinical situation will match the test, but we don't have a written prescription.

MR. JANICE: It sounds like you've got a bunch of hostile doctors up in Amarillo.

MR. DADARI: I won't comment.

MR. FELDMEIER: I sort of think of an analogous situation where maybe a patient comes into the emergency room and talks to the nurse and says I've got a brain tumor and I've had a bad pain and I need 75 milligrams of demarol. If the nurse talks to the patient, the tech talks to the patient, it's kind of -- the patient doesn't have any records. That nurse in the emergency room or that tech in the emergency room would be nuts to give that patient 75 milligrams of demarol without having the physician there to

approve it.

I rally think it comes down to who the licensed physician and who the licensee is. I think for the physician's protection, the technologist's protection, and for the best care of the patient, that when it is a confusing situation that really calls for the doctor to make a determination.

MR. DADARI: If I'm understanding correctly, you mean every patient walking into our department will have one prescription in their hand.

MR. FELDMEIER: If it's a confusing -- if there's no written directive or -- yeah. I would think so. If you have a patient that comes from a referring doctor and says my doctor sent me to have a liver scan, and you say, well, gee, you don't have anything written. You'd say I'll go ahead and call your doctor's office, you talk to the doctor's office, yes, my doctor wants the patient to have a liver scan.

I would go back to my nuclear medicine doctor, if I were the technologist, receptionist or whatever, and say this patient came, doesn't have any paperwork, I called the physician's office, everything seems to be reasonable. What I would do is put that office on hold, go back to the doc and say, hey, I've got Dr. so-and-so's office on the phone, this patient showed up, it seems appropriate to me.

If I had confidence in my technologist and I was up to my elbows in alligators, it sounds like a reasonable situation, I'd say okay, it sounds reasonable, I'll sign the prescription. If I had any questions at that point, I'd pick up the phone and say can I talk to Dr. Smith and get some clinical history on this patient.

MR. DADARI: But again you're going back to the order report or prescription.

MR. FELDMEIER: Sure. But I think that's the physician doing that. And the physician, your physician, then determines whether there is enough clinical information to give the directive for the study to be done.

MR. DADARI: In our situation, it's a lot different. If the patient is scheduled through secretaries or nuclear medicine technologist, it's in the computer. And if all the questions have been answered in the form that has referring physician, name of the patient, and so on, and the reason.

If that reason matches, we don't have any problem. I mean we accept that No. 3 100 percent. Do you buy that as a prescription, just putting the information in the computer.

MR. TELFORD: Written referral.

MR. DADARI: On the paper.

MR. TELFORD: It's got to be signed by the

referring physician.

MR. FELDMEIER: David is talking about a form that they fill out.

MR. DADARI: No. We are not talking about that. We are talking about doctor's office scheduling a patient with our department. It goes in the computer.

MR. TELFORD: In whose computer?

MR. DADARI: In our computer in the hospital.

MR. TELFORD: Who puts it there?

MR. DADARI: The secretary or nuclear medicine tech.

MR. TELFORD: In your department.

MR. DADARI: General hospital computer for the whole hospital.

MR. TELFORD: But they took the information over the phone.

MR. DADARI: Exactly.

MR. TELFORD: Okay. That's an oral referral.

MR. DADARI: If you include that, I don't have any problem. I'd say prescription or oral referral, if you accept that, we'll comply with the No. 3.

MR. FELDMEIER: I would accept it if your doctor looked at it and said okay and signed it, but I would not accept it --

MR. DADARI: Look at the computer screen, there is

nothing to sign. It's just information.

MR. FELDMEIER: You can't get a printout from the computer screen?

MR. DADARI: We can get a printout in schedules.

MR. TELFORD: We've got hands up over here.

MR. HAMMOND: We've gone round and around in the real world. We tried what you're talking about. Four years ago, John Sharp said you can't do anything unless the licensed nuclear physician specifically authorizes each individual study that's ordered. I'm going to tell you it lasted about 20 minutes in each hospital because the referring physician said, by God, I ordered whatever, do it. I say I can't because the health department says, you got your techs in the middle, then you call the radiologist up and say, look, you've got to talk to Dr. so-and-so because he didn't understand, and he's say what.

You've got a standing order from me to do anything he orders and anything this other doctor orders, and that one and that one and that one, and only this guy I don't authorize everything, and don't call me again, just write down who you talked to.

That's the way it really worked. So we kind of had to say this is pretty much bogus. We made a bunch of phone calls for nothing. You're not going to get written referrals on 100 percent of the patients, but you can't -- I

think that the oral referral could be from the referring physician or from the nuclear medicine physician with his approval, but you can't just accept I'm sending Betty Jones over for a liver scan.

There has to be some clinical information that comes with it. David, in your situation, your QA report has got to be so far out of line the QA ought to have eaten you alive.

MR. DADARI: Ours is the best.

MR. HAMMOND: What you've been describing is you get a phone call that says I'm sending Betty Jones over for a liver scan. There is no clinical information. That's an inappropriate study --

MR. DADARI: In that case, probably I misexplained myself. I'm not emphasizing on that patient which doesn't have any information. We will hold that. I'm having a problem with the other ones that have clinical history and correct order. But I don't have a written request.

MR. HAMMOND: I think in the real world, whether you make it a law or not. In effect, in Texas it was a law. When the guy who is writing the license says your license condition 19 says X, it is law because you're bound by that license condition just as though it were regulation or anything else.

But it's not practical for a radiologist to call a

referring physician every time to verify some study that he wants because he's not going to be the contracted nuclear physician at that facility very long, and the referring physician is not going to take time out from his practice.

You've got doctors referring from 100 miles away, how much time are you going to dedicate and spend on the phone. You asked what the cost of this program was, 300 to 500 hours does include the time to call and verify every outpatient that comes in, which is probably 90 percent of our business, without a written diagnostic referral.

An oral referral with some kind of initial information that you can use to evaluate. If they say a liver scan and the patient's got a hangnail, obviously it's not going to fit. It needs something that has to do with the liver scan that you can say it -- that's where I think the diagnostic referral -- all you need to do is change it to say it means a written or oral request by a physician for the procedure that includes, and you've got the things you need, the patient's name, the clinical procedure you want, the clinical information is supported.

Then you have written criteria that's been signed by the medical staff of the hospital, the clinic, wherever you're at, that the authorized user approves that says if a patient presents and they have trauma to the abdomen, doctor has ordered a liver scan, do it. There is your written

authorization from the nuclear physician.

It's essentially a standing order that says if the patient comes in with the following conditions, then do it.

MR. TELFORD: That's a standing order from the nuclear physician.

MR. HAMMOND: Right.

MR. TELFORD: What do you do if it goes outside that?

MR. HAMMOND: Then you've got to get specific authorization from the nuclear physician because unless it meets the criteria that he's set up as a standing order, you don't have an order for it. I don't know how the NRC interprets it, but in Texas the referring physician can only request an exam. They cannot order the administration of radioactive materials to a human. You need that written order from the licensed nuclear medicine physician in order to legally administer the radiopharmaceutical to the patient.

So if it's outside -- say it's ten criteria for liver scan. If it comes in with a diagnosis No. 11, you'd better be calling the licensed nuclear medicine facility.

MR. TELFORD: Standing orders. Does that work?

MS. WALKER: It did for a long time.

MR. TELFORD: Anything outside that, they have to get the sign-off from the nuclear physician.

MS. WALKER: We instituted a prescription on each and every patient primarily to comply with the JCH, but before that we had a procedure manual and standing orders and it didn't cause any problems. It didn't cause any misadministrations.

MR. TELFORD: You may have just said something there. If we allow standing orders, would the NRC tell the agreement states it's okay to allow standing orders. Is there really any relief? Are you saying that the JCHO is still going to require the prescription?

MS. WALKER: They don't require it. If you read it, it looks like they'd be real happy if you did it. That's not a big deal for us.

MR. HAMMOND: Joint Medicare didn't require it, but they'll accept standing orders based on standardized protocol.

MR. FOSTER: It's like your Objective No. 5. As long as it's with the diagnostic clinical procedures manual, that is your standing order, basically that standing order is going to be in your procedures manual. So that covers getting an oral referral and having it run through the radiologist and getting him to sign it. In the real world, I don't know if that's really going to happen that often. You're not going to find a physician real happy. It's fine if you've got plenty of radiologists sitting in the room

doing nothing, but if they're in the middle of a procedure, a special procedure, there's not going to be everybody around so you can go to them for 20 patients that we do on an outpatient basis and have them sign 20 times.

MR. TELFORD: So you're really setting up some special conditions in your description of the real world.

MR. FOSTER: I'm not setting up special conditions. I'm just saying I think it would be appropriate that oral referrals would be okay without having them signed. They're signed when they're read, but not when they're referred to.

MR. HAMMOND: You have to take three, four and five together. All these objectives work together. One works with three, and four and five, and if you've got three that says you have either written or oral, it's got to be in compliance with four and five, which are the clinical procedures manual.

MR. TELFORD: So if you get an oral referral, took the information from the patient's chart, which is written at the other end, you write it at this end, the referral has to agree with the clinical procedures manual, which is, in effect, a standing order from the nuclear physician. If all those conditions are met, then you can do it. But if those conditions are not met, then you should go back to the nuclear physician for a sign-off.

MR. JANICE: Or you should go back to somewhere in the system where the system failed, wherever it is.

MR. HAMMOND: The nuclear physician is the only one that can authorize any variations. You start with him and if he says I don't know -- like David says, the nuclear physician doesn't have any more information than you do, then you go back to the referring physician and start all over again. But that's going to be the exceptional case where we're talking about the real world out here.

You're going to have a few that you're going to have to go back on because you simply don't know what to do.

MR. TELFORD: It's a small percent of all your patients.

MR. HAMMOND: Yes. Real small percent.

MR. TELFORD: David, what I've just described, is that reasonable?

MR. DADARI: It's reasonable. It's a very small percent, but the majority -- if it were oral, it would work out.

MR. FELDMEIER: Again, I don't practice this type of medicine, so it's not fair for me to comment, but I may note that if I have a patient in the hospital that needs milk of magnesia, the nurse better not give that patient milk of magnesia without me authorizing it.

Even though milk of magnesia, anything that's

white and chalky and comes in a dark bottle is pretty benign, but even -- but that being the case, unless they get on the phone and call me and say can I give Ms. so-and-so 30 ccs of milk of magnesia, she better not do it and I better sign that order after the fact or the medical records section is going to put me on probation and lift my credentials because I haven't signed that order.

So I don't really understand why at some point along the way, and if I were a nuclear physician I would want it that way. That the nuclear physician, in writing, authorizes the study. Now it doesn't have to be necessarily before the fact. If he or she has got confidence in the technologist and everything is all sorted out and there's a procedures manual and the technologists are following that, I understand that. But I really think the documentation, the quality assurance, and the protection of everybody involved, those things ought to be reviewed by the physician and there ought to be a written indication that that particular case was reviewed by the physician.

MR. TELFORD: Dr. Walker?

MS. WALKER: I agree with that. The nuclear medicine physician is going to be in the nuclear medicine department. The radiologist who is doing BEs and just wants to drop by the department at 5:00 to read a couple of bone scans and make a few extra hundred bucks, they're going to

be bothered.

MS. WOOD: I wouldn't want to be the one to try.

MR. TELFORD: Pardon me?

MS. WOOD: They are authorized users and you can't rescind the authorization.

MS. WALKER: They have a responsibility that goes along with that. If they accept the --

MS. WOOD: That's not the real world.

MS. WALKER: Let's do it right.

MR. TELFORD: Let's take about a 15 minute break.

[Brief recess.]

MR. TELFORD: Let's go back on the record. We were discussing No. 3. Do we have any more remarks on No. 3 before we go to No. 4?

MS. ROY: Yes.

MR. TELFORD: Yes.

MS. ROY: No. It was just a remark. If we were to change the definition of diagnostic referral to diagnostic referral containing the request for the diagnostic medical use that includes the patient's name, diagnostic clinical procedures, and clinical indication. If it read like that, it would not say verbal or written, leaving that to the discretion or the capabilities of that department.

MR. TELFORD: Are you still building in the

standing orders that are inherent in the clinical procedures manual?

MS. ROY: That's not underneath No. 3.

MR. TELFORD: That's correct. It's not under No. 3. Okay. Sounds like that's a good start.

MS. ROY: That's just my comment.

MR. TELFORD: All right. Are we ready to go to No. 4? No. 4 just says that make sure the responsible individuals know what to do. A direction either comes from a prescription or from the referral and the manual. Would you like to delete, modify or retain this objective?

MS. WALKER: Delete it. I think an intelligent person would do something if they didn't understand what they were supposed to do.

MR. TELFORD: Okay. It's not necessary.

MS. WALKER: I know what some people will do, but they're not intelligent, but the person who is not intelligent enough not to do it wouldn't pay any attention to that.

MS. ROY: To begin with --

MS. WALKER: Any way, I don't think it would work.

MR. JANICE: Delete the whole statement.

MR. FOSTER: I agree to deleting it. If you delete No. 4, you would still have it covered in No. 5.

MR. HAMMOND: I agree with Dr. Walker. I agree to

delete No. 4.

MR. TELFORD: Over here.

MR. DADARI: It seems like the same thing you're talking about in No. 5.

MR. TELFORD: If you have No. 5, you don't need No. 4. Any other comments on No. 4?

MR. HIDALGO-SALVATIERRA: What are the comments so far? To delete it? It's unnecessary.

MR. TELFORD: There are two suggestions, both of which say delete No. 4. They have different reasons. The first is that No. 4 by itself won't do it because you have to have intelligent technologists who have the right training. If they don't have that, they won't pay attention to No. 4 anyway.

The other reason is that if you have No. 5, then you don't need No. 4.

MR. HIDALGO-SALVATIERRA: These apply to therapy also?

MR. TELFORD: Yes. Four, you notice, says prescription, need a prescription for all therapy. So it applies to therapy.

MR. HIDALGO-SALVATIERRA: Now comes my comment. In that case, that statement really helps us because we were having the problem of prescriptions that were not really clear, especially oral prescriptions, and the patients were

treated. And I'm talking about several cases. It was getting so bad that we had to have a special meeting to talk to the doctors, and this meeting is called now the mortality and morbidity meeting, where we talked to the doctors and we told them the reason that we made this effort is because the prescriptions were not clear.

It was so bad that the doctors now, they say if the prescription is not clear, don't treat the patient, which is good, but I don't see anything wrong with leaving it in there.

MR. TELFORD: Well, let me ask the question following the logic of four is not required if you have five. First of all, here we have a written prescription. Now, it has the information content and it's specified on Page 1447. If we have No. 5 which says you have to follow it, are you saying that we need something else that says if you can't understand it you don't do it?

MR. HIDALGO-SALVATIERRA: I don't mind redundancy. Redundancy is part of our QA program. Otherwise we wouldn't be asking for double-checks, and in some cases triple-checks. If it is a redundant statement, I don't mind.

MR. TELFORD: Well, what if we took the understanding part and put it over here?

MR. HIDALGO-SALVATIERRA: That would be fine. The point is that the prescription should be not only

understood, but it should be unambiguous. It has to be very clearly stated.

MS. WALKER: Are you talking about the referral?

MR. HIDALGO-SALVATIERRA: No. I was talking about the prescription for therapeutic brachytherapy or --

MS. WALKER: It says the isotope and the dose.

MR. MOK: [Inaudible]. So you would write a prescription to be clear and understood by all other persons involved. For a simple case, especially for the diagnostic, all you have to do is say they want a liver scan or whatever. That is clear, but for therapy sometimes there can be problems.

MR. TELFORD: You're not saying retain No. 4 for therapy, are you, prescription?

MR. MOK: No. I agree with Oscar. It probably should be left.

MR. TELFORD: You agree it should be left, retained for therapy. I see a hand over here.

MR. JANICE: I was just going to say why can't we combine one, five and the last part of four just to have one objective; ensure that the medical use is indicated for the patient condition and as in accordance with either the diagnostic referral, the diagnostic clinical procedures manual, or prescription, and is understood by a trained individual.

MR. TELFORD: Okay. Your logic is that that accomplishes everything.

MR. JANICE: It damn sure does. It wraps everything into one.

MR. TELFORD: You're supposed to say I guarantee.

MR. JANICE: I guarantee.

MR. TELFORD: Comments?

[No response.]

MR. TELFORD: Not going to touch that.

MS. WALKER: I think it's saying ensure that you do the right thing.

MR. JANICE: That's all it's doing.

MR. FELDMEIER: It might be repetitive, but I think it's fairly harmless.

MS. WALKER: It's harmless.

MR. FELDMEIER: It's like saying before you open the door, turn the doorknob.

MS. WALKER: Or open the door before you walk through it.

MR. FELDMEIER: If it helps Oscar or Ed to beat up on their oncology physicians to have a clearer prescription.

MS. KELTY: I guess I have one comment about how would we document --

MR. HIDALGO-SALVATIERRA: Understood.

MS. KELTY: Do we have an objective we have to have to show how we document that it's met?

MR. TELFORD: Wait a minute. This is one of the eight things to do. So what you'd have to have here is a procedure that says how you do it.

MS. KELTY: Exactly.

MR. TELFORD: You might have training. You might give quizzes. You might hire a certified technologist.

MS. KELTY: So it's global. Continuing education.

MR. TELFORD: Continuing education.

MR. HAMMOND: I think Nellie raises a real good point. When you send an inspector out there and the guy says how did you meet Objective 4, they're going to want to see that documentation. You expect a person who doesn't know what they're doing to admit that, no, I didn't understand that, but I did it anyway. You give them a checklist to document something, they're going to check it off if they understood it.

I mean, if you're going to require this, there's going to have to be documentation to support it somewhere, even if you just say -- if you say we're going to hire only registered technologists, we're going to inservice them once every two weeks or whatever you come up with, you still have to document that for that patient they did that.

MR. TELFORD: Let's try this. We've got this

objective. Let's say this is the real thing. Send in an application that says your program will have certified technologists. You will have continuing education. You will have a procedure that says if they don't understand something, they have to question it.

You have all these procedures or programs in place. Now, that becomes part of your license conditions. An inspector comes and inspects you against your license conditions. So they would say let me see your procedure that says they'll ask questions. Let me see your continuing education program. What do you for these folks that you've got those things and you can prove that you've doing what you're supposed to be doing as far as your license conditions.

But you don't have to have a form, a checklist that says that before the technologist did something, they checked a box.

MR. HAMMOND: But then he's going to say show me the last time one of them questioned, show me where this thing works. If they don't, the Joint Commission will --

MR. TELFORD: If we have an inspector here, why couldn't the inspector go to the technologist and say do you ever do that. Without bringing the procedures to the attention of the technologist -- suppose the technologist would say, gee, I'm curious. Do you know we're getting

strange funny-looking requests that are a little ambiguous, do you ever ask about those things. What would you ask. You will find out real quick the procedure is working. Or he could just sit there and observe for a while.

MR. JANICE: That's the NRC. That's not JCH. JCH wants to have documentation on everything.

MR. HAMMOND: When you write, JCH is eventually going to read it and they're going to require documentation.

MR. JANICE: It depends on how tired they are when they get to your department.

MR. TELFORD: So you're worried about this because JCH is going to ratchet NRC.

MR. FELDMEIER: It would be pretty easy for us in therapy to go back and document that. All you have to do at the end of the treatment is look at the daily treatment record to make sure that the total dose prepared was identical to the prescribed dose. So for therapy it's fairly easy for us to do that.

We can demonstrate that the prescription was understood by the responsible individual by demonstrating that that responsible individual, the technologist gave the dose prescribed.

MR. JANICE: If you followed that analogy and go back to the liver scan that was ordered, pull that chart out, look at the prescription for a liver scan. There's a

report for a liver scan.

MR. TELFORD: Right. And the dose administered for that liver scan equals what was in the manual. Therefore, you have proven to this inspector that the technologist understood what to do, because they did the right thing.

MR. HAMMOND: If the idea is to prevent your doing a reactive something instead of something that's proactive, some mechanism that's proactive, you're wanting to make sure it came out all right, you say fine. If it didn't come out --

MR. TELFORD: Couldn't you be proactive with the training, continuing education mechanism?

MR. HAMMOND: I'm not saying the mechanism is not going to work. I'm saying we're going to be required to document it, and how are you going to document that your tech understood every prescription that came through there? Because if the inspector walks in and asks him, he's going to say yes, I understood it.

MR. TELFORD: Okay, Mr. Inspector.

MR. KLINE: I don't know how the state of Texas would conduct their activities and how they're going to arrive at a rule that addresses these elements on compatibility, but our objective does not address documentation. It's performance-based. The evaluation

criteria we used covered a number of issues and they're even called out in regulatory guide 2.1 and 2.2, which John will address later, examples of how you can confirm that people understand things; making sure that when there are ambiguous or apparently possibly erroneous information written down, to bring this up to the physician, to ask them what's going on here, why does this appear that this might be incorrect; can't read their handwriting.

It's not so much that we want a checklist, but we want you to show us on paper that, yes, we checked off all these areas, and, yes, we understand all these. I think it's more that if there are ambiguous or unclear or erroneous areas, they need to be brought to attention to prevent them. It's more of a proactive stance.

Now, in regard to your other question, I think you were addressing the interpretation by the inspectors; you were worried about how the inspectors would view that objective. How are they going to come in and measure it; how are they going to come in and critique your program and whether or not they would hold the verbatim to the tightest possible interpretation.

The NRC is very aware that this is a performance-based rule that is quite different from anything that's been proposed in the medical community. In the reactor community, they do have these sort of rules and they have

had these problems already where you have inspectors who might interpret it a little bit differently based on the region, and consequently the states might interpret things differently, but there will be a concerted effort to train the inspectors and the licensing people and they will be reviewing these documents as to what is the intent, and these objectives, and this will be documented in the documents that we talked about earlier, which we've already generated and which are also being reviewed.

As we get feedback from everybody, this documentation addresses each of the objectives, what is the intent, what do we want the inspectors to look at, what do we want the licensee to approve as a good license when you submit your program addressing those objectives for a license action.

MR. HAMMOND: I don't have a real problem that everybody from the NRC that is in this room understands that this is a performance-based document, and I don't have too much of a problem accepting that most of the NRC inspectors will get it. But after you go to the agreement state folks and go to the program directors and say, okay, here is the new performance-based standard, and we've got 30-some-odd of them, and they go back to their 60-some-odd license writers and they say this is a performance-based standard, and they go back to the other 60-some-odd compliance officers and

say, okay, this is a performance-based standard, and then you go to some 200 inspectors out here or however many there, by the time it gets watered down to there, you've got an inspector who has not been in the reactor industry who doesn't understand performance-based criteria and who has been in the prescriptive mode for all of his professional career.

He comes out and he's going to -- human beings being what they are, they're going to go with what they're familiar with, and familiar is prescriptive, and that's the way they're going to inspect you.

MR. TELFORD: Therefore, what would you do with No. 4?

MR. HAMMOND: I would delete No. 4.

MR. TELFORD: Any other comments on No. 4? Delete, modify or retain?

MR. HIDALGO-SALVATIERRA: I still say I like it.

MR. TELFORD: You like it.

MR. HIDALGO-SALVATIERRA: I like it because it will force an institution to hire only the appropriately trained personnel; to keep them updated on the new techniques, and a new service to teach them how to understand the prescriptions. But I'm talking from the point of view of therapy; either brachytherapy or teletherapy.

This objective, to me, is to ensure that the institution has hired the proper personnel and has a training program, to make sure that people doing the treatment understand the prescription.

MR. TELFORD: Okay.

MR. FELDMEIER: This does not say you've got a training program. It just says that you've got responsible individuals.

MR. HIDALGO-SALVATIERRA: The prescription is understood. How do you ensure that a prescription is understood? By teaching your people.

MR. JANICE: But that doesn't say that it's required that you have continuing education. It just says that you have responsible individuals that understand that prescription.

MR. TELFORD: He's saying that's one way to meet that.

MR. HIDALGO-SALVATIERRA: Yes. That's one way of meeting that, because you have to ensure that. How do you ensure that?

MR. JANICE: You're going to have to go back in your own institution, whether you're calling it performance, quality assurance or whatever, you're going to have to plug that into that objective there.

MR. TELFORD: He would have as part of his program

that he would hire the qualified folks and he would have continuing education, etcetera, and that's what he said he's doing for No. 4. That's a way to do it.

MR. DADARI: Maybe he's talking on prescription. He's emphasized how -- it might be important on brachytherapy or something else. I don't believe it's that important in nuclear medicine. It's as clear as it could be. There is no understanding about it. If he means education, I don't know about other states, but the state of Texas requires everybody to be licensed and to have continuing education. We have that every year. So hospitals have to comply with that.

MR. TELFORD: Or you can easily make the point that you're already doing it.

MR. DADARI: Exactly, and it doesn't need to be here.

MS. WALKER: I think JCH is also pushing that, too. I know they are in nuclear medicine. I don't know if they are in brachytherapy or not.

MR. TELFORD: JCH has the same sort of requirement and inspection standard. Are there any other comments on No. 4? Why don't we move to No. 5. No. 5 is -- MR. BELLEZZA: In therapy in my department, the technicians have to initial every time they give a treatment. I'm not sure how it is in other places, but initialing the chart, they're

giving that daily treatment, is a statement by the technician that they understood and gave the treatment for the prescription.

MR. TELFORD: What form did they initial?

MR. BELLEZZA: The daily treatment chart. They write down the time, the dose, and then they initial and date it.

MR. TELFORD: So if we have a very prescriptive-minded inspector, they could check that point.

MR. BELLEZZA: I don't see why that couldn't be done here, as well

MR. TELFORD: Do you have a dose log?

MR. DADARI: Yes.

MR. TELFORD: Do you use a dose calibrator?

MR. DADARI: Yes. We use a dose calibrator and it will print out a slip that shows time, activity, isotope, and we keep it --

MR. TELFORD: Do your technologists have to initial --

MR. DADARI: Yes.

MR. TELFORD: -- that they measured --

MR. DADARI: Exactly.

MR. TELFORD: -- dose in the dose calibrator?

MR. DADARI: Yes.

MR. TELFORD: And voila, the dose matches the

referral?

MR. DADARI: Not the referral. The authorized users or our manual.

MR. TELFORD: The clinical procedures manual?

MR. DADARI: Exactly.

MR. TELFORD: Okay.

MR. BELLEZZA: Do they initial some sort of patient chart?

MR. DADARI: The only thing we initial is a dose calibrator. That's all we initial.

MR. JANICE: They should indicate in the patient's chart on the flowsheet that they have injected the patient with something and signed it.

MR. DADARI: What about outpatient?

MS. GOODWIN: That's indicated on our request that the doctor dictates. The tech has to write down what they gave.

MR. DADARI: The end report, when it comes, it says the patient injected 20 millicuries STP technetium 99 intravenously and so on. It tells exactly method of injection, type of chemical, the type of isotope, and it's signed by the radiologist or the physician.

MR. TELFORD: Do you want to make your point now?

MS. GOODWIN: I was saying the same thing, that that would say that they did understand it. If you have

them write down exactly how they administered it, what they administered, everything, the tech does that on every patient. It's done on the reqeust and the physician reads it, but that's required. Medical records has to have that. Then if they check any charts, they know exactly what that patient had and anybody can see that it matches what they ordered.

MR. JANICE: But your tech originally put how much he gave of what, and the doctor goes back to read that.

MS. GOODWIN: Exactly.

MR. HAMMOND: I agree. We do the same thing. No. 4 says ensure prior to medical use that it is understood. The fact that you wrote down what you thought --

MS. GOODWIN: You were asking about proof that it was understood, and we were just discussing how we could prove it.

MR. HAMMOND: The fact that you wrote down what you thought you understood doesn't mean that you necessarily understood. I can understand where Oscar is coming from, that there is a big variance in therapy. Just take out the reference to diagnostic.

MR. TELFORD: You want to take out prior to medical use?

MR. HAMMOND: No. Because if it's really needed in therapy and B is the part that really needs it because

the prescriptions can change and however it works, then take out the A part and leave B in there because prior to medical use -- obviously, prior to diagnostic use, you're going to have to understand pretty much and it's easily documented by the things we've been talking about here. But in therapy there's a real question as to which way you're going to -- just leave the B part and just modify it and take A out. A is covered by three and five. Just take it out. You don't need it.

MR. FELDMEIER: Except in the prescription manual, it includes therapeutic isotopes by nuclear physicians. Are you willing to accept that?

MR. HAMMOND: I'm willing to accept that, yes. I-131, now you're talking about a potential risk.

MR. TELFORD: Moving on to No. 5. No. 5 says be in accordance with --

MR. JANICE: I still say put five and four together.

MR. TELFORD: You would like to reassert your suggestion to combine five and four.

MR. JANICE: One, five and four. The last part of four. Ensure that the medical use is indicated by the patient's medical condition, in accordance with either diagnostic referral, diagnostic clinical procedure manual, or the prescription, and is understood by the responsible

individual.

MR. TELFORD: The B part on No. 5, you would have the understanding part of four.

MR. JANICE: Right.

MR. TELFORD: Let's talk to this group over here. Do you want to delete, modify or retain?

MR. BRAHMAVAR: Combine.

MR. TELFORD: You want to combine, too. Okay.

MS. ROY: Sure. Combine.

MR. TELFORD: Terry says yes.

MS. ROY: It combines all the ideas of those three objectives. It's a little wordy, but we could work on that, if you want.

MR. TELFORD: Don't worry about the words.

MR. DADARI: I would combine it or delete No. 4 and leave five on there. It seems like it's a little different than No. 4.

MR. TELFORD: It's a little different from No. 4. So you would combine one and four, btu you would leave five separately. Is that what you said?

MR. DADARI: I would delete four, keep five.

MR. HIDALGO-SALVATIERRA: I believe once you analyze the substance of the objective, not necessarily how they're written in separate parts, if they're in separate parts, I don't see anything wrong with that because it's

more clear.

MR. TELFORD: Okay.

MR. HIDALGO-SALVATIERRA: What you analyze is the substance; is the objective reasonable or not. How they're written, we can leave that for another group to analyze that part. But what about the substance of the objective? That's what we should address. That's what we should focus on.

MR. TELFORD: What do you think about the substance of No. 5? Would you delete it, would you modify it, or would you retain it?

MR. HIDALGO-SALVATIERRA: Again, talking from a therapeutic point of view, I believe that the -- when it comes to apply the treatment, to deliver the treatment, it has to be exactly like it was prescribed. I don't see anything wrong with five. It shouldn't be done any other way.

If the doctor says do it this way, that's the way it should be done.

MR. TELFORD: That's for therapy.

MR. HIDALGO-SALVATIERRA: Yes.

MR. TELFORD: How about nuclear medicine?

MR. JANICE: Standing on its own, there is nothing wrong with the objective.

MS. ROY: You're looking at standing orders there,

again.

MR. TELFORD: The standing orders are contained in the procedures manual. The administration should be in accordance with those standing orders.

MS. ROY: Right.

MR. TELFORD: Therefore, you would do what with No. 5?

MR. ROY: I'm still going back to the diagnostic referral definition.

MR. TELFORD: Actually you could take out referral here, couldn't you?

MS. ROY: Yes.

MR. TELFORD: Because you really want it to be in accordance with the standing order. You could just forget that.

MS. ROY: Yes. Get rid of that.

MR. TELFORD: The A part could be procedures manual and B part is prescription. Does that make it easier for you?

MS. ROY: Yes. That would be good, because that would be either standing orders, which are prior approved by your nuclear physician, or your prescription which is written by your authorized user.

MR. JANICE: And you would have already had a referral sent to you.

MS. ROY: Right.

MR. JANICE: So you've got the referral, you've got the procedures manual and/or the prescription.

MR. BENNETT: I have some problems with it. It's just that four, you're telling them to understand what you're telling them, and then in five you're telling them to do what you told them to do.

MR. TELFORD: Do you like the substance, as Oscar says, of No. 4 or No. 5 or do you think you ought to put them together?

MR. BENNETT: Basically, if you don't understand what I'm telling you, ask. Then once we've got it clarified --

MR. TELFORD: That last part says to me retain No. 5. Is that your message?

MR. BENNETT: I guess so. I don't like the way either one of them -- what they imply.

MR. TELFORD: You've got the blue pencil in your hand. What do you want to do to No. 5?

MR. BENNETT: I would just say in No. 4, now that you understand any ambiguities, just carry out the prescription.

MR. JANICE: To me you just said combine four and five.

MR. BENNETT: Right.

MR. FELDMEIER: I think there are two differences between four and five. No. 4 says, the one thing that distinguishes it from five initially is prior to medical use. Five doesn't say prior to medical use. So it looks like you can go back after the fact in five. Four looks like you'd have to do it respectively.

The other thing is, as has been said, four says that it has to be understandable and five says that it has to be done in compliance with it. I guess you can conceive of the situation where the technologist understood what was to be done, but, on their own initiative, went ahead and did something else, which shouldn't happen, but I guess it could.

What I would do is combine them, leave five pretty much as it is, except take out diagnostic referral, as you said. And for Oscar's concerns, add a phrase that written directives should be clear, legible and unambiguous.

MR. HAMMOND: I'd take out diagnostic referral because a diagnostic referral, at least in Texas, is not significant because you can't do anything with it anyway. You have to have clinical procedures.

MR. TELFORD: Any other comments on five?

[No response.]

MR. TELFORD: You're ready to move to No. 6.

MR. JANICE: No. 6 is presupposing that all of

your patients are outpatients and you ought to be able to do something with outpatients.

MR. TELFORD: Why do you say they're outpatients?

MS. ROY: The prescription is written.

MR. JANICE: That's true.

MS. ROY: In the chart flow.

MR. JANICE: And you'd be able to look at the chart and look at the patient bracelet, or whatever, or shake the hell out of them and say wake up and tell me who you are.

MR. TELFORD: No. 6, would you like to delete it, modify it or retain it?

MR. JANICE: You say retain it.

MR. BRAHMAVAR: Retain it.

MS. ROY: Retain it.

MR. BENNETT: Retain it.

MR. JANICE: Do you mean we have 100 percent this time?

MS. ROY: Let's move on quickly.

MR. TELFORD: Let's move to No. 7. No. 7 is identify deviations; identify and evaluate deviations. So perhaps you could delete the referral here and just use the manual or the prescription. Would you like to delete, modify or retain this?

MR. DADARI: I would like to clarify what you mean

by deviation and what is your range?

MR. TELFORD: What do you mean deviation?

MR. DADARI: If you're talking about isotope measurement deviation from my calibration, my calibrator to somebody else's, it's minimum ten percent deviation.

MR. JANICE: I think they're talking about the procedure itself.

MR. DADARI: On a unit dose base, I order five millicurie. I call the pharmacy, it's 4.9. In my calibrator, it shows 5.6.

MR. JANICE: You got a reqeust for a liver scan, and you do what? You do regular routine injection and you come around and do a flow study on the patient as well. That's a deviation from a liver scan because you added another procedure.

MR. DADARI: I'm talking about --

MR. TELFORD: Let's keep it real simple here. If the procedures manual says five millicuries and you measured 5.6, does your manual allow you to inject that 5.6?

MR. DADARI: Yes, it does.

MR. TELFORD: You said previously that you measured in the dose calibrator and recorded the amount and measured it at 5.6. You said you've identified this deviation from the manual, .6 is the deviation. You've identified it, you've evaluated it -- actually the

authorized user has evaluated it because in that set of standing orders it says the range within which you can go ahead. If you were outside of that range, then you would have to go back to the authorized user and say should I actually give this, do you want to change your prescription.

MR. DADARI: You would allow me to put that range or are you telling me what your deviation is?

MS. WALKER: It's already regulated.

MR. DADARI: If they go with that --

MS. WALKER: It's already in the regs.

MR. TELFORD: The ten percent and 50 percent are definitions for misadministrations. This is just any deviation. This would be the .6 percent. If it were a diagnostic case -- let's say we're talking about technetium and the deviation is .6 millicuries and the prescription is five. You measured 5.6. This is barely above ten percent. It's within 50 percent, so it's certainly not a diagnostic misadministration. But everybody's clinical procedures manual should say within a range, it's okay to give that, or, if it's outside that range, the authorized user has to say it's okay and has to approve it to give it because it may not do what they want it to do, but it's not necessarily at all a misadministration. It's just any deviation.

It could be barely greater than ten percent deviation for diagnostic, but certainly not less than 50

percent. This just says identify and evaluate. You identified it, you evaluated it. So it's a very small deviation.

MR. DADARI: On a unit dose basis, my dose calibrator is brand new. I all the time noticed the deviation between mine and -- he's telling me 4.9 and mine shows 5.5 or 5.6. The reason I'm emphasizing this deviation, we've been written up by the health department because according to regulation, if you inject more than 30 millicuries of Iodine-131, you have to keep the patient. It's got to be inpatient, not outpatient. But after that, you can treat the patient.

What kind of deviation or which sources are you going to follow?

MR. TELFORD: What did the prescription --

MR. DADARI: Thirty millicuries I-131.

MR. TELFORD: So this is a prescription.

MR. DADARI: Prescription.

MR. TELFORD: What did the prescription say?

MR. DADARI: Thirty.

MR. TELFORD: Thirty. And you measured 31?

MR. DADARI: 31.5 and the pharmacy measured 29.something.

MR. TELFORD: Forget what the pharmacy said. You've got a dose calibrator and it said 31.1. You

identified the deviation and you evaluated it. You did it, but that's not what I'm asking you. What do you want to do with No. 7? Would you like to delete it, modify or retain it?

MR. DADARI: I identified the deviation. So what should I do now?

MR. JANICE: You tell him what you do now. That's what he's asking. What do you want to do?

MR. TELFORD: What do you want to do with No. 7? Do you mean procedurally what do you do next? You satisfied the objective.

MR. DADARI: That's all you want to know, the deviation.

MR. TELFORD: It says identify it and evaluate it. You did it.

MR. DADARI: I don't have a problem.

MR. HAMMOND: I think the key word is unintended. If we're talking about something like what David's got, you've got plus or minus ten percent on your dose calibrator, you recognize that plus or minus ten percent is a possible deviation, so you don't really have to do anything with plus or minus ten percent. If he's got a patient that's not receiving the therapy dose, that's another issue, separate from this unintended deviation.

If you say plus or minus ten, that's an acceptable

deviation and you don't have to do anything. If it's an intended deviation, you have to identify and evaluate it.

MR. TELFORD: If I say to you any deviation, does that give you the same message or is that different?

MR. HAMMOND: That's different. Unintended implies that there is some tolerance. If you intend it, at the flow study or liver scan there was an intended deviation from accepted practice, if you had a therapy patient and you intentionally changed -- I know we had a discussion at the first workshop about they put seeds in a patient and did teletherapy. They couldn't get all the seeds in, so they changed the prescription which intentionally varied from the first prescription to teletherapy so they could get all the seeds in. That was an intentional deviation.

So if you take out the word unintended, you have a real problem with it. But as it is, I don't have any problems with it.

MR. TELFORD: Oscar?

MR. HIDALGO-SALVATIERRA: I'm not proposing to change it, but to me it will sound better if I say ensure that any -- identify unintended deviation and evaluate it. I would place identify before unintended.

MR. TELFORD: You would say ensure that any identified deviation --

MR. HIDALGO-SALVATIERRA: Unintended.

MR. TELFORD: Identified unintended deviation. Let me play the devil's advocate just for a minute. I didn't see it. I didn't identify it. Therefore, I'm not going to have to do anything.

MS. ROY: Because if you don't identify it, it's a misadministration. You don't have to do anything about it. Say that, yeah, I gave him 30, I was supposed to only give him 20. You're identifying it.

MR. HIDALGO-SALVATIERRA: What I'm saying is that the only way you have an unintended deviation --

MR. TELFORD: You reason that you know that it's unintended is because you identified it.

MR. HIDALGO-SALVATIERRA: No. Because you have a problem, you were able to identify unintended deviation.

MR. TELFORD: Okay. You're saying you're going to identify all the unintended deviations and you just want them evaluated.

MR. HIDALGO-SALVATIERRA: Right.

MR. TELFORD: Dr. Walker?

MS. WALKER: How do you evaluate something you're not aware of?

MR. TELFORD: The wording, the unintended?

MS. WALKER: No. The identified.

MR. TELFORD: What would you do with No. 7?

MS. WALKER: Four, five, seven and eight don't

upset me, but they strike me as unnecessary.

MR. TELFORD: Could we live with No. 7?

MS. WALKER: I could.

MR. TELFORD: Okay.

MS. WALKER: Any unintended deviation by techs are going to be identified and questioned. I guess I'm living in an ideal world where I expect people to do their job right.

MR. TELFORD: Okay. So already in your department the deviations are identified.

MS. WALKER: If they see something that's not according to the routine stuff, yes.

MR. TELFORD: Therefore, they're evaluating it.

MS. WALKER: They'll take it to somebody and ask about it. They don't make decisions about doses and changing the procedures on their own.

MR. BRAHMAVAR: Did you mean to say instead of identify, documented?

MR. TELFORD: No.

MR. BRAHMAVAR: Because if you know it's unintended, you already identified it. Otherwise, how would you know it's unintended? You already noticed it. I think it should be -- and plus I think if they bring all the cases that are unintended and they're corrected on a routine basis, would you want them to be documented?

MR. TELFORD: No. This doesn't ask for documentation.

MR. BRAHMAVAR: That's what I'm saying. The wording itself. Identify that you meant to make it document.

MR. TELFORD: No. That wasn't the intention. The only documentation would come at the time of the audit. You had your hand up?

MR. JANICE: It leaves me hanging.

MR. TELFORD: No. 7.

MR. JANICE: David and I were just talking evaluate and what? If you're going to evaluate, you've to do something with it, but David says if you can evaluate it, you also have to document it. Well, not necessarily. But I feel that necessarily. You look at it say, yeah, it happened, but what are you going to do with it?

MR. TELFORD: Okay.

MR. BELLEZZA: For me, we say in our clinic of a prescription is say 100 and a they see 102 and delivers that -- now, rather than write down 100 units today and know that tomorrow she has to give 98, and then write down tomorrow 100, that way it looks like nothing happened. There is an evaluation also in that this physician will say fine, do that. If she punched in 200 units and takes it to the physician, the physician may not want to just cut off the

prescription, may want to distribute the dose differently. So there's an evaluation going on there. But whatever is done, there is identification and evaluation. To me it seems very straightforward.

MR. FELDMEIER: I think what both gentlemen are saying is that it sort of leaves you hanging. I think to complete it, it should say and corrective action is taken where appropriate.

MR. TELFORD: Okay.

MS. WALKER: The adage is like they were saying about evaluating the documentation. If it's not documented, it wasn't done because that's what most of the agencies say.

MR. TELFORD: In the case of diagnostic and this 5.6 case --

MS. WALKER: I think they're nightmares.

MR. TELFORD: You measure the dose in the dose calibrator and you find 5.6 and then you evaluated it before you gave it in this case. Then in the report that you sent out documents that you gave 5.6. Even if it said and corrective action is taken if appropriate and through the evaluation that in that case there was no corrective action needed, but documented what was done in the report you sent out.

MS. WALKER: But you haven't documented that you evaluated it.

MR. TELFORD: Oh.

MR. FELDMEIER: This is a consistent problem with David's dose calibrator. And rather than take ten percent off, it's 25 and 30 percent off. What if it's a consistent pattern? It seems like that corrective action ought to be to maybe send that calibrator back to standardized. Maybe in David's case that's not appropriate. Maybe corrective action might be to rectify the operation of the dose calibrators.

MR. DADARI: There is another point to this. I don't know about radiation therapy. In nuclear medicine, the doses are varying so much from hospital to hospital, we vary the doses by weight. Say, for example, for a bone scan, I've seen standard dose around 18 millicuries up to 28 millicuries from Dallas to Amarillo. If we're into that range, it depends where you put your line.

MR. TELFORD: Why is that relative? You're talking about a single patient here. You've taken all those things into account to determine the dose for that patient. So whatever you're supposed to do that patient, why is all that other stuff relevant?

MR. DADARI: I don't believe that No. 7, if it's placed in the same organ, I cannot get the intent of it. I'm talking about nuclear medicine.

MS. WALKER: Certainly the first time I read it,

it did occur to me that someone could be picky and have to include a difference from 5 to 5.6. If that's going to happen, it's going to be a nightmare. Every time I'm going to have to reinitial that the tech gave 5.6 instead of 5, unless I can put in my procedure manual that a deviation of 50 percent. Then I don't have to write it on each individual thing.

MR. JANICE: That's what your procedures manual says, that you have that tolerance.

MR. TELFORD: Some folks have sort of said they didn't particularly like evaluated because it's hard to document that you've evaluated it. What if it says deviations identified and an appropriate actions taken.

MS. WALKER: If necessary.

MR. TELFORD: If necessary.

MR. JANICE: Leave evaluate alone because that will give you leeway.

MR. TELFORD: From your point of view. Could you amplify on that?

MR. JANICE: If you go ahead and put something on the end of it, when they come around and they say you evaluated it, what did you do about it, and ther you've got to go back and show them what you've done with it.

MR. TELFORD: True. You've got a clinical procedures manual and your manual allows you to do that. In

your case, you've identified it and evaluated it.

MR. JANICE: That's right.

MR. TELFORD: And are you worried about documentation?

MR. JANICE: Not if I say I evaluated it.

MR. BRAHMAVAR: Unless it's required by the inspector. We have normal questioning; do you have any unintended incidents; you say yes; then I want to see them; what am I going to show him?

MR. JANICE: But if you answer no, then forget it.

MR. BRAHMAVAR: But if you say no, that's very hard to believe.

MR. HAMMOND: I agree. I don't think we ought to add anything past evaluated. I think you need the leeway to decide what you want to do to evaluate it. If you want to reprimand the tech, if you want to adjust your dose calibrator or whatever, then you need to evaluate it. It's an ongoing problem with our people. Same situation with the 5.5 case. They shouldn't use the dose in the first place because it's greater than ten percent variation from the expected dose that they were going to receive. And the dose calibrator had recalculated the dose.

MR. TELFORD: Are you talking about the I-131?

MR. HAMMOND: I'm talking about the 5.5 he was talking about.

MR. JANICE: What do you term unintended deviation? Is an unintended deviation of the dose? Is it an unintended deviation of the exam or what? What is unintended deviation?

MR. TELFORD: No.

MR. JANICE: Ensure that any unintended deviation from either the diagnostic referral and the diagnostic clinical procedures manual. The prescription is identified and evaluated.

MR. TELFORD: You've got this five millicuries that's called for out of the clinical procedures manual. Any deviation from the five millicuries is captured here. Second example; in therapy, five millicuries of I-131. Any deviation is captured here. I think we put in the word unintended originally to make sure -- say if it were five millicuries of I-131 was the prescribed dose, but you get it from the pharmacy and now it's six, go back to the authorized user and say should I give six; okay, yes; here's a prescription signed for six; now you go give it. That's intended there, it's not unintended.

But from my point of view, I could delete unintended and still capture what I mean, which is any deviation from that which is prescribed or that which is in the clinical procedures manual.

MR. HAMMOND: I think in the scenario you've just

described, you identified it when you had the six. You're evaluation was you went back and the documentation is and changed it. The prescription is six so it was an acceptable deviation. That doesn't agree with you can leave unintended out and have the same meaning in that objection. I think you slammed the door a little bit too much because any deviation would be -- the procedures said for a liver scan you order five and you got 5.3. That is an any deviation.

But if you intended to have a ten percent spread in there, it wasn't an intended deviation, but it was a deviation.

MR. JANICE: You've got your clinical procedures manual that says you have that tolerance.

MR. HAMMOND: That's why I said unintended needs to be in there. It lets you use that procedures manual. If your procedures manual says 5.3, then later on says it has to be plus or minus ten.

MR. TELFORD: But what is intended by the clinical procedures manual is the five millicuries plus or minus whatever it specifies.

MR. HAMMOND: Why do you want to take it out? Let me turn it around. Why do you want to take it out? I think it's obvious and somewhat confusing because people that stop and thing what's intended or what unintended; of course, it's unintended.

MR. TELFORD: Ray, you were going to say something.

MR. FOSTER: I just have a question. If you consider 4.97 millicuries unintended deviation from five, you're going to be writing up proposals for every patient that you do. I don't think you're ever going to get 5.0.

MR. TELFORD: Why do you have to write something?

MR. FOSTER: That's where the question comes into it. Identify and evaluate, that's simply the dictation on the reports. They gave 4.95.

MR. JANICE: What you're saying is unintended and intended are synonymous. If you have a deviation it's going to be unintended.

MR. TELFORD: Yes.

MS. ROY: Not in all factors.

MR. JANICE: I'm just saying what I thought he said.

MS. ROY: In some cases you may have had deviation which is intended, but is not in your clinical procedures manual. That's for your five millicuries. You would have a range in your clinical manual, but you may have a deviation, but it would be unintended. If I had a senior citizen that was under the weight which was a pediatric weight, I would still be giving a pediatric dose, though it would be to someone that was over age; that would be an intended

deviation. It wouldn't be an unintended deviation.

MR. TELFORD: It would be, in fact, the dose that you should give to that patient.

MS. ROY: But it's a deviation from my clinical manual because adults would be listed underneath such and such, but I could make my clinical manual state weights.

MR. TELFORD: We could fix your manual, couldn't we?

MS. ROY: Right. But on those cases, I would have my authorized user initialize that deviation.

MS. KELTY: A scenario of an unintended would be infiltration of, say, a sulfur colloid dose. It's not going to be absorbed. You're going to give the patient a second dose.

MR. TELFORD: Try that again.

MS. KELTY: You unintentionally give a dose, so that's an unintended deviation from a procedure, but then you intentionally give another three millicuries. Are you intentionally giving six millicuries when the procedures manual says three millicuries?

MR. BRAHMAVAR: But when you do that, you gained the permission of the authorized user because you have to redose the patient. So he has signed off and approved that.

MS. KELTY: Yes.

MR. TELFORD: On No. 7, so far you've said take

out diagnostic referral here.

MR. JANICE: If you're going to get a referral for a liver scan but you add a flow study to the liver scan, that's a deviation from the diagnostic referral.

MS. WALKER: It's retained. It's part of the manual.

MR. JANICE: It depends on your manual.

MR. TELFORD: Your point is you could do a diagnostic study that's in accordance with the procedures manual, but it bears no relationship to what the patient is supposed to get. Therefore, you need to keep the referral. Good point.

It sounds like you're telling me to keep the whole thing just like it is.

MS. ROY: Retain the whole thing, including the unintended.

MR. TELFORD: Any other comments on No. 7?

[No response.]

MR. TELFORD: Are you ready to move to No. 8? No. 8 just says make sure your therapy planning is in accordance. Would you like to delete, modify or retain it?

MR. HIDALGO-SALVATIERRA: I'd retain it.

MR. BRAHMAVAR: It's fine.

MR. TELFORD: Do you agree, Ed?

MR. MOK: Yes.

MR. TELFORD: You . re

MS. WOOD: Retain.

MR. TELFORD: Any c . nts on No. 8?

[No response.]

MR. TELFORD: All right. Let's move to B. Final part of 35.35. Again, these are cryptic descriptors here of what we mean. There is Paragraph C, I believe, in your handout, which is the Federal Register, Page 1649. It's D, sorry. Licensee shall develop procedures to conduct a comprehensive annual audit, verify compliance, shall evaluate each of the audits and determine the effectiveness of the basic quality assurance program.

The intention here is to have a review, comprehensive review of the program each year; to have someone say it's still good enough or that it needs changes; and to build in the feedback loop that's internal to the licensee's organization that allows potential improvement.

Like we were saying earlier, if you have eight problems the first year, you widdle it down and you've got eight the next year, six the following year. Maybe you'll always have six thereafter, but at least you've taken the chance each year to kind of go through this.

So let me ask you, would you like to delete it, modify it or retain it?

MR. HAMMOND: Can I ask a question? Is the audit

intended to be a recording mechanism that's addressed into management? Is it not just an annual evaluation of the QA program or is it an audit of the daily collected 12 months?

MR. TELFORD: Well, let me answer that by saying the audit could be what some people may call a program review. It might be based on a randomly selected sample of all the cases you had that year. So you look at those cases and you see if the administration was in accordance with. And you have an audit report or a review report that says management evaluation and some folks might have a QA committee or something else that is set up; maybe they meet quarterly; but give the result back to that entity.

There is an overt step of determining that the program is still effective. And then the need to make modifications to prevent recurrence for all those things that were determined up here need to be fixed. So it's all those things.

MR. HAMMOND: Again, I think you ought to modify No. 1 because if your reporting mechanism is only on an annual basis, that certainly does not assure that No. 4 is carried out to assure that you have the prompt notification to prevent recurrence.

MR. TELFORD: How would you modify No. 1?

MR. HAMMOND: Typically, if we're talking about something that's some semblance of a quality assurance

program, they're reported monthly or quarterly. It does no good to do 6,000 studies a year and you wait a year to find out you screwed up on half of them. If you do 6,000 a month and you do it once a month, there's only 500 people or 250 people. I'm not saying necessarily that, but something less than annual if that's the only reporting mechanism.

MR. TELFORD: You're saying quarterly.

MR. HAMMOND: There needs to be an annual review of the program in its entirety, similar to what Joint Commission requires. They require monthly or quarterly reporting, but once a year you have to come back and say we didn't find anything. If you didn't find anything, you're looking at the wrong places. So you change your program.

But if the only reporting mechanism is once a year, that's too long an interval. We need either a monthly or a quarterly basis and report to management and maybe the yearly evaluation of that program.

MR. TELFORD: What are you doing quarterly or monthly?

MR. HAMMOND: You're reporting the data that you collected, we did so many patients, so many were corrected, not corrected, whatever, we met these objectives, and we fell out on these objectives. We took these evaluations, you can report that information somewhere, just collect it and keep it in the department. You've got four techs and

they all know what they did.

It's like you did all the work but you don't take any credit for it.

MR. TELFORD: So you would report that back to the QA committee or something.

MR. HAMMOND: In your scenario there, I would try and stay away from the QA committee. I would report it back to the management or department management. Maybe even assistant administrator in the hospital that you answer to or whatever.

MR. FELDMEIER: The way this reads is that you should conduct a comprehensive audit at intervals no greater than 12 months. So if you choose locally to do it at weekly intervals or daily intervals or monthly intervals or quarterly intervals, you're still in compliance. I think it's really better to keep a regulation at the Federal level that's less restrictive. If you choose locally or if there are other regulatory agencies that require you to do it more frequently, you're still in compliance with this regulation.

MR. BENNETT: I agree with that. Leave it at a year. If you find that for the first three years you need to do it on a quarterly basis, you get everything under control, and then you can fall back to a year. If you say you're going to do it on a quarterly basis, you're stuck with it forever.

MR. HAMMOND: I realize that.

MR. BENNETT: Any program like is would be reviewed as necessary and modified immediately as necessary if it's a good program. But to have a comprehensive review every week or every month or every quarter.

MR. TELFORD: You said monthly or quarterly.

MR. HAMMOND: I think you need an annual audit. I agree with an annual audit to reevaluate the program in its entirety. But if there is no reporting mechanism set up, what are you going to do with the information you collect? It's kind of like Item No. 4, have a responsible individual make sure he understands what he's doing.

It's real nice, it sounds real good, but does it go anywhere. When you collect data for 12 months and then say, oh, my gosh, nine months ago we really did something bad.

MR. TELFORD: Did you have your hand up, Ray?

MR. FOSTER: My comment was going to be basically what was said prior. I think you should leave it that way. Internally, you could do quarterly reports. I know I wouldn't want to collect information for a year to report. I would do quarterly reports and followup on it. But I think we shouldn't be required to have to submit to you every quarter.

MR. TELFORD: Not to us internally.

MR. FOSTER: I don't think we should make it any lower.

MR. FELDMEIER: I was going to say the same thing. I think we all probably agree that an annual audit -- I mean, if this is all you're going to do, if you're going to let things go long enough and look at them at 12 month intervals, you're not going to have a good quality assurance program. There are other regulatory agencies that are going to require you to have them more frequently.

But I think this regulation as it is, this part of Part 35 is fine. It's not as restrictive as maybe it should be, but it leaves room for you to go ahead and interpret this regulation and other regulatory documents and if you choose to do it on a monthly or quarterly basis, there's no reason why you can't.

MR. TELFORD: Terry?

MS. ROY: I have a comment on whose doing the auditing. I noticed in the pamphlet here --

MR. TELFORD: Reg guide.

MS. ROY: Yeah.

MR. TELFORD: We'll get to that tomorrow.

MS. ROY: Even though we're talking about the audits right now.

MR. TELFORD: Yes.

MS. ROY: Okay.

MR. TELFORD: If you can find something in this paragraph here on 1449.

MS. ROY: No. Okay. But that's where I had found out about the auditing itself. I didn't care for the way that was worded.

MR. TELFORD: We'll fix that tomorrow.

MS. ROY: Okay.

MR. TELFORD: How about the word audit? Is that a problem for anybody?

[No response.]

MR. TELFORD: How about licensee management, does that bother anybody?

[No response.]

MR. TELFORD: It was suggested earlier that we say department, department management or department check.

MR. HAMMOND: Management is fine.

MR. TELFORD: Licensing management is okay. What other comments do you have on all of this?

MR. HIDALGO-SALVATIERRA: To prevent recurrence.

MR. TELFORD: You've got to look at these words.

MR. HIDALGO-SALVATIERRA: Promptly.

MR. TELFORD: Promptly implement modifications within 30 days that will prevent recurrence of errors in medical use. Here we even have documentation. Licensee shall maintain records of each audit and management

evaluation that are often performed for three years. Does that answer your question, Oscar?

MR. HIDALGO-SALVATIERRA: Yes.

MR. TELFORD: Any other suggestions on this one, this part?

[No response.]

MR. TELFORD: Okay. In that case, how about did we miss something in 35.35 in objectives, in having the program, in having it reviewed each year? Have we overlooked anything?

MR. JANICE: I just go back to what I said this morning. I guess it is covered and isn't covered. You've answered my question one time, but in the case of treating patients with I-131 or even a thyroid and you bring them back on intervals, it's not the referring physician that's bringing them back anymore. It's you. So, in essence, how do you go about getting a referral slip? Is the mere fact that this document is in the patient's chart and signed by the user as a fact that the patient comes back?

MR. TELFORD: You've got a prescription, you're clear. No problem. Anybody have any additions?

MR. JANICE: There was nothing said about -- little was said about the computer. I was interested in how one maintains the fact that source changes or computer programs or whatever locks maintaining, so that those are

changed so that you don't forget to go back and actually do changes in your protocols.

MR. TELFORD: That I think we will cover in the regulatory guide. We talked about the regulatory guide and source changes. We have a paragraph on that. It's not too popular. We have to hear a lot of suggestions for how to replace that paragraph tomorrow.

Any other comments or additions?

[No response.]

MR. TELFORD: All right. We come to the last item on our agenda today. I want to give you some more individual air time, another three to five minutes, and make sure that we get your two cents worth in. But I would like to hear your final thoughts or conclusions on Part 35.35.

Keep in mind that tomorrow morning we will go through the guide. Tomorrow afternoon the reporting requirements both for diagnostic and therapy. So this is just the proposed 35.35.

Now, if you've already said it, you don't have anything more to say, I'm not going to twist your arm, but I certainly want to give you the opportunity to say anything else you'd like to say. Let's start over here with Ray.

MR. FOSTER: I don't know. I've already put in my two cents worth. I think we got a lot of positive comments and some changes that might be necessary. I really don't

have anything to add.

MR. HAMMOND: I've gotten four cents in.

MR. JANICE: I think we more or less put our dollar's worth in.

MR. BELLEZZA: Nothing.

MS. KELTY: Nothing.

MR. SHAFFER: I just have a question. The comments that are discussed here, what happens to that afterwards? Does it go back to the drawing board again and whose discretion to add, delete, modify?

MR. TELFORD: Well, let me say that it will be about five people that are technical types with NRC who will rewrite this. Three of them are in this room. I have made sure that we had at least three in every session of the workshop. So those that will be working on it heard the comments firsthand and understand and know your concerns, they know your desires.

We will take all of those and for all those that have merit, backed up by logic, more than likely will get into the final rule. That's why we're here. That's the answer to the question. Anything else?

MS. WALKER: Since I won't be here late tomorrow, I'll put in my comment and say that I think you're all good people, you're doing a good job, but in accordance with -- I feel the same way that the -- I don't feel that QA is NRC's

job.

MR. TELFORD: What if we called it, as you suggested earlier, performance guidelines?

MS. WALKER: Well, you're putting a wolf in sheep's clothing. It still is a QA program. I don't think it will do too much harm except if JCH and NRC inspectors conflict with each other, and I can see that.

MR. TELFORD: Your comment is directed at nuclear medicine.

MS. WALKER: Yes.

MR. TELFORD: Specifically.

MS. WALKER: [Inaudible.]

MR. TELFORD: Okay. Anything else?

MR. FELDMEIER: Just a quick statement and a question. I think it's very good, the approach to putting forth 35. I think it's a good thing having a trial period and soliciting input from the people out in the field practicing. I would just suggest that although we all are well intentioned and recognize the fact that it's very difficult to write a regulation, I think I would suggest that the NRC keep an open mind and after this has been widely applied, after it's been in effect for a year or two, I would suggest that we give serious consideration to another plan reevaluation at that point, because I think as it's applied widely there are going to be some problems or

some concerns or some misgivings or some difficulties.

So once this thing is published, it's not going to be chiseled in granite. The feeling that I think you've all demonstrated is that you need input from the field, and I think there ought to be a plan to relook at Part 35 after it's been in effect for some period of time.

MR. TELFORD: That's great. I haven't heard that before.

MR. FELDMEIER: The question I have, and I've asked this many times in many forms, and maybe you don't have the answer. Probably a practicing physician should know the answer to this question already. There is already a misgiving about quality assurance programs or any like activities when you actively sit down and criticize yourselves. The tendency is not to always be as honest and open as maybe you should be.

I have a concern that this information is discoverable in a court of law by attorneys or by plaintiffs. I wonder if the NRC has any feelings about that or if there's been any lega. thought or any opinions rendered by legal experts as to what the discoverability of such programs is.

MR. TELFORD: I can give you a quick answer to that. Currently, misadministrations are public information. So they're intimately discoverable.

MS. WALKER: QA minutes, per se.

MR. FELDMEIER: I've not heard an attorney say that.

MS. WALKER: I don't think it's been tried yet.

MR. TELFORD: I'm not an attorney, so I won't answer that. But something did come to mind that I should say in response to Dr. Walker, to Mr. Shaffer. After these workshops, we will go talk to the JCHO, find out how to get together with them. Also, we're going to talk to AAPM and American College of Nuclear Medicine. So we're going to touch all the bases.

MS. WALKER: [Inaudible.]

A transcript will be in the public document room. It was a good meeting. I got a lot of out it. We went through the program that was submitted. We reviewed it and compared it to the eight objectives. We also looked at the JCH inspection standards, and this is strictly all nuclear medicine. We didn't do it for brachytherapy, but we were given credit for it. There is a philosophical difference that remains.

We left off over here.

MR. MOK: I'm very happy to see NRC do this program. I think it's on the right track and the objectives are very good. However, I agree with Dr. Walker that quality assurance is a very important term. I think we

should be given a chance to call it something else or leave it to some other agency to care for quality assurance and NRC should stick to the regulation of the safe use of isotopes and radiation. So I think what we are doing is very good. I wish we would leave our objective just to the safe use of radioisotopes.

MR. TELFORD: David?

MR. DADARI: No comments. Nothing.

MR. TELFORD: Nothing more?

MR. DADARI: No.

MS. WOOD: I've been sitting here mulling over all the information, the additional information on how to use it and how to implement it. I think probably what's foremost in my mind is going back to my hospital, my radiation safety committee and saying this is what it was all about and these are the things we're going to use.

The institution has its radiation safety committee now, and that's what this is all about; using radiation safely. We're using these people to do all these things. I don't have anything else.

MR. BRAHMAVAR: I don't have any specific comments, but it's a good program and it's been beneficial, at least for us, to participate in this program because we have learned a lot regarding other people's QA programs and I hope that it gets off the ground, and the final document

comes for our people to use.

MS. LaFRANCE: I don't have any comments.

MR. HIDALGO-SALVATIERRA: I will have comments after I see the whole thing tomorrow.

MS. ROY: No further comments today.

MR. BENNETT: Nothing.

MS. GOODWIN: Nothing.

MR. TELFORD: All right. Before I forget, tomorrow begins at 8:30, not 9:00 as today.

[Whereupon, at 5:03 p.m., the workshop was recessed, to reconvene the following day, September 14, 1990, at 8:30 a.m.]

REPORTER'S CERTIFICATE

This is to certify that the attached proceedings before the United States Nuclear Regulatory Commission

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were held as herein appears, and that this is the original transcript thereof for the file of the United States Nuclear Regulatory Commission taken by me and thereafter reduced to typewriting by me or under the direction of the court reporting company, and that the transcript is a true and accurate record of the foregoing proceedings.

Betty Morgan

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