OFFICIAL TRANSCRIPT OF PROCEEDINGS

Agency: Nuclear Regulatory Commission

Title: Quality Assurance Workshop

Docket No.

LOCATION: Rockville, Maryland

DATE: Thursday, October 25, 1990 PAGES: 1 - 210

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

UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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QUALITY ASSURANCE WORKSHOP

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Holiday Inn-Crowne Plaza

The Rockville Room

1750 Rockville Pike

Rockville, Maryland

Thursday, October 25, 1990

The meeting convened at 9:20 a.m., pursuant to notice, John L. Telford, Chief, Rulemaking Section, Regulation Development Branch, U.S. Nuclear Regulatory Commission, presiding.

PARTICIPANTS:

U.S. Nuclear Regulatory Commission:

John L. Telford

Josie Piccone

Anthony Tse

Darrel Wiedeman

Brookhaven National Laboratory:

Edward Kaplan

Kevin Nelson

Riverside Hospital, Jacksonville, Florida:

Jonette Roberts

Penrose Hospital, Colorado Springs, Colorado:

Gerald White

University of Pittsburgh:

Andrew Wu

PROCEEDINGS

MR. TELFORD: Good morning. My name is John Telford. I am the section leader for the Rulemaking Section of the Regulation Development Branch. We are the guys who are responsible for developing this rulemaking.

I want to welcome you to the fifth post-trial period workshop that we have done. This is what we are calling a makeup workshop, to collect everybody that hasn't been to a workshop previously. We wanted to go the extra mile to let everybody have the opportunity to give us their feedback, because it has been very useful so far. I would anticipate that this group would also give us similarly good feedback.

I want to call your attention to the agenda that I have on the viewgraph and tell you basically what we are going to do in the next two days or day and a half or however long it takes.

Once we get through a few introductory remarks, then Mr. Darrel Wiedeman will tell you about the findings from the site visits and program reviews.

Then there is a little block of time, which is the discussion of the proposed rule 35.35.

Next on the agenda is a block of time devoted to discussing the reg guide.

Lastly we have a block of time that is devoted to

discussing the reporting requirements. If you agree, we might move the discussion of reporting requirements just after we do the rule in the interest of a few people who may not be able to stay all day tomorrow.

At this point on the agenda, I will let you introduce yourselves. For this self-introduction, I would like you to say your name and the hospital or clinic you represent and maybe what your position is, the size of the hospital or clinic, its location, and kind of tell us if it's an urban location or a rural location, and what departments participated in the trial period, whether it's teletherapy, brachytherapy or radiopharmaceutical therapy or diagnostics or all of the above or some combination of the above.

MS. ROBERTS: I am Jonette Roberts. I am a nuclear medicine technologist at Riverside Hospital in Jacksonville, Florida. Riverside is a 185-bed hospital. It's an urban hospital. The program is done in the Nuclear Medicine Department, diagnostic and therapy.

MR. WHITE: I am Jerry White. I am a member of the medical physics group at Penrose Hospital in Colorado Springs. We are in the program for everything with the exception of radioisotope teletherapy. We don't do that anymore. We have two hospitals on that license and we probably have a total of 400 beds in them.

MS. ROBERTS: I might add that we only do I-131 therapy.

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

MR. TSE: My name is Anthony Tse. I work with the NRC in the Regulation Development Branch. I am the project manager of this program.

MR. WIEDEMAN: My name is Darrel Wiedeman. I am the technical assistant to the Director of the Division of Radiation Safety and Safeguards in the NRC Region III office in Chicago. I am also one of the site evaluation team members.

MS. PICCONE: My name is Josie Piccone. I am in the Medical and Academic Section with NRC here in headquarters. I was also a member of the QA team who did some of the evaluations and site visits.

MR. KAPLAN: I am Edward Kaplan from Brookhaven National Laboratory, Department of Radiological Sciences.

MR. WU: I am Andy Wu. I am from the University of Pittsburgh. My primary function is medical physicist in the Radiation Oncology Department. We have two hospitals under the university license.

MR. TELFORD: How many beds?

MR. WU: Six hundred some beds.

MR. TELFORD: What departments participated in the

trial program?

MR. WU: Department of Radiation Oncology and Nuclear Medicine.

MR. TELFORD: Thank you. Let's move to the next item, which is to remind you of what we told you at the pretrial period workshop. This viewgraph here that's on the right is what the participants can expect. So part of this morning's program is to confess to you the criteria that we used to do program evaluations and to do site evaluations, and for you to learn the results of those two.

Just before lunch, we will hand out the checklist of the results of the program review. If your site was one of the 18 that was visited, then we have a site evaluation checklist as well. But we're really here to talk about the rule and the guide and reporting requirements. What we will be doing is we will be listening to you because we will step our way through the rule and the reporting requirements on the guide and listen to your feedback, because we really would like that help to improve the proposed rule.

Now, the last thing on this little welcome session in the groundrules. The groundrules are that we listen to you. We will from time to time have observers that will sit in the back and come in, but they will be refrained from asking questions or making comments, because we're here to listen to you.

So with that introduction, I would ask Mr. Darrel Wiedeman to come up and tell you about the results.

MR. WIEDEMAN: Good morning, Ladies and Gentlemen. Welcome to Rockville, Maryland. All of you remember the proposed Part 35.35 objectives. This morning I'm going to talk about the background, the evaluation criteria that we used, and the program evaluations, and about the site visits.

First, about the background, the first thing we did was formulate a team. The team that we looked for were people that were NRC employees, that had experience in nuclear medicine, brachytherapy, teletherapy, and radiopharmaceutical therapy, familiar with hospitals and how hospitals function. Then after we found that team -- and, also, one important thing they had to know, inspection techniques and licensing techniques.

The next thing we developed was an evaluation criteria. The evaluation criteria was used for the material that you submitted to us demonstrating how your QA program would operate. Then we went into preparing a program evaluation criteria, and that would be basically what we would use during the site teams to evaluate your program.

We want to be able to be consistent in our evaluation and reviewing a license application. So that was the basic premise behind the program evaluation criteria.

Sooner or later, when the regulation, if it does go into effect, this is probably the criteria that will be used by our licensing reviewers to assure consistency throughout all regions.

Same thing with the site evaluation criteria. This would probably be the data, the information that we will use for evaluating from an inspection standpoint. To give you an idea of what we are looking at, 18 licensees were randomly selected from this list. Eleven of them were from NRC and seven from the agreement states. We looked over 15 diagnostic nuclear medicine programs, 12 therapeutic radiopharmaceutical programs, five brachytherapy and eight teletherapy.

Geographically, they were pretty well scattered throughout the United States, from the east coast, the midwest, quite a few down in this area, out in California. We hit quite a few; a couple of military facilities, the Army Medical Center, the Bethesda Naval Hospital, the VAs in Texas were represented. We looked at just about all types of programs in the medical field that you can imagine.

The four programs, of course, that we were looking at were the four basic programs that you will find in a hospital. If you have any questions, don't hesitate to speak right out.

Now, on this particular slide, what we're looking

at is we've broken down in NRC and agreement state facilities, PP meaning private practice. Interesting thing; normally, you would expect the brachytherapy to be in a hospital. However, we were able to evaluate one out-patient brachytherapy facility using a high dose of remote afterloader.

Now I'm going to go through the eight objectives for the diagnostic nuclear medicine program. The first thing that we looked at was the medical use indicated, which would be Objective No. 1. You'd say, well, what does that mean, medical use indicated. Well, the team decided that this would be the criteria that we would use. Either the authorized user reviews all cases or the procedures are ordered by a physician.

Now, that means that the technologist is not the one ordering the particular nuclear medicine study. It's not left up to the scheduling clerk. It is ordered by a physician. We found that in every single case during the site visits that the licensees were 100 percent in compliance with that.

To give you an idea of the workload, out of the 15 nuclear medicine programs, the workload averaged about 18 procedures per year, up to a maximum of about 7,500 procedures per year. When it came to pharmaceutical therapy, the average ran anywhere from three procedures per

year, which is very small, up to 50 or approximately 50 procedures per year. When it came to brachytherapy, the average worked out to about 40 patients per year. Teletherapy was 400 to 500 patients per year.

Now, on Objective No. 2, this really wouldn't apply for a prescription because that would apply for pharmaceutical therapy. However, diagnostic referrals. We found that every single facility that we visited, that was not a big problem.

Medical or instructions understood. What we would look at during our program evaluation is we would try to confirm the statement that the licensee would follow the egulatory guide or commit to it, or they confirm that they are going to follow the regulation. Now, we looked at this item, personnel instructed on the importance of accurate and clear records, and we found that in all cases that most of the facilities, that was not a major problem.

They may not have procedures written. However, they were instructed in one way or another, either through annual retraining or through a procedure that they had implemented.

On the medical use in accordance with the instructions, remember that 35.35(a)(5) is in accordance with the prescription or a diagnostic referral and a clinical procedures manual. We found that all 15 facilities

that we visited had met this criteria.

When it came to the understanding of the current QA, we would look at these key procedures, we'd interview the authorized user, find out what his procedures are or her procedures, and then we would talk to the technologist. If the two matched up, then we would normally rate that as an excellent understanding. If there was some discrepancy on the procedures from one person to another, we would rate that as good. I don't believe we had any that were graded as fair.

Patient's identity, which would be the next, we found that there were very unique situations that we ran into. Of course, on the in-patient, you always have calling of the patient's name, checking of the arm band, verifying the procedure ordered in the chart, and, in military facilities, you have photo identification of the patient.

In several of the facilities, they would sit down with the patient, the technologist would sit with the patient and explain your doctor, Dr. Jones, has ordered this type of scan and we're going to do this, and explain it to them. If they detected a discrepancy where the patient had been admitted for, say, bone problems and you're doing a liver, the patient questions why am I getting a liver scan when I have bone or brain problems.

Then they would stop everything and go back and

review and make sure that they are doing the right procedure. We were looking basically for a redundant patient identification system. We found when it came to out-patients that it wasn't quite as tight in that area.

We found some very creative ways of coming up with the redundant system. Several hospitals, once the out-patient showed up, the technologist would come out and ask the receptionist where is Mrs. Jones, and the receptionist would say she's sitting right over there. The technologist would go over to Mrs. Jones and say, excuse me, what is your name and if she said Mrs. Jones, then that would be considered a dual redundant system.

Some of the facilities would confirm the patient's address from a registration slip. And, of course, once again, with the military out-patients, it wasn't a big problem because they had photo identification. Eleven out of the 15 facilities met this objective. However, it did not always meet it when it came to the out-patient program.

Unintended deviations were another area that we looked at. During our program evaluation, we would try to get confirmed that the unintended deviations would be reviewed. If they stated that they would commit to Reg Guide 2.3 and 2.5, that would be satisfactory. When we were looking in the programs themselves on the site visits, there were different areas that we would look at. One thing is

the regulation in 35.53 is already covered for checking and measuring the dose and recording the dose.

Remember in the Reg Guide 2.3/3.5, that states that you'll stop work of a discrepancy in records, observations or physical measurements is made, and you may resume once that discrepancy is resolved. We found in many cases -- well, in all cases, that if a discrepancy was identified, normally the technologist would go back to the authorized user physician and discuss this; say, well, my prescription or my procedures manual states 20 millicuries and you want me to give ten. If the authorized user says that's why I want to give ten, that would be satisfactory.

Objectiv No. 8 would not apply in nuclear medicine. That applies to brachytherapy. Any questions on diagnostic nuclear medicine?

[No response.]

MR. WIEDEMAN: The next area is on radiopharmaceutical therapy. The team, after getting input from previous workshops, decided that idohippurate, I-131, it would not be totally practical to require a prescription for hippuran because of some of the large facilities that do a lot of kidney scans, they do 20-30 cases a day, and the various different participants felt that this would be impractical to have the physician write out a prescription for such a routine procedure.

Once again, we were looking for the medical use indicated. How did we interpret that? We interpreted it as the authorized user reviews each case or the physician working under the supervision of the authorized user. Now, when it came to the prescription, we found that almost every time, it always would list the isotope, it would list the dosage. However, I think there were quite a few cases where it would not list the chemical form nor the route of administration.

We were very flexible in this area, because if you're doing nothing but iodine therapy, route of administration -- I should backtrack. If you're doing nothing but iodine therapy and you're always using capsules rather than liquid, it is assumed that it would be by oral administration and it may times would be listed in the procedures manual that we only give iodine capsules and it's always given orally.

But when you get into the more complex pharmaceutical therapy, such as P-32, this is very important on the route of administration because of oil versus soluble phosphate. The next objective, diagnostic referral made, this would not apply to pharmaceutical therapy. Remember that 2.1 on the reg guide, that is a prescription and a diagnostic referral will be legible and written clearly; 2.2 states workers are to request clarification if they're

unclear, ambiguous records.

Personnel instructed; we found that the technologists review and assign the procedures manual annually in many, many cases. All new employees, technologists are given an indoctrination period. We found in our site evaluations that 12 of the participants met that objective.

Once again, the key procedures that we look for in trying to determine if they have an excellent, good or fair understanding is discussing this with the authorize users, the technologists, seeing if everything matches up, procedures were in place, everyone has a good understanding of how things are done.

Telephone referrals was kind of a sticky situation. Many of the facilities would accept a telephone referral, but, once again, the authorized user would always examine the patient and make the determination of the dose. Most facilities would not do "emergency" radiopharmaceutical therapy. They said if there was an "emergency" where they wanted to do it right away, the authorized user is always directly involved.

Once again, patient identity verified. We were looking for some form of a redundant verification. Once again, the out-patients, that was the bigger problem. It wasn't a problem identified in the in-patients because you

have all these different ways of doing this; by calling names, arm bands, verification of chart.

The physician, of course, has examined the patient. We found that in 80 to 90 percent of the cases, the physician is the one who administers the dose. In military, we have the photo IDs. Out-patient, they don't have arm bands and many of them do not have charts.

However, once again, the same rule would apply as the diagnostic nuclear medicine. There are some creative ways of doing a redundant verification system.

Unintended deviations; we found that this was not a major problem at the site visits. All 12 met the objective. Technologists routinely consult with users to resolve discrepancies. One of the discrepancies that you could run into is -- let's assume that the authorized user physician prescribes ten millicuries of I-131 for a thyroid therapy, and your pharmacy delivers 9.5 millicuries.

Well, that would be contrary to what the prescription says. However, the technologist would always go to the physician and say, well, we're short some iodine; we have 9.5 versus your 10.5 that you wrote on the prescription. As long as the physician signs, dates, and acknowledges that he's going to get less than his original prescription, that would be more than adequate.

Treatment planning in accordance with

prescription. On Objective No. 8, this would not apply for pharmaceutical therapy. It only applies to brachytherapy.

Any questions on pharmaceutical therapy?

[No response.]

MR. WIEDEMAN: Now we'll go into brachytherapy. Once again, we were looking to make sure that the authorized user reviews all the cases. This was not a major problem that we could identify. All authorized users review the case in brachytherapy.

Prescriptions being made. We were looking for three things; either radioisotope, treatment site, total dose, or treatment time, number of sources, and combined activity. In all the facilities that we looked over in the site visits, they met that type of criteria one way or another, sometimes using different terminology, but the intent was still there.

On Objective No. 3, of course, that applies only for diagnostic, not for brachytherapy. Now, keep in mind this is what we look for in our program evaluation and this is what we're looking for at the site visit. Personnel instructed to clarify unclear records. When it comes to brachytherapy, this can be a very sticky situation, especially for a dosimetrist who doesn't quite fully understand what the physician really wanted.

However, everyone knew that if you have a problem,

if you don't understand, you go back and you ask the authorized user or the medical physicist, whichever would apply.

Here, procedures to verify radionuclide source strength with prescription. We found various different situations. One would be using a procedures for identifying serial numbers, color codes of the sources, and various dose rates measured from those particular sources.

For remote afterloading devices, we only had one program that we looked at on the site visits. Once again, we would look at the key procedures, looking at the prescriptions, emergency conditions, there are types of situations that you could run into in brachytherapy that's considered emergency; patient identification; once again, a redundant patient identification system; and some way of clarifying unclear records or requests.

Now, with brachytherapy, it was a little different than with pharmaceutical therapy or diagnostic. We found that most of the oncology groups that we talked to, they say that they have a very close working relationship with the patient because they have examined the patient, they have had a formal referral from the referring physician, and in many, many cases, they'll have a photograph. They take photographs of the patient. They'll have a photograph inside the patient's chart.

Ninety-nine percent of the time, brachytherapy is done as an in-patient, so we also have a chart, we also have an arm band that we can use for redundant verification of the patient.

Unintended deviations would probably be very common in brachytherapy. The reason I say that is because many times patients cannot tolerate the therapy and many times the patients will fall under sedatives, will pull out the afterloading devices, remove the sources, physically cannot tolerate the treatment. Therefore, a total prescribed dose of so many -- you may not be able to deliver that dose.

So as long as the authorized user goes back and records why he couldn't give the full treatment and has it documented, it should be no problem. We also identified during one of our site visits, we asked to look at three cases of recent brachytherapy. You would think that when the NRC shows up at your facility, asks for three good cases, we identified that there may have been an unreported therapeutic misadministration.

I thought, well, gee, I think if it was me, I would have pulled three good cases rather than one that's questionable.

Treatment planning, we looked for various different ways. We changed the word here. It used to say

current industry practices. We said that's not really current industry practice, it's just acceptable practices. We were looking for various ways to calculate the dose; by using radiographs, nomagrams, dose tables, other equivalent methods.

Some people say, well, I like milligram hours. They say you predate yourself when you say that, but some of the facilities are still using milligram hours of treatment.

In this area, manual dose calculation, we were looking for a procedure or a way of detecting math errors; correct transfer of data, using the proper nomagrams, computer-generated calculations. We were looking for a procedure or a system that you would ensure that you're getting the proper input/output of data.

Computer-generated calculations seem to be more and more common. However, if you enter the wrong data and you get out the wrong data, then the wonderful system that you have is really worthless. But I was quite impressed with some of the systems. However, I was told that some of these computer-generated programs, they have a lot of problems; that you will buy this program, use it for a while, and then all of a sudden, six-eight months later, you get an update of the program where someone has identified a problem. All along you think, well, gee, I've been using that for six months.

When it came to verification of treatment time, dose calculations, and patient setup, we were just looking at what kind of a system was in place for doing these various things.

Any questions on brachytherapy?

MR. WHITE: Yes. I'm interested in how some of the clinics met the prescription criteria for brachytherapy. Oftentimes our physicians don't decide on a final dose until after the implant is in place.

MR. WIEDEMAN; That is correct.

MR. WHITE: How did people do that in the program?

MR. WIEDEMAN: We found that in many cases what would happen is the physician will write a prescription giving a range, 3000 centigray to 3500 centigray; with cesium-137, so many of them millicuries. Then after the source or the dummies and the applicator are loaded and the radiographs are taken and nomagrams or used or computer calculations are made, then the medical physicist or the dosimetrist will determine what dose it is to the different organ.

Then a discussion is made with the authorized user and if it was agreed that this is the configuration we want, then they load the sources as prescribed earlier. Then the physician will go back and rewrite the prescription, saying that we plan on giving X number of centigrays to -- and then

spell it out, sign it and date it. We found that that's probably about 95 percent of the cases.

MR. WHITE: How did people meet the requirements and the regulations to determine that the prescribed dose did not differ from the administered dose by more than 20 percent of the prescribed dose? That seemed to us to be technically difficult in many cases.

MR. WIEDEMAN: Yes, it is. Keep in mind the only time that you run into problems is if, of course, you forget to remove the sources at the predestined time, or if the patient removes the sources before the treatment -- or some unique situation where the sources are removed before the treatment is completed.

As long as the authorized user goes back and documents that, we had to remove the sources because the patient couldn't tolerate the treatment, the patient removed the sources, we're going to finish up on teletherapy or on the accelerator and give them the complete -- and that would be acceptable.

MR. WHITE: It seems to us that there are a number of situations in brachytherapy where the prescription itself can't be calculated to within 20 percent. Two examples that come to mind are iodine seeds that come from 3M have a radial asymmetry of -- their limit is 20 percent coming out on the shot.

Another example would be brachytherapy where the prescription point is close to the source; for example, vaginal applicators where 20 percent error results from a one millimeter displacement of the coordinates. That seems to be a difficult Federal regulation to meet.

MR. WIEDEMAN: I think that we've heard that comment before. Wasn't there some discussion that maybe --

MR. TELFORD: Yes. We'll get into that discussion when we get to the reporting requirements. Did you have a question, Dr. Wu?

MR. WU: My question is similarly along that line. I just don't want people to look at just the trees and forget about the forest. I think the overall errors involved in the whole procedure; brachytherapy procedures, external procedures; the main errors are -- the first one is prescriptions. I mean, if you take 100 doctors and ask them to prescribe the same patient, they give you a range of plus or minus 20 percent dosage. There's no problem.

The second is -- like Gerry said, it could involve as much as a 20 percent error. If we just concentrate on some of the individual cases, it's all about 20 percent or ten percent over a dose, and then probably we're not doing the job to regulate the overall accuracy. We just concentrate on something which is not really significant.

MR. WIEDEMAN: That's a good point. Any further

questions on brachytherapy?

[No response.]

MR. WIEDEMAN: Okay. We'll go into teletherapy. Once again, the regulation, medical use indicated, how well the licensee complied with that particular requirement, where we felt that the authorized user should review the case. We find that it's standardized operating procedure in teletherapy for the authorized user to sit down with the patient, discuss the proposed treatment plan, write a prescription. A medical physicist will calculate the dose or the dosimetrist and the technologist will implement the treatment plan and maintain documentation.

When we looked at prescriptions in teletherapy, this is what we were looking for. Key words; total dose, number of fractions, treatment site, prescription changes are written, dated and signed. We find that in every case that is fairly typical in the industry to have this data. I hope those of you who have teletherapy are saying, yeah, we do that.

Diagnostic referral; this would not be applicable for teletherapy. Instructions understood by responsible individuals; this is what we would look at during our program evaluation. During our site visits, we would look into these areas. We find that there is a very close working relationship between the technologist, dosimetrist,

medical physicist, and authorized user, and usually if something doesn't make sense, like the physician has signed a prescription for treatment of the left hip and, however, the patient is complaining of problems with the right hip, then everyone knows that we should stop and go find out what the problem is, because all along we've been taking x-rays of the left hip, why are we treatment the right hip, that type of thing.

Although we just recently had a case like that. The patient finally said, hey, why do you keep pointing that machine at my left hip. It's my right hip that's bothering me.

Once again, we have current industry practice, but this is not really current industry practice. We find that there is a way to look for daily errors in the cumulative dose, and we find that many, many of the facilities have a minimum of a weekly chart check where the authorized user, the dosimetrist, the technologist, they pull all the charts, they look them over, go through all the different slots to make sure that everything is filled out, any missing data, are we doing the right treatment, a quick recheck of the calculations.

Once again, we talked to the key people; the dosimetrist, the medical physicist, authorized user, technologist. We look at this type of -- are the procedures

in place, does everyone know what to do. Emergency conditions are considered under teletherapy. Occasionally they'll have a compressed superior venal cava or compress the spinal cord.

However, we found in every single case that the authorized user is consulted. They just don't do it unless the authorized user is available. Now, there was a case, if I remember right, where the authorized user -- no, no. The scenario came up that he may be out of town. They wanted to know by consult over the telephone with the authorized user, if that would be acceptable, and we considered that as acceptable.

Patient's identity is verified. We were looking for a redundant system. There's charts, photos, arm bands, port shots, that type of thing. Photos inside the teletherapy file, we found that that's fairly typical anymore, where you will have not only the patient's head and face, but you also may have a photograph of the treatment site, showing the tattoos or the marks.

Unintended deviations are identified. We were looking for cases where possibly the patient cannot tolerate the treatment. The total prescribed dose was, say, 6000 centigray, could only give the patient 4000 centigray because. If it was documented in the chart, that's what we would consider as acceptable. It's the ones that originally

prescribed 6000 and gave 4000, there was nothing in the chart that would describe why we stopped the treatment, assuming they stopped it.

We were looking for procedures to confirm the dose calculations to make sure that they're accurate prior to completion of treatment, independent check of full calibration measurements; that's presently required by the regulation. Full calibration includes check of beam modifying devices. We were looking for unique situations.

Now, some of the facilities we found do some hemibody teletherapy treatments. Hemibody in some facilities is very, very rare; one or two patients per year. We want to make sure that you're using a different source to skin distance or depth dose distance, if you're using a different field size, that some type of evaluation has been made, such as a direct physical measurement.

Some people felt that using inverse square is good enough. I don't 100 percent believe that. I feel a physical measurement is better than going by inverse square, because there's too many variables.

Any questions on teletherapy at this point?

MR. WHITE: Yes. Did you inspect against the reg guide criteria for checking computerized -- it's 5.10 -- before the first use of a computer program for dose calculations? And it lists several things.

MR. WIEDEMAN: Yes.

MR. WHITE: How did people -- what was the com .iance with that?

MR. WIEDEMAN: It was very good. Let me think. I remember the Army was that way. Yes, Josie. Can you remember what --

MS. PICCONE: Yes. We didn't inspect against the particulars that are in the reg guide. What we inspected against were the procedures they said they were going to use to check the computer program. You may not have come in with a procedure, and most people didn't, that is like that reg guide procedure for that.

MR. WHITE: So people proposed all --

MS. PICCONE: So people proposed alternate procedures and that's what we looked at on the site evaluation. Unless they said we were going to do the reg guide procedure, most of the therapy facilities did not buy off on those reg guide procedures. They submitted procedures to us. So we just looked to see that they had some procedure in place that they used to check a new computer program, be it that they looked at some standard patient periodically, they did a measurement the first time for one configuration, whatever. It wasn't that we looked at all of those details of the reg guide.

MR. WIEDEMAN: Any further questions on

teletherapy?

[No response.]

MR. WIEDEMAN: Let me give you some statistics on some of the facilities that we visited. Ed mentioned earlier about the private practice facilities. Bed size; the smallest hospital is 150 beds all the way up to, I think, a little over 1,000 beds. I'll give you an idea of the diagnostic nuclear medicine facilities, their workload. I think that was out in California versus -- I think that was the Bethesda Naval Hospital.

Pharmaceutical therapy. Once again, this was California, three procedures per year. To them, they thought that this was really a big thing when the State of California granted them the authority to do iodine therapy. The word spread throughout the hospital that they were going to do iodine therapy and everybody wanted to come down and watch on the first treatment.

Well, after the first treatment the word got around it's no big deal. The patient sits there, you give them a pill, and they walk home. They were expecting something really sophisticated.

Let me explain what we're looking at here. Here we are looking at Objectives 1 through 8, we're looking at the nuclear medicine facilities. There are 15 of them. Therefore, you will never see anything above here.

The program of review criteria, this is what the licensees told us that they were going to do in their procedures. This, the dark is what we found during the site evaluation. I'll give you an example. Objective No. 1, ensure that the medical use is indicated, remember that was where our interpretation of that would be that the authorized user reviews all cases, number one, or it's ordered by a physician.

Well, everyone told us that they were going to do this and when we went to the site visit, we found that everyone was doing that. Now, when it came to writing a prescription, we had several facilities that told us that they were going to use a prescription method for ordering diagnostic nuclear medicine studies.

Well, there were what, three, two? But when we got out there, we found out that their interpretation of a prescription and ours were not the same. It was really a diagnostic referral. Keep in mind, eight is blank because that only applies to brachytherapy.

So, in essence, you can see what you've told us and what we find. Usually we find more than what you tell us, and this applies in just about every one of these. Pharmaceutical therapy; medical use indicated, you told us that and we found that. You told us you're going to use a prescription; we find that only those, you are using the

prescription. This would not even apply.

Here's a case where, on Objective No. 4, so many licensees told us this and, yet, when we out there we found that they're doing it 100 percent. Same thing here and here.

On brachytherapy, interesting. There is a case where just about every one of the objectives -- other than this one, medical use indicated, almost every one of them, we found more information by the site visit than we did by reviewing the criteria that was submitted for review.

Same thing with teletherapy. We find more by going out on our site visits than by reviewing the material that was submitted.

Any questions?

[No response.]

MR. WIEDEMAN: Later on this morning I'm going to pass out to you a copy of your program evaluation. Yes, you have a question?

MR. WHITE: Yes. When you reviewed the compliance with the diagnostic referral/prescription for ordinary diagnostic nuclear medicine procedures, there was a line item there for telephone referrals.

MR. WIEDEMAN: Right.

MR. WHITE: Was that a satisfactory solution if the paper trail actually began in the hospital?

MR. WIEDEMAN: Where we ran into that moreso was on out-patient clinic. I remember one of them where they had 100 percent of their patients as out-patients. Many times the physician would call and say I'd like to send Mrs. Jones over for a cardiac study. Fortunately for this facility, they had cardiologist authorized users right there on-site. So when the patient showed up and they didn't know if it would be a mugga or a thallium or whatever, they would go directly to their authorized user and say Dr. Jones has referred this patient, and then it would be the authorized user that would decide what would be done to the patient, and he would write out on the prescription or the slip or diagnostic referral.

MR. WHITE: In your inspections, if you came to a facility where the referring physician called up and ordered a bone scan for Mrs. Jones, Mrs. Jones showed up without any paper --

MR. WIEDEMAN: It happens all the time.

MR. WHITE: Did that fall into the satisfactory or unsatisfactory category?

MR. WIEDEMAN: Well, we ran into very different scenarios. We always asked that same question. Every facility was a little different. We had one facility over in Indiana say that if Mrs. Jones showed up with -- we got a call from the doctor's office saying that we're sending her

over for a bone scan, we would tell the doctor that we expect the paperwork in two to three days to come.

If it was a receptionist from the doctor's office that called, they would turn around and call the physician some way or one of his associates and say your receptionist contacted us for a bone scan on Mrs. Jones, is that really what you want, and you will submit the paperwork within several days.

So there were various different scenarios. I think most -- everyone I can think of was acceptable. That's just the way things are done in the medical community. Yes, Josie?

MS. PICCONE: Let me add a little bit to that. Because we were evaluating the programs against the draft rule as it's currently written, if there was nothing written, we did not assume compliance. As Darrel said, many places use the telephone referral system to initially schedule patients, to get them, and it so happens many of the facilities, they were trying to put some written system into place anyway; not just for nuclear medicine, all of radiology, because in many cases nuclear medicine fell into that department.

So they were using this as just one additional push to get the physicians to give the patient a written referral when they came in. So some facilities who

participated in this pilot made a real effort, and we're talking about 18, just the 18 that we looked at, made a real effort to meet this. So that they sent letters to physicians telling them that they must do this, reenforcing that they will do this.

But across the board, for not just nuclear medicine, for radiology, all radiology procedures, as well, many times the technologists, the way they addressed this problem is when they were doing the telephone referral, that they got more information than the patient's name. So over the phone, they got some additional information. They got a little bit of patient history.

So that when the patient came in, there was some way of being able to confirm that, yes, in fact, this is the patient and this is what the doctor wanted. But for the purposes of this site evaluation, if there wasn't something in writing either before or that came with the patient, we said that they didn't strictly -- not strictly -- they didn't meet the requirement.

But certainly that is something that we're going to be discussing. In Darrel's summary, if you can turn to your sheet on diagnostic nuclear medicine, that's Objective No. 3, and you can see that out of the 15 facilities, I think ten met that objective. Twelve said they were going to and ten met it. The five that didn't, didn't because

there was nothing in writing.

So that, in general, is what we found. As I say, many of the facilities, they made a real effort in one way or another to try to meet this. Some had started procedures along this way before in order to try to get this fixed. Some facilities already had in place if the patient didn't present with the piece of paper, they wouldn't do it, and they found after sending patients back or calling the physician a few times, that that took care of that situation. They pretty much came with it.

And remember we're not talking about emergency kinds of situations either, because there is an exception process for that. That was sort of a longwinded way to answer your questions.

MR. WHITE: That's what I wanted to know.

MS. PICCONE: We expected something at this point because we were looking at what is the draft right now, but there have been other things that have come up in other workshops along this. One of the things is what I mentioned to you; if it is just a telephone referral, what else is going to be done to ensure that that is truly what the physician wanted on the patient and that it's what should be done, and that's where people are getting additional history or whatever.

MR. WHITE: But you still need that piece of paper

from the referring physician.

MR. WIEDEMAN: I remember one facility, I believe it was one in Illinois, they have in the hospital a Records Policy Committee, some kind of a records committee to make sure that the referring physician fills out the patient's chart before it goes to the medical records office. Apparently the physicians do have a tendency to forget to fill out the patient's chart. Even though the patient has been discharged, gone home, the record is incomplete.

Well, this hospital implemented a procedure where if they get an out-patient referral and they tell the doctor you have to submit your diagnostic referral within three days, if he doesn't submit it within three days, they turn it over to the Policy Committee and the referring physician gets a letter from the administrator saying that you made a verbal referral to the out-patient nuclear medicine department and now we need a piece of paper to confirm that that's what you wanted.

That was another way of complying. I thought it was a unique situation. We only found that in one hospital though. Any furthe questions?

[No response.]

MR. WIEDEMAN: Okay. Thank you very much.

MR. TELFORD: Let's take about a ten-minute break and come back at 10:35.

[Brief recess.]

MR. TELFORD: Let's go back on the record. Welcome back from the break. Now we're going to take a few minutes and give each of you some individual air time to talk about your experience in using and trying to use the proposed rule. Let me just suggest that you take three minutes, five minutes, ten minutes, whatever you would like to use, and tell us about your experience during this 60-day trial period and your observations that you might make, just in general because we'll get to the specifics later.

But you might comment on the extent of the change that you made to your existing QA program in order to meet the proposed rule. You might want to say some comments about the incremental work or incremental cost. But, in general, just some sort of overall impression, comments that are based on your experience during this 60-day trial period.

I started over here with Jonette before, so let me start with Dr. Wu this time. Let's be fair.

MR. WU: Let me just talk about my experience. It was in only two areas, the brachytherapy and teletherapy. In the program starting June 1 and ending July 31, 60 days, and most of the items which are listed on 35 have already been implemented, with a few changes. I'll just emphasize certain things that we have been doing.

I have a few points. One is that the first goal that you tried to -- okay -- so the medical use indicated for the patient's medical condition. It's very difficult to quantify. In other words, we did not have a program implemented. I think the medical malpractice probably effects the physician's practice more than this particular regulation. I think the physicians are extremely conscientious about this. But we don't have particular procedures to reenforce this particular goal.

The second point I would like to make is in terms of treatment planning system, I think it should be the manufacturer's responsibility to make sure that their dose calculation software is accurate enough to be applied to the clinical use. I think this program sort of takes that responsibility and it falls onto the users, the consumers' shoulders. They have to verify that the software for treatment planning are actually doing their job.

I think when the manufacturer, the vendor tries to sell a piece of machinery, they have to sure that it actually does reflect the real dose calculation in the patient. The third point I would like to make is that if you look at the overall procedures, brachytherapy or teletherapy, one of the most uncertain factors involved is the physician's prescriptions.

If you ask them about 4500 centigray, is that

really what you want, and they can back down to 4000, they can increase to 5000. That's just to keep you in ten percent variation up there. The second biggest uncertainty is the calculation algorithm in the treatment planning system and that we depend so much on what tne computer tell us what the dose is. There's a great deal of uncertainty involved.

With such a large uncertainty, one tries to just monitor small deviations, like I think there were rules in the 35 that if single fractionation, if it's less than half, it's reportable fractionated dose. But sometimes biologically it doesn't make any difference if you gave the patient 200 rads or 100 rads. There is no biological damage done to the patient.

I sort of think that the whole objective of this proposal is to protect the consumer, protect the patient's welfare. If there are some factors which do not have any biological consequences, we really shouldn't spend much time or effort or resources to monitor it.

I'm really for the ten percent overall deviation of the dose, which means that ten percent is -- the order of magnitude of the uncertainty of the physician's prescription, maybe it was in the same order of magnitude as the dose calculation. But if you try to tighten that limit, it doesn't really give any better care to the patient.

MR. TELFORD: Okay. Is that all?

MR. WU: That's all.

MR. TELFORD: Okay. Gerald?

MR. WHITE: Well, we did start with the nuclear medicine part of it first. Rather than just agree to follow the reg guides, we wrote a little proposal. We thought it was generally similar to many of the objectives, but perhaps not all of them. We wrote it in such a way as we intended it basically to reflect what we were doing, with a few very minor changes that people agreed we probably ought to be doing. So for us the implementation was fairly straightforward.

The most difficult item for us in the diagnostic part of nuclear medicine was the written referral because we don't do that. Our hospitals exist in a competitive environment where not only do you have to properly care for patients, you have to properly care for referring physicians. The thought of sending a sick old man back to his referring physician for a written prescription was just horrendous. The physician was likely not to send him back to our hospital for the actual test.

We compete with a number of nuclear medicine institutions that do what we think is lower quality nuclear medicine, but have better public relations, and you have to be very careful about that.

So basically we changed the authority a little bit in who reports to who and how the management interacts. We changed the audit procedures a little bit. We changed the clinical -- the part about is the right patient getting the right radioisotope. That seems to occur a couple places here. I think that's the real crux of what this is all about.

Basically, what we do is we receive either a telephone or a written request for a study that has to include an indication. The study is not performed unless the technologist finds out what it is the referring physician intends. For most studies, then, the technologists, who are all registered nuclear medicine technologists; that is they have some familiarity with the nuclear part and the clinical part; they do a brief clinical history of the patient prior to injecting them.

If the clinical history doesn't seem to match the indication, then they stop and investigate further. Then during the exam, although admittedly it's post-injection, they do a more complete clinical history. We have a set of folders in each exam room with a two-page form specific for each exam; for a bone scan, different cardiac exams; that they fill out with a more complete clinical history.

Then for certain other studies, we have an additional -- what we have found in the past is there are

some studies that are prone to problems. Thyroid is one of them. Although we haven't had that problem, certainly there is the potential for a horrendous accident here. So thyroid tests for anything other than just a standard I want 23 uptake, are reviewed by the authorized user. We do a fair number of whole body iodine scans where patients get a substantial dose of I-131.

We've also had a problem with renal scans. That's a sort of nebulous request and there are a lot of different things that you can look at, a lot of different ways to look at kidneys. So every request for a renal scan is also reviewed by the authorized user prior to the study being done. That's something that we have always done.

Then the written prescription for therapy doses of any type. In addition, at least in our clinic, for patients who get iodine therapy for cancer, 100 millicurie type doses, that dose is actually assayed by the authorized user. That's one of our policies. He goes in, he puts the dose in the dose calibrator, reads the number himself, and then personally administers the dose to the patient. We think that that's an important thing.

That worked pretty well. The implementation was fairly easy since we were already doing almost all of it. We did have a couple meetings with the technologists and the physicians. We came up with an estimate of what the whole

thing would cost and it's sure hard to do that kind of thing, but basically we looked at how much time we spent putting it together, having the meetings, looking at the audits, and multiplied it out by the ratio of two months to 12 months.

Assuming the tradeoff, that we had some extra time involved in the startup process, but then we had a lack of effort because there was going to be no inspection. It didn't have to work, basically. I think that that's a real important part of it. We came up with about $20,000 a year for virtually no changes. We were basically doing all this stuff anyway.

For the brachytherapy, we felt that neither the reg guide nor the regulations were possible to fulfill, so we wrote, again, some different requirements about how things would be prescribed. We dropped the requirement that dose calculations have to be done from the actual source radiographs. The only thing we really changed there that we hadn't been doing in the past is to have the dose calculations reviewed by a second qualified person shortly thereafter, which was fairly easy for us.

We have three physicists in the group who cover two hospitals. So if a guy is at a meeting or on vacation, we always have another person who is available. It would be much more difficult to do that if we had a one-physicist

shop. We're of the opinion that having it reviewed by a second person is not as important as having it reviewed by a second person who knows what they're doing, and I think that that's an important thing to keep in mind.

The three physicists talked about doing the teletherapy part with our accelerators, just to sort of try it out. We read it over and we just didn't feel that either the reg guide or the regulations were sufficiently far along that a trial was warranted. They just didn't look easily doable or clinically relevant.

We don't do much brachytherapy. We probably had like two or three patients that fell into this. We do a lot of nuclear medicine studies. We've got nine gamma cameras. I asked the technologists and the physicists what their impressions were just sort of informally and basically they, again, didn't see any big changes. They were all puzzled as to the relationship between the program and the objectives, these objectives and the basic objectives of the program to reduce misadministrations.

Nobody saw a close connection between those two things. They didn't feel that that was likely to occur. In our facility, almost all the misadministrations have occurred for reasons other than this; basically overworked, tired technologists, on a very busy afternoon, a lot of patients, pick up the wrong syringe.

We generally don't have misadministrations due to misidentifying patients or wrong referrals. We've had in the past. Ten years ago, as everyone did, a request for a liver scan and trying to figure out if it's ultrasound, nuclear medicine, has been a problem and we spent a lot of time dealing with that and that's over with now.

So that was the biggest impression of everybody, sort of why are we doing this, it's not going to change our procedures, our misadministration rate here, and it's probably not going to change the misadministration rate at the sleaze-ball nuclear medicine clinic down the street who is not going to do it right anyway.

MR. TELFORD: You wanted to say something, Josie?

MS. PICCONE: Yes. May I ask for clarification?

MR. TELFORD: Sure.

MS. PICCONE: I guess I'm a little unclear of where the financial burden, so to speak, how that was determined. Is it just for nuclear medicine, you gave this $20,000 just for nuclear medicine?

MR. WHITE: That was for the whole shizole, although in therapy there was very little expenditure because the physicists do all that.

MS. PICCONE: And in nuclear medicine, everything is -- you were doing most everything already anyway.

MR. WHITE: That's right. I took my time, all the

time that I spent, the time that the physicists spent putting together this program, the time we spent talking with the physicians, instructing the nuclear medicine department. You know, you get 12 nuclear medicine techs and three physicians in a room for an hour-and-a-half, that's a lot of money.

MR. TELFORD: So this is implementation costs.

MR. WHITE: Everything we did because you guys came up with this.

MS. PICCONE: Okay.

MR. TELFORD: But how would that relate to annual operating costs?

MR. WHITE: Because you have to produce this document, it has to be real, it has to really work. You have to instruct everybody in it, you have to audit it to be sure it's happening. You have to negotiate with the state, something we didn't have to do, to see that -- to agree that this document that we create meets their needs. You have to go through the inspection process.

I've already spent an hour with the state inspector on this issue and it's not even a regulation yet and we're going to have to do it. I think that's all real cost that you really need to think about.

MS. PICCONE: So this is what the cost would be, the recurring cost each year?

MR. WHITE: I think it's hard to predict exactly what the recurring cost is. I don't have any reason to believe that the startup costs and the costs incurred with inspection and actual compliance with a law will be different. I just guess that they would be the same. I don't think they're going to be trivial. I really don't.

The cost sending one patient away who walks -- the patient comes into our clinic for a cardiac study and gets sent back to the referring physician, costs the hospital thousands of dollars.

MR. TELFORD: Did you consider that in your $20,000?

MR. WHITE: No, I sure didn't. I didn't even include one of those.

MR. TELFORD: Okay. We were just asking for clarification. We're not doubting your numbers.

MR. WHITE: They're just guesses. I just added up all the hours multiplied by six.

MR. TELFORD: Jonette?

MS. ROBERTS: My 60-day trial period was carried out without any incidents or misadministrations and recordkeeping was in order. We already have a QA program and hopefully it meets all the objectives, although I did have to pull some papers on the therapy part of the policy procedure manual to send to you.

We have a QA officer and once a month we meet with the QA officer, who is a radiologist. That includes the cat scan department, x-ray department, nuclear medicine department, ultrasound department, and right now we're monitoring indications to make sure you know that we're getting indications on the orders.

If an order comes down from the floor that does not have an indication on it, we will call the floor and say you have to reissue an order with the right indication and we won't scan the patient without it. We monitor the arm bands and we also have the chart with the patient, and we review the chart and we have a patient information sheet that they fill out.

As far as therapy goes, we do very little therapy. We just do I-131 and we have probably three or four cases a year that are below 30 millicuries, and maybe one every two or three years 30. As far as the cost goes, I don't think it cost anything to do this.

MR. TELFORD: Because you were already doing it.

MS. ROBERTS: We were already doing it.

MR. TELFORD: Okay. Yes?

MR. WU: May I add a couple things on that? There are two additional impressions I got from this pilot study. One is it can be implemented easily in the large institutions because we have multiple physicists,

dosimetrists who can check one another, do many independent checks. If some physicists practice all by themselves in a rural area, that would be very difficult. As far as we're concerned, we don't have any problem with it.

The second point is that there are certain things, when this was written, I think it was to oversee the principle of -- when there was a suggestion to check that the practice source independently, one suggestion is to look at the serial number. Anyone who has been in the field long enough, it's just not possible to look at the serial number of the seeds and source every time you load it. It's just not possible.

So the seeds and source have a color code to identify the sources. Also, if you need an independent check of the loadings before you treat a patient, you need two people to go up there and load this. One loads, the other one has to unload and load again or watching the other people loading it, or both of them look at the serial number.

This is not practical. So what we implemented was whoever unloads the source will be different than the person who loads the source. So they can double-check the loadings. However, it's after the fact, after you've already treated a patient. Even with large institutions like ours, we just don't have the manpower to have a two

people going up there to double-check the source loading, then two people go and unload the patient.

I think there are certain things that, unnecessary exposure, one should try to avoid to our staff.

MS. PICCONE: I think just to put it into perspective, some of the procedures that Darrel mentioned are not procedures being espoused by NRC specifically. These are the procedures that licensees have in place to meet that objective, not that NRC is saying you must check the serial number or you must load and unload and have another person unload and reload.

Although what you say, it's not practical for you, we did visit facilities that do that routinely. They read serial number and that's what they do to confirm the doses. I inspected a large facility in D.C., big broad-scoped program, that does that routinely. That happens to be their procedure or their solution to whatever problem they felt.

That doesn't mean that that is what we feel is the only way it can be done. There are a number of ways. It's for you to develop or determine the way that you feel would be most applicable to confirm that you've loaded properly.

Darrel mentioned two or three ways. But you could sit there and list another five or six. People segregate doses by activity, they're in different drawers, there are pictures on the wall on where things are. So there are a

number of ways that you could come up with, just as Darrel mentioned some of the procedures that we encountered on our site visits.

MR. WIEDEMAN: There was one facility that they had already set up a little -- I don't know what you would call it, but they would place the needle at a certain point and three or four feet away they'd have a GM set up, and they knew that a five milligram needle will give you X number of millirem and a ten will give you so much and a 15 will give you so much and a 20. That was their way of verifying that they had the right source.

If the doctor asks for a 10-10-5, they'd pull out what they thought was the ten, even though they can see the color on there. They would do a verify; yeah, it measured X number of millirem at so many feet, and they have a little checkoff list. That was another creative way that they did it.

MS. PICCONE: And some facilities are using those, recently on the market, brachytherapy dose calibrators. A number of facilities have gotten those, as well. I mean not in response to this, but on their own. You make a good point, but we are not saying that that is what you must do to meet that objective. It so happens that that is what we found.

MR. WU: How do the other institutions do the

double independent check for the loadings?

MR. WIEDEMAN: In a couple cases I can remember, there were two people that go down there. One would pull the needles out of the drawer. The other one would, okay, what serial number do you have, and they'd check off, that's the ten, that's the ten, that's the five. They'd have a little checkoff list. That was in quite a few cases.

The other, like Josie said, they had dose calibrators. One would drop the needle into the dose calibrator. The other one would record that, yes, that's the ten milligram.

MS. PICCONE: They may not use two physicists, and we only site visited -- I forget the number now -- five brachytherapy facilities, a small number that we actually went on site visit. A couple of those facilities did this not with to physicists, with the physicists and a dosimetrist or a physicist and a --

MR. WIEDEMAN: I remember one where it was the dosimetrist and the technologist that would do the dual verification.

MS. PICCONE: So we're only telling you what we saw, what people did to meet this, at this point; not that we say there is only one way that you can verify this, and that's what you have to do. Nothing could be further from the truth.

MR. TELFORD: Okay.

MR. WHITE: Let me just ask a question. This is individual, I guess, but we submitted a separate -- an alternative program. Was that acceptable? Did anybody look at it to say, yeah, in real life --

MR. TELFORD: We're going to get to that.

MR. WHITE: Okay. Great. Report card?

MR. TELFORD: There's no fault. It's just information. There is no grade. But if we didn't think that your program met one of the objectives, then we did try to say why, but it's a no-fault kind of grade.

MR. WIEDEMAN: Some of them you'll see need more information because we were not 100 percent sure. It wasn't directly stated that ensure that medical use is indicated, how you met that, and we'd just check off needs more information.

If it was a licensing action, we would normally send what we call a deficiency letter or a phone call saying, hey, do you mean that this is how you're going to meet this criteria, is this what you were going to do, and then we would confirm it in writing.

But in this case, we didn't do that. We just figured that if we do a site visit, we can find that information.

MR. TELFORD: Okay. Let me call your attention to

the next item on the agenda. Just before we break for lunch, we will give you your checklists back, your information. I'd like to propose that we move to the discussion of the proposed 35.35 QA rule and see if we can do a few of those items before we break for lunch.

You will find that item at 1:00 on the agenda. It says first we're going to talk about the purpose, and then we're going to talk about each objective and the audit provisions. So let me start with the purpose of 35.35. Some of you have made some comments this morning about the purpose of this.

Let me say that the way I'd like to do this is I'll be asking you, would you delete this, would you modify it, or would you retain it. One other proviso is that the words I have up here are the cryptic descriptors of the actual words. So you will need to look at the copy of the Federal Register Notice. If you don't have one of those, just hold up your hand and we'll get you one. I want to make sure that you can look at the actual words.

This would, I think, be on Page 1449, if I remember. This would be Paragraph A under 35.35. That paragraphs basically says --

MR. WHITE: Do you really have all those little paragraphs memorized? That's very impressive.

[Laughter.]

MR. WHITE: What's on Page 14?

MR. TELFORD: Thank you. What the paragraph basically says is that each licensee shall have a written basic quality assurance program. It will be designed to prevent, detect and correct the cause of errors in medical use and will have as an objective to provide high confidence that errors in medical use will be prevented.

So what we're about here is to prevent errors. Let me say that medical use is the term that we used in this proposed rule. It has an unfortunate connotation in that it brings up the thought of medical use in the broad sense. But what we meant was its definition in 35.2, which is the administration of byproduct material or radiation therefrom.

So the essence of this objective is to have the nuclear physician give a directive for what to do and to have that directive carried out. So that we are happy, crudely speaking, if what was prescribed is what was administered. Those two are of importance.

The quality assurance thought is that you try to detect any errors, try to prevent them, and correct the cause as you might make mistakes.

MR. WHITE: It's not just what is prescribed. If you have a physician who sends -- a family practitioner sends -- some physician sends a guy to the hospital for a bone scan because his kidneys aren't working right. That

ought to be caught, but isn't it part of the objective to --

MR. TELFORD: I agree. That would be both preventing and detecting. You would like to prevent the -- that's just an inappropriate referral, I think is what you're describing. But that's the role. Notice I said the nuclear physician. We would like the nuclear physician to be in charge. That's the person who ought to be deciding if this patient should get a dose of byproduct material and, if so, how much and in what manner, what form, etcetera, etcetera.

But that's what we're trying to say here. We're also trying to say that we're shooting for high confidence that errors will be prevented. In other words, this is not zero defects, but, rather, high confidence. You would design a program such that you could have high confidence that you prevent errors or actually administer what was prescribed.

The big change here from what has been tried before, what is current in Part 35 at least, is that this would be a performance-based regulation, where each licensee gets to develop a program to meet the eight good things to do, which are the eight objectives. So each licensee would get to say exactly how they would do it.

So if I ask you what would you do with this Paragraph A, would you delete it, would you modify it, or

would you retain it? Tell me what you would do, tell me why, or tell me how to modify it.

MR. WHITE: That's kind of the crux of the whole thing, though. This sets up the entire multiple pages that follow and it's one of the things that, in our group at least, with the nuclear physicians and the chief tech and the physicist, we've discussed a lot.

One of the things that our group feels is that there's a difference between having a program that does this, which we feel is good medical practice, we certainly agree with that, and making it a regulation. It's the word "require" that puts an entirely different complexion on this.

To say that it's appropriate medical practice is something that we all want to do. To say that it's a regulation invites a lot of other questions; how significant is this really, is it worthy of regulatory concern, is the regulation likely to affect the outcome that's desired, and then is the regulation likely to be implemented.

I think that there is in our -- the thing that I was supposed to come here and tell -- I get a lot of instructions.

[Laughter.]

MR. TELFORD: Yes. You're here to represent your licensee. We understand that.

MR. WHITE: Yes. Well, people kept grabbing me the lapels and saying will you get out there. People are, first of all, not sure that this is necessary, that when you put into perspective medical misadministrations of radiopharmaceuticals with other problems in medicine, that it's not a significant problem.

I don't know if you saw this article that was in JAMA about prescribing errors for stable pharmaceuticals where they did a survey looking at how often do people make mistakes prescribing drugs that are not -- basically, they didn't say not radioactive, but that's what caught my eye, and it's immense compared to the radiopharmaceuticals.

MR. TELFORD: Is it 20 percent?

MR. WHITE: Well, actually it's up to four-tenths of a percent, half of which are significant. When you look at the prescribing errors that were mentioned in the Federal Register, it was on the order of ten-to-the-minus-fifth or ten-to-the-minus-sixth. I remember it was an incredibly tiny number.

If you haven't seen this, I made a copy of it if anybody wants to have it. But that was what the physicians wanted me to come and say, is that we do an infinitely better job than any other prescribers in the hospital, and perhaps this is not something that's going to make the situation a whole lot better.

The second question is given that this really is necessary, if we don't agree with it, will the regulations proposed meet the objectives? I'll wait and talk more about that as they come up. The basic feeling at our facility is that a regulation for this is not warranted based on the evidence that was described in the Federal Register. Looking at those numbers, they thought, damn, we're doing a real good job.

MR. TELFORD: But that's nuclear medicine, diagnostics and therapy?

MR. WHITE: Yes.

MR. TELFORD: Or were you talking teletherapy, brachytherapy or all four?

MR. WHITE: I calculated them up separately here.

MR. TELFORD: We acknowledge that nuclear medicine departments and therapy departments are doing a great job and there's doubt about that. In comparison to administration in the non-radioactive drugs, the performance does look good. But the mission here for this Paragraph A is to say that we'd like to make sure that -- like to ensure that the public is adequately protected.

Our job is not the practice of medicine. Our job is to make sure that the dose that they're supposed to get of byproduct material, that it's administered properly and administered as prescribed.

So how would you modify this?

MR. WHITE: Other than deleting it entirely, which we think has a lot of merit, we would change the word "require" to "encourage."

MR. TELFORD: Let me just pursue that. If you said let's delete this, then that's tantamount to saying let's don't have a quality assurance rule.

MR. WHITE: I think -- and that's a tough question. I think everybody in our department has agreed that quality assurance is important. We're not in agreement about whether it ought to be constrained by regulation or not. I think that if it were to be constrained by regulation, our philosophy would be entirely different.

One of the things that we made differently in our report, in our procedure, is that our feelings of the most important thing in a quality assurance program is qualified personnel. This is something I'm going to say later, I think that ought to be changed in there.

The other thing we feel is important, at least for diagnostic nuclear medicine, is measuring the doses prior to administering them to the patient. In the first meeting I went to in Dallas when you listed all the different misadministrations, I had read these previously and I looked at all those, I didn't see a whole lot of them that would have been prevented if these were in effect, but almost

every one of the big ones would have been prevented if, A, you would have had qualified people doing the tests, and, B, they would have had a dose calibrator into which they inserted the dose.

Those two things alone -- I think you listed 12 --

MR. TELFORD: That was in nuclear medicine.

MR. WHITE: In nuclear medicine. Basically, the misadministrations were thyroid problems. To be real blunt, other misadministrations are trivial. You're talking about 100 rads being probably not -- and we're talking about half a rad or two rads or three rads. It's just not significant.

My kids got more dose than that because I moved them from Philadelphia to Colorado. I think all of those thyroid misadministrations could have been prevented -- might have been prevented with those two things, and all this other stuff is superfluous.

MR. TELFORD: Your nuclear medicine department or your hospital, is it a member of the JCHO?

MR. WHITE: Yes.

MR. TELFORD: So that program is voluntary.

MR. WHITE: Yes. And I think this would be a great program if it were also voluntary, but it's not. I keep saying that about the enforcement. I can't tell you how important that is.

MR. WIEDEMAN: Let me ask a question. If you have

implemented a QA program and you're quite proud of it, should the guy down the street also implement a QA program?

MR. WHITE: I think that's a great idea.

MR. WIEDEMAN: If it's voluntary, he can say, no, if we implement the QA program, we'll have to turn patients away and we want to bring those extra bucks in.

MR. WHITE: I think that one of the differences between the sleaze clinics and the hospitals is they're very sensitive to regulatory compliance. If you guys pass this rule or the State of Colorado passes it, our hospital is going to do all this stuff. They're going to spend a lot of money doing it. They're going to do it right. The guy down the street is going to sleaze by.

There's going to be something written for every patient. We're not too sure where it's going to come from. When the inspector comes in, there's going to be a lot of paperwork. And when you get written up for non-compliance, they'll get written up for it. It's not going to hit the newspaper.

If Dr. Jones has some non-compliances, you're never going to hear about it. If Penrose Hospital, the second largest employer in the city has non-compliances, it's going to be in the newspapers. I think those are real differences. There are already a lot of regulations that both of those institutions need to follow, and, quite

frankly, they don't.

I know, because I do the physics for both of them.

[Laughter.]

MR. WHITE: I agree with you that this is a great idea. It's just the regulatory framework. It's the "require," second word in Item No. 1 that I think puts an entirely different complexion on it.

MR. TELFORD: Yes. For us to do our job, we have to have an enforceable regulation. If it's voluntary, then Hospital A can decide to do it and Hospital B can decide not to do it. So that doesn't produce any uniformity or any consistency of making everybody come up to some minimum standard.

MR. WHITE: I think that's a tough issue. Our position, our feeling is that if these become regulations, our patient care will be worse and not better because we will take time that's currently devoted to clinically-productive activities and transfer it to non-productive regulatory activities. We'll be doing the same thing, but spending more time at it.

MS. ROBERTS: I think it's a good idea, myself. I think it promotes awareness on the technicians' part and if there are set rules to go by, they're going to go by them. If not, you know they're going to say, well, I won't check this arm band this time, I'm in a hurry or whatever.

MR. TELFORD: Well, let me ask you that now that you've made that point, we acknowledge that point and you made it very well, we hear you. But now let's assume that there would be a final regulation, it will be enforceable. Since you're from an agreement state, then it would be a matter of compatibility for agreement states.

So you would be dealing with the State of Colorado on these regulations. So if we make that assumption, then how do we make this have a minimum impact on you?

The other point that you made about, in essence, causing you extra work, to spend extra time here that you'd rather spend in someplace else, we'll keep those thoughts in mind as we go through the objectives and let's figure out there how we can say those such that it would have minimum impact and minimum distraction from your principal business.

So with the thought in mind that there would be some final rule, what would you have it say in Paragraph A? How would you modify this?

MR. WHITE: If there's going to be a rule, I wouldn't change it at all. I would agree with all that stuff. You have to do it. How could you disagree with that, really?

MR. TELFORD: It's not so much disagreement. You can disagree on some words and then tell me a better word. Step down from disagreement to something like fix, polish,

modify. The exact words, of course, are on Page 1449. Are there any thoughts or words there that you would change?

MR. WU: I don't like that word -- of course, I don't like the requirement. I completely agree with you. I fully agree with Gerry, and we have a very comprehensive QA program at our institution.

The second word I don't like about it is the error. Errors implies that they did it wrong. With the perspective that the physician has ten or 20 percent variation of their dose, dose calculation with a certain amount of variation of dose, if you don't have a very well defined prescription, what is right, then the errors --

MR. TELFORD: What word would you like instead of errors?

MR. WU: We had it before as deviation or -- I don't understand -- if you don't have it well defined what is right, how do we define this error?

MR. TELFORD: You're setting up a paradox, but I'm going to take it away because if you can't tell me what you're going to do, you can't do it. So a very fundamental thought is that you've got to be able to write down what you're going to do. If you're going to do radiopharmaceutical therapy and if you're going to give 30 millicuries by oral administration, if you've written it down, people know exactly what to do.

An error in that case is easily defined. But if you --

MR. WU: But it's different --

MR. TELFORD: But if you want to talk about brachytherapy administration where it's harder to calculate the dose that's going to be administered, then this is a qualitative statement. What you're thinking of is a quantitative difference, which we'll get to in the reporting requirements.

MR. WU: Right. I mean, all the goals you set here, total of eight goals, they are noble goals and nobody can object to that. The problem to me is that sometimes -- I heard of one case where the patient was -- carcinoma on a node, and they used this superficial unit to treat. Originally, it was supposed to be 400 times five or something like that. Due to the calculation misstatement, the patient got almost like 1500, one shot.

MR. TELFORD: Fifteen-hundred rads?

MR. WU: Yes. One shot, single shot. The doctor came to the patient and apologized, the techs made a mistake, and so on and so forth. The patient, said, fine. The doctor says you don't have to come in any more. The patient is very happy. That patient went home and actually it saved a lot of the patient's time and effort actually because the disease actually was cured.

Now, it's the deviation from the prescriptions, but there is no biological damage to the patient. If the purpose of this proposal is to protect the public, protect what? Protect biological damage. Then I will say in this case there is no biological damage. It is a deviation and maybe it's an error, but no biological damage is done and it saved the patient another four trips.

MR. TELFORD: Your example is a very good one to apply to the reporting requirements. So let's pick that up.

MR. WU: But the goal you set here, like I said, it's very noble and nobody can object to that. Nobody can object to that.

MR. TELFORD: We'll allow you to object, no problem. You use the word mistake. You said the technologist made a mistake and you've used the word deviation. Would you prefer one of those instead of errors?

MR. WU: But somehow you're not -- you said you protect the public.

MR. TELFORD: Yes.

MR. WU: Protect the public from what? Protect the public -- what's the definition? What are you trying to protect?

MR. TELFORD: Protect them from any harm, any adverse effects of an improper administration of byproduct material, misadministration.

MR. WU: Therefore, if this "misadministration" does not cause any biological damage --

MR. TELFORD: We've stepped into a problem here, because what's a misadministration? We don't get to that until we get to the reporting requirements. At this level, we're talking about qualitative things, nothing quantitative. We're just talking about preventing errors, preventing mistakes, not how big they are, but just --

MR. WU: Mistakes in numbers, mistakes in final --

MR. TELFORD: Anything, any mistake, either in number or in kind or in amount. The thought here is to have the byproduct material administered as prescribed. Any deviation from that is a mistake, is an error.

MR. WHITE: I think the point is perhaps not an error for which the public --

MR. WU: A deviation is not an error.

MR. TELFORD: We don't even know yet what the public needs to be protected from. We won't know that until we get to the reporting requirements. Here we're just talking in general about mistakes or errors. That's not even the point of the thought here.

The point is that the QA program should provide high confidence that these mistakes will be prevented. Two prime thoughts here, high confidence is prevented. So is there anything that you would modify there? What would you

change?

MR. WHITE: I think that's good language.

MR. TELFORD: Dr. Wu?

MR. WU: Up to this point, fine, before we talk about the quantitative.

MR. TELFORD: All right. Let's move on to the first viewgraph on the first four objectives. Maybe we can get through one or two of these before lunchtime.

MR. WHITE: If you hold us up for lunch, we'll talk faster.

MR. TELFORD: No. No cruel and unusual punishment. We'll just see what we can get done. Now, we set up Paragraph A which says each licensee should have a written QA program. Now we list the eight good things to do, the eight objectives. So the same thought carries over here. Would you delete, modify or retain these? Let's take them one at a time.

Let's take No. 1. Let's put that on the table and say do we delete, modify or retain this objective. Dr. Wu?

MR. WU: I'm talking about radiation oncology.

MR. TELFORD: Okay.

MR. WU: I think, as Mr. Wiedeman surveyed, almost 100 percent, they are doing that. I don't think putting this in -- I think it's more of a conscientious effort, plus that the risk of being sued by a lawyer, malpractice suit by

a lawyer. Therefore, they put a lot of effort in the first goal, but I'm not sure whether if you put it in it will make things even better.

MR. TELFORD: We put it in because this is a logical first step. Somebody needs to decide that this patient should get byproduct material or radiation therefrom.

MR. WU: If the physician comments on this, that it's their medical position, then you don't have to tell them whether the patient need or need not have the procedure.

MR. TELFORD: Therefore, I think you're saying you would keep it.

MR. WU: I think it's not necessary.

MR. TELFORD: Not necessary, you would delete it.

MR. WU: Yes.

MR. TELFORD: Okay. Gerry?

MR. WHITE: I think it's like apple pie. How can you disagree with that? You could have just as easily substituted or added patients shall not be physically abused during nuclear studies. That's why they come to us. The real question is what happens when you make this an objective and people are going to try to do. Is this the wrong thing to -- I mean, to disagree with that would be to say that we should not ensure that medical use is indicated

for the patient's medical condition.

Well, how could you agree with that? You have to agree with that. The question is does it meet the objective that you stated before, and that is to provide high confidence that errors in medical use will be prevented. The real question in my mind is does Item No. 1 there provide high confidence that errors in medical use will be prevented, and the answer to that I think is clearly no.

It clearly will not do that in radiation therapy since radiation therapy physicians already carefully evaluate the -- the physician who prescribes the procedure is the one who evaluates the patient. It's the same guy or the same practice.

In nuclear medicine, I think that in a number of facilities, even if that rule is in effect, there is no indication that the procedures that people use to follow that objective will, in fact, ensure that errors in medical -- high confidence that errors in medical use are prevented. I don't see the correlation between those two.

MR. TELFORD: Good point. Jonette, do you have anything to add?

MS. ROBERTS: Not on that one.

MR. TELFORD: Not on that one, all right. Let's move to Objective No. 2, then. This one says that you should have a prescription for a teletherapy procedure, a

brachytherapy procedure or a radiopharmaceutical therapy procedure, or any procedure involving more than 30 microcuries of iodine-125 or I-131.

Let me remind you that prescription is something we define that's a written directive or order dated and signed by an authorized user. So this is signed by the nuclear physician. This prescription has certain information content. The content varies depending upon whether it's for teletherapy, brachytherapy, or radiopharmaceutical therapy.

Now, would you delete, modify or retain this objective? We're making the assumption that we're going to have a rule and what should it say.

MR. WHITE: One of the things that I would suggest, and we talked about this while we were having coffee, is that for brachytherapy, prescription prior to medical use is sometimes problematic. There are a lot of reasons for that. I think one of the things that would make that better is, at least for brachytherapy, to ensure that in connection with medical use or as part of the medical use, the word prior is a problem for brachytherapy.

MR. TELFORD: Okay. Prior to medical use is a problem because -- you tell me.

MR. WHITE: It's a problem because medical use occurs when the sources are placed, let's say, within a

patient or on top -- applied to a patient. Oftentimes the physician at that time has not yet determined what his final therapeutic goals will be. I think it's inappropriate to ask a physician to write down what his goals will be before he has the clinical information to formulate them.

One of the things that a physician does in determining how he's going to treat patients with brachytherapy, and this is different than the others, is to look at the relationship between the nuclear sources that you regulate and the patient's various organs. You don't know that oftentimes until the sources are applied to the patient.

I think it's not reasonable to ask a physician to make a prescription before he has the clinical information that he needs to determine the course of the patient's treatment. Again, in a non-regulatory sense, setting, it might be appropriate to ask a physician to devise a treatment plan or something like that prior to applying sources, but in a regulatory context, when you say we would like a prescription, it's not something the physician can do.

MR. TELFORD: So are you saying that you would change prescription to pre-plan for brachytherapy?

MR. WHITE: No, I wouldn't.

MR. TELFORD: What would you do for brachytherapy?

MR. WHITE: I would ensure that a prescription was written in connection with the brachytherapy procedure, but not necessarily prior.

MR. TELFORD: Meaning after implant.

MR. WHITE: Possibly, possibly before.

MR. TELFORD: You mean before, if possible, but -- I think what you're saying --

MR. WHITE: I wouldn't say that. I definitely wouldn't say that, because somebody has got to then decide if it was possible for that doctor to write a prescription ahead of time or not, and the guy that's going to decide may be a well qualified inspector who is familiar with clinical medicine and may be some guy that's never been in a hospital before.

Again, that's the difference between the regulatory process and the voluntary process. I think what I would say is a prescription has to be done in connection with the procedure.

MR. TELFORD: Now, the purpose of having something written is -- and let's take the case of brachytherapy. I think what you're saying is that -- an example might be if you were trying to implant 22 seeds and you find out that you can only get in 19. If you wrote the prescription based on 22 seeds before you went into the OR, then you would have to modify it when you come out. So if you had a pre-plan

That says you were going to implant 22 seeds, each of a given strength, when you got out of the OR and you found out you could only get 19 in and you found out their exact location and you know their strengths, then you can calculate how long they should be in there.

It's really at that time that you could write the prescription.

MR. WHITE: That's right.

MR. TELFORD: And that's why you're saying in connection with.

MR. WHITE: You can write the prescription when you have all the information you need to decide on the radiation dose to the patient, and that includes not just the number and activity of the sources, but the position of the sources in relation to various anatomical structures of the patient. Oftentimes you don't know that until the implant is underway.

MR. WIEDEMAN: Shouldn't there be some kind of a directive to tell you as the medical physicist that I plan on doing something to that patient, iodine seeds to the prostate? The scenario you're giving, you don't feel it should be prior to, but maybe it's a treatment plan, the wording of treatment plan rather than prescription.

But it seems to me like what you're saying is the physician could say I want to do something to the patient in

OR with brachytherapy and I'll write the prescription after I put the sources in. To me, that's backwards. It should be that I plan on doing this to the patient and if that doesn't work out after we go into OR, I'll revise the prescription. I think that would be -- they know that they're going to put iodine seeds in there.

MR. WU: But they don't know how many seeds.

MR. WHITE: Suppose the physician wrote I'm going to apply radioactive iodine-125 seeds to Mr. Smith's prostate, signed Dr. Jones. Would that satisfy this?

MR. WIEDEMAN: I think it should also have a range of what the goal is. We're going to implant so many seeds or --

MR. WHITE: That's a real good point. That is not the physician's goal. The physician's goal is not to implant so many seeds and it is not necessarily to do anything like that. It's to deliver the maximum possible dose to the tumor without exceeding the dose to the critical structures given the anatomical constraints of the application, those three things. Those are really the goals of the physician. You're asking us to put that in terms of strength of sources and number of sources.

Our position is that a physician can't do that. A physicist could do that. I'm on the other side of the fence now. Usually what I do is I'm telling these guys give me 55

seeds of half a milligram equivalent of each and they need to be spaced a centimeter apart. They look at me and say, you've got to be kidding, I've got my finger in this guy's rectum, my hand in his prostate, I'll do what I can.

So I guess I'm taking the physician's part now in saying that it's not as easy as that and it's not fair to ask them to write that down and document it ahead of time to a precision that they're not ready to commit to. It doesn't reflect the biological and anatomical constraints that exist in humans.

MR. TELFORD: Those are good thoughts. Let's use them. For No. 2 objective, for brachytherapy, if we said do a pre-plan prior to implant, what would you include in the pre-plan for clinical purposes or for regulatory purposes?

MR. WHITE: Those are different and I think you guys need to understand that.

MR. TELFORD: Okay. Give us both.

MR. WHITE: For clinical purposes, I'd ask a physician what his goals are and get some information about the anatomy of the patient, if we can, and we do one or maybe several options; this is Option A, this is Option B, this gives a rectum this much dose, and present those all to him ahead of time. Let me him pick one that's going to be a goal. He may then -- if it's a seed implant that's irretrievable, he'll go in and attempt to meet that goal.

Whether he does or not is a mystery. You just don't know.

MR. TELFORD: That's clinical.

MR. WHITE: That's clinically.

MR. TELFORD: How about from a regulatory point of view?

MR. WHITE: What would I do?

MR. TELFORD: Where I'm going to is you have a pre-plan prior to implant. Then you have a prescription after implant because the big question then is how long do you leave them in.

MR. WHITE: From a regulatory point of view, I think what you guys -- I don't want to put words in your mouth. What you're interested in doing is seeing that a physician who goes to the OR expecting a bunch of seeds of half a milligram equivalent, sticks them all in the patient, gets back to the lab and finds out that they were two milligram equivalent, or you put in a bunch of cesium sources in the patient and the physician says I'm too busy to look at the numbers now, put in a ten-ten and 15-15, and four hours later he finds out it was a 50-50 and 50-30-30 or something like that.

I think that's what you're looking at and I think that if you want a prescription or if you want something that says that, the physician needs to be able to make it that vague. It's my intent to use iodine seeds for this

activity or I am aware that the seeds with which I have been presented have a one millicurie activity or we will preload this patient with ten-ten-15-15, which has nothing to do with the dose that the patient -- none of those things have anything to do with the dose that the patient receives.

MR. TELFORD: That's for the pre-plan.

MR. WHITE: It's not a pre-plan. One of the problems you have with nuclear medicine and therapy is you've got this radioactive source and it's sitting there and I can look at see that that's a red and white peppermint candy and I know what it's going to be, pretty much, but you set a cesium-2 or an iodine seed on the table, the doctor doesn't know what's in it.

I think the problem that you're trying to regulate is when the doctor sticks this in the patient, does he know what he's sticking in. I think that's -- I suspect that may be your goal. What you've written there, though, is asking the physician to describe some medical treatment that is a combination of the activity of the sources, plus all the other stuff, like the location, the duration of the implant, and things like that.

The thing that you can talk about ahead of time is how active are the sources. What you can't talk about ahead of time is what's the dose distribution going to be within the patient and is that what I want it to be.

MR. TELFORD: Okay. That's for the pre-plan or what you can specify prior to going to the OR. Anything to add to that, Dr. Wu?

MR. WU: I think one of the things -- for instance, we had a case that a woman had a big tumor under her pelvic wall and the doctor doesn't even know whether he's going to do an implant or not, depending on whether that tumor is completely central or not.

What can we do? We just, all right, I order 40 seeds for you and see how many seeds -- how much you can take, how many seeds you can implant. He doesn't even know at that point and we can't expect him to write a precise --

MR. WIEDEMAN: In a roundabout way, I disagree because he planned on putting 40 seeds in -- see if I got this right -- but because of the tumor wall, the tumor on the wall of the uterus or whatever, he was unable to put the full 40 in. He was only, say, able to put 20 in. Okay. Well, the original prescription, the way I see it, would say Iodine-125 or whatever, 40 seeds --

MR. WU: He doesn't know that it's 40 seeds.

MR. WIEDEMAN: He ordered 40 seeds. Now, after he goes into OR and he can only get 20 in, then he would just go back and I put 20 in because the tumor wall, that will give me a dose of X number of centigray and --

MR. WU: One point I think you missed is that even

the 40 seeds, he's just guessing. There is no ground for him to say it has to be 40 seeds.

MR. WHITE: The prostate is a good example. In here, there's an ice cube in here. If I rattle it around and you can do anything but look in there and feel in there, and you can do any kind of test you want as long as you don't look at or touch the ice cube. But you have to decide on the volume of that ice cube ahead of time. That's a tough thing to do.

And then later on I'm going to let you reach in there and take the ice cube and wrap it with aluminum foil or something. If you guess the wrong amount of aluminum foil that you'd need, you're going to have to write that down as a change. It's not a change. We don't see how that protects patients.

If a physician goes in and says he's going to use 40 seeds and the organ is smaller and he uses 20, how is that protecting the patient, making that prescription change?

MR. TELFORD: I hear you making a suggestion basically that we not use prescription prior to implant, use something like a pre-plan to talk about in general what the physician is going to need, so many seeds of a certain activity.

MR. WHITE: Kevin here asked me, there's an actual

text here in the log, definitions. For prescription for brachytherapy, the total dose, the treatment time, number of sources and combined activity, radioisotope and treatment site. If you specified -- what doctors want to know ahead of time from me is what's the isotope, are these seeds iodine or cesium, and what's the activity in each seed.

MR. TELFORD: Okay.

MR. WHITE: Those are things that are reasonable for the physician to know ahead of time, I think. The other stuff is speculation.

MR. TELFORD: How about how many seeds go into the OR? Is that worthwhile to know?

MR. WHITE: No. We send up as many as we've got.

MR. WU: Usually, it's a common practice to order ten percent more so that if he wanted, he could put more.

MR. WIEDEMAN: Ten percent more of what?

MR. WU: More seeds. We speculate on how many seeds. But it's just speculation, nothing better than any other speculation.

MR. WHITE: But the number of seeds to the OR is irrelevant.

MR. WU: Yes.

MR. WHITE: Why does it matter whether you send up 50 or 100 or --

MR. WU: It could be a 100, it doesn't matter.

MR. TELFORD: Just to make sure you don't lose any.

MR. WHITE: We've got plenty of regulations about that.

MR. TELFORD: I think you're calling that a pre-plan.

MR. WHITE: No, it's not. I'm just calling it tell the doc what he's got in his toolbox.

MR. TELFORD: Okay. Now, the physician implanted so many seeds in the OR. Now you're getting up to the point where you can write a prescription.

MR. WHITE: That's right. Then I do the plan and say here's what you did, this is the placement of the sources in relation to the patient's organs. What kind of dose do you want to give him; then he looks at that, and then he writes the prescription.

MR. TELFORD: Okay. So then he's decided how long to leave them in, in essence.

MR. WHITE: Yes.

MR. TELFORD: So that's your proposed modification for two.

MR. WHITE: Actually, I think the suggestion Kevin made is a good one. Really, for brachytherapy, you need to modify what a prescription -- well -- the pre-prescription needs to be modified to reflect activity and isotope.

MR. TELFORD: If you're going to do something prior to implant, but it can't be as explicit as we've described it.

MR. WHITE: Can't be -- they just don't know that. They could write it down, but they -- and it's just as good using it as a dart board. There's no benefit to the patient. It doesn't meet the objective that you started out with in the beginning to reduce risk to the patients. Where do the mistakes occur in brachytherapy misadministrations?

MR. WIEDEMAN: Wrong sources.

MR. WHITE: Wrong sources, wrong time.

MR. WIEDEMAN: Misunderstanding what was prescribed by the physician.

MR. TELFORD: Wrong activity sources, also.

MR. WHITE: There you are. So if you had the physician write down that I know the activity of the sources we're putting in and I know the isotope, that covers that.

MR. TELFORD: Except for time.

MR. WHITE: But the time comes in afterward. You don't decide on the time until after they're in.

MR. TELFORD: Agreed. I didn't know if you were talking about the pre-plan or the prescription.

MR. WHITE: I don't think anybody disagrees that, although it's hard, sometime after the implant starts, you need to get the physician to write down what he wants to do.

Somewhere he needs to write, after he's seen all the plans, I want to give such and such. If we say in connection with, then -- now you've got the problem that the seeds have been implanted in the OR, and now we're going to say you have to have a prescription. But the question is when, how long after the implant do you go before you allow a prescription to be written. That's crap shoot. Better after than before is the first step. And then the second step is how long. I think -- I don't know how to specify that. If you have an implant that's destined to take -- that the doc's guess is it's going to be in there for four days, you don't have to have a number in an hour.

If you have an implant that's going to be in for 18 hours, better do it pretty quick and maybe it needs to be a percentage of the total implant types.

MR. TELFORD: Okay. Let's take the case of the 18-hour implant. Is within one hour sufficient or two hours?

MR. WHITE: I'll just speak from my own experience. We do that within a couple of hours and we're constrained solely by the amount of time the computer takes to do the calculation and the amount of time the physician takes to mull over the plans.

MR. TELFORD: So two to three hours is sufficient based on your experience.

MR. WHITE: Yes; from a clinical point of view. From a regulatory point of view, you need some caveat in there for extenuating circumstances. I hate to go on about examples, but this is real world. I've got one doctor who can never make up her mind. She'll want to see ten different arrangements of the sources. She'll want me to take the seeds in and out and it takes me 45 minutes to run up a single plan. If I have to do five of them, I could spend six hours.

MR. TELFORD: But this is post-OR.

MR. WHITE: This is post-OR. A lady up in her hospital room with iridium seeds in her breast; the doctor says, well, you know, I think maybe if we move these sources out and put some other ones in and -- it will be six hours before you get something out.

MR. TELFORD: Okay.

MR. WU: It happens all the time. It's very frequent.

MR. TELFORD: Because we are here -- I mean, I agree with you. What we're trying to do is prevent the mistakes. So how can a mistake that's happened -- what if you the wrong isotope or the wrong activity or --

MR. WHITE: We've taken care of that part.

MR. TELFORD: We've taken care of that part because now they're implanted. Now the only other variable

that we're really worried about is time. We're worried about how long to keep them in. So you have to have a fairly quick calculation and determination of how long they should be in and the signoff, the prescription, so that people will know what the directive is and take them out.

So your suggestion is like a percentage of the time and something on the order of two to three hours, given that's it's an 18-hour implant, would be sufficient.

MR. WHITE: That's just a guess, yes.

MR. TELFORD: Dr. Wu, what was your experience?

MR. WU: Our experience was very similar to this. Even though we don't have breast implants, we have GYN implants, usually we take a couple hours to do various plans and show the physicians. Then they pick one. So we load accordingly. Then the next day we have chart rounds and three doctors find each other and decide on different loadings.

We have so-called differential loadings. You take certain sources out and leave in the pick for X number of hours and put it back again. Those sorts of things are being done all the time. They don't know when all the sources should come out until -- it's sometimes, oh, my God, it's coming out in the middle of the night. I don't want to come in in the middle of the night. Add another couple hours. It happens all the time.

If you audit those charts in the different hospitals, how many sources actually come out in the middle of the night? Very few.

MR. TELFORD: Well, that's influencing the decision of when to take them out, but let's say the example is this is post-OR and it will be determined at a later time that 18 hours is the right number. But how long do we go before we say that that must be determined?

MR. WU: To write the prescriptions?

MR. TELFORD: Yes; to write the prescription.

MR. WU: Within one working day.

MR. TELFORD: Well, one working day might be 24 hours and the seeds are going to stay in 18 hours.

MR. WIEDEMAN: How about a percentage of the treatment time, such as 25 percent or 50 percent?

MR. WU: The percentage really bothers me a lot, when we talked about it at the beginning. The purpose of this proposal is to protect the public. I keep asking myself protect the public from what? Protecting the public from any possible --

MR. TELFORD: Let's take this example. This is brachytherapy. The problem we want to prevent here is leaving the seeds in too long.

MR. WU: How long is too long to cause any biological damage.

MR. TELFORD: Let's not go into the quantitative damage yet. Let's just say the problem is to prevent them from being kept in too long. So this is post-OR. You've just done the calculation and determined that 18 hours is the right number. So the question is how long should be allowed for that calculation and the signing of the prescription to fix the 18 hours.

Gerry is saying it takes them two to three hours. That's a practical limitation. Twenty-five percent of the 18 hours is a way to look at it and say that should be long enough. Fifty percent would be nine hours. That's a whole working day.

So is there a reasonable time period? This is the thought of having a pre-plan; don't have a prescription until after implant. But you can't really say in connection with because you could actually sign that prescription two days later when it was an 18-hour implant.

So that will not prevent the problem of leaving them in too long.

MR. WHITE: I would think from a clinical point, some percentage would be appropriate. Again, from a regulatory point of view, I don't know. One of the problems that we have clinically that we guard against, that we hope we don't have, is to do a loading where the guy says, yeah, this is what I want to put in, you put it in, eight hours

later you find out that another loading would have been better, but by then the ratio between the rectal dose and some other dose is already too poor to retrieve.

I think from a clinical point of view, we want to try to prevent that. Again, my point is that maybe from a regulatory point of view, that's not something that's possible to do. But I think that after the sources are in, once the patient is actually getting the protons, electrons tearing through their vital tissues, that somebody needs to look at that promptly.

I think when we sit in the clinic and say somebody needs to look at that promptly, everybody sort of has a feel for what that is. The problem we have here is that you have to say 2.76 hours is promptly, and, by golly, if it's 2.77 hours, you've made a mistake, and if it's 2.75 hours, you're okay. Therein lies the problem.

I think what we're willing to do is say that it needs to be done promptly and you guys need us to put a number on it. It's hard for me to do, to put a number on it.

MR. TELFORD: Okay. Let me suggest that we take a break for lunch and come back to Item 2, because there are other things in Item 2, like teletherapy and the use of 30 microcuries of I-131, etcetera.

So unless anybody objects, let's come back at

1:15, an hour.

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

AFTERNOON SESSION

[1:45 p.m.]

MR. TELFORD: Let's go back on the record. We left off with Objective No. 2 and discussed what we'll do with prescriptions for brachytherapy. What about teletherapy? What would you do with a prescription for teletherapy? What modifications would you make here?

[No response.]

MR. TELFORD: None? You might want to look at the definition of prescription for what information content that we were looking for on teletherapy.

[Pause.]

MR. TELFORD: There is no complication there in teletherapy, is there, on that prior to administration?

MR. WHITE: Not for us, no.

MR. TELFORD: Dr. Wu?

MR. WU: We're conscientious about this.

MR. WHITE: Did you get any objections to that at the other meetings?

MR. TELFORD: No. We got some suggestions on what ought to go into the prescription, not for just doing it.

MR. WU: The physicians change their minds all the time. What we require them to do is cross it out and sign it.

MR. TELFORD: That is just writing another new

prescription when you change it, put in a new condition, like you said, date it and sign it. That's good.

MR. WU: But there's one -- well. There's one gray area, really. If you remember that the misadministration, reportable misadministration, what if it's wrong part about an entry, wrong machine or one of those is --

MR. TELFORD: Wrong site.

MR. WU: Wrong site or something like that.

MR. TELFORD: Yes.

MR. WU: Now, it happened to us, I don't know -- we're debating how to interpret this, but you have a block trays, sometimes the tech forgets to put a block tray or forgets to put part of the block tray. Therefore, the area underneath the block, which is not supposed to be treated, is that reportable?

MR. TELFORD: The prescription for teletherapy is supposed to have the total dose, number of fractions, and treatment site.

MR. WU: Treatment site is usually very general; pelvis.

MR. TELFORD: So you've got a pelvis you're supposed to treat and you've got a block --

MR. WU: The pelvis, usually you have a dose of four corner blocks.

MR. TELFORD: Okay.

MR. WU: And one day the techs forget to put the blocks in.

MR. TELFORD: So you treated some site that you didn't intend to treat.

MR. WU: You treated an area of the body which you don't intend to treat.

MR. TELFORD: Then you treated the wrong site.

MR. WU: Not the wrong site. The same pelvis.

MR. TELFORD: Why were the blocks there?

MR. WHITE: That's one of the reasons I think this is a good definition of prescription and it's something that we'd like to see in regulatory language, that it's not overly detailed. Our physician would prescribe 180 rads to the mid-plane of the pelvis; forget to the put the block in, that patient got 180 rads that day to the mid-plane of the pelvis.

There are other areas that were not in the prescription that were treated differently than had been intended. But what you have asked for here, and I think it's important to note, is a prescription, the number of rads to a place. Now, when you treat --

MR. WU: To a point or to a region?

MR. WHITE: It depends on what the physician writes. If he writes 180 rads a day to mid-point of the

pelvis, then that's what the prescription is. Now, implicit in that is a lot of other stuff; no dose under certain blocks and more dose at the d-max and exit, a lot of stuff that gets churned up that is implicit, but not written.

I think for it to be a misadministration, it ought to be a violation of just the prescription the guy wrote. If the guy writes no more than 4500 rads to the core and you give 4800 rads to the core, then that's a misadministration. But I think it's important that the violation correspond to the prescription. If he hasn't written it in the prescription, you can't violate it, it can't be a misadministration.

Does that make sense?

MR. WU: Then suppose they treat the wrong site, which is not --

MR. WHITE: Like instead of treating the pelvis, they treat the shoulder. Then that's a misadministration. If he says 180 rads a day to the pelvis and you treat the guy's shoulder, that's a misadministration. The potential problem that we see with that is that if this gets more detail, when we do plans, we do -- we make -- there may be dose information presented to the physician that's 5000 points, and we have dose matrix that's thousand-by-a-thousand, maybe five or six slices on a patient.

Do we have to guarantee to within five percent of

each one of those points on the plan? I don't think you can do that. That's my point here.

MR. TELFORD: So you're saying that you like the definition of prescription for teletherapy. You think it's efficient.

MR. WHITE: I think if it were more detailed it would be a problem.

MR. TELFORD: Dr. Wu?

MR. WU: Usually, there's only two ways to get it prescribed. They usually say mid-line, mid-plane of the pelvis. Sometimes he prescribes 80 percent, X amount of dose to the 80 percent. There is nothing beyond that to describe the blocks. The blocks under which the -- the part of the body not supposed to be treated, but it may be the negligence of the technologist if they are treated.

Actually, a part of the body which is not supposed to be treated, you treat. I'm not sure that's reportable or not reportable, if it's included, not included.

MR. TELFORD: Well, we're not to reportable yet. We're going to talk about reporting requirements right after we talk about the rule.

MR. WU: But it's something to do with the prescriptions, because the prescription does not specify shape of the blocks. They just say X rads to a certain point.

MR. TELFORD: As we've defined prescription, it would ask for the treatment site. So if the site is the mid-line of the pelvis, then you've satisfied the definition of the prescription. But what this is about is having a prescription prior to medical use so that the technologist knows what to do. This is the creation of a written directive so that what to do is clear in the beginning.

Would you modify this in any way? Dr. Wu says no. Gerry?

MR. WHITE: No.

MR. TELFORD: All right. Shall we go to any radiopharmaceutical therapy? Do you do this already for any radiopharmaceutical therapy?

MR. WHITE: Written prescription.

MR. TELFORD: Written prescription. Do you do radiopharmaceutical therapy?

MR. WU: I personally don't do it, but --

MR. TELFORD: Your department?

MR. WU: Yes. They don't have any problem.

MR. TELFORD: They don't have any problem, they would do a prescription for that. How about the D part, greater than 30 microcuries of I-131? What do you do currently?

MS. ROBERTS: Written prescription.

MR. TELFORD: Prescription for that. Okay.

MR. WHITE: We do the same thing.

MR. TELFORD: Before we came along, did you have a similar threshold or what did you do for I-131? Did you have all I-131 --

MR. WHITE: No. For therapeutic intent.

MR. TELFORD: Okay.

MR. WHITE: So if someone came along who needed like a two or three millicurie iodine whole body scan, they would not necessarily have a prescription.

MR. TELFORD: Okay. But this would require that. This would require a prescription for a person who doesn't have a thyroid, but they're going to have a whole body scan, they're going to get one or two millicuries. But because it's greater than 30, would you modify this?

MR. WHITE: I think that's probably a good idea. Now our people go and consult with the authorized user and it wouldn't be any different to have them do that in writing. And these are low-volume procedures. I mean, if you do five or six in a year, that's a lot.

MR. TELFORD: Okay. Dr. Wu, how about your department?

MR. WU: I don't know about this -- I don't think this will present any problem.

MR. TELFORD: Okay. Shall we go to No. 3? Objective No. 3 is all about having a referral. Page 1447,

we have the definition of referral. What it says is that it's a written directive dated and signed by a physician, meaning any physician and not necessarily a nuclear physician. So that we have -- this creates a written directive that comes in with the patient.

The thought is that you have a clinical procedures manual for all the diagnostic procedures. What your department receives is this referral. It matches with the procedure that is, in essence, a standing order from the nuclear physician because the nuclear physician has approved of the clinical procedures manual and said for all these cases you do the following.

So in the proposed rule, we thought the idea case was have a written directive. So would you delete, modify or retain this objective?

[No response.]

MR. TELFORD: What does your department do with referrals? How does it ensure that it gets the right directive from the referring physician? How do they know -- the person on the phone said gallium but really meant thallium. How do we fix those problems?

MS. ROBERTS: Well, we usually question it to begin with because if they order in a thallium study, we ask if the patient has a referring cardiologist. If the patient does, then we have to get that cardiologist to stand in on

the treadmill. We usually ask what their diagnosis is. We always ask what their diagnosis is.

If they were looking for a soft tissue tumor, we wouldn't do stress thallium.

MR. TELFORD: So you're asking when you get the phone call for a patient that is to have a diagnostic study, then you ask for some sort of clinical history.

MS. ROBERTS: Yes.

MR. TELFORD: And a diagnosis.

MS. ROBERTS: Yes.

MR. TELFORD: That you can show to someone, to a physician within your department or to the technologist to make sure that this makes sense?

MS. ROBERTS: Yes.

MR. TELFORD: Is that what you do with that? Do you write that information down on your end?

MS. ROBERTS: Yes.

MR. TELFORD: Whoever is taking the call, do they write --

MS. ROBERTS: Yes, we do. It's written in the --

MR. TELFORD: Let's say we're talking about an out-patient, not an in-patient.

MS. ROBERTS: Right. I'm talking about an out-patient. But on in-patients, we review their charts. If we go up on the floor to dose the gallium, we review the chart

to make sure that gallium is ordered, that it is written on the chart.

MR. TELFORD: Okay.

MR. WIEDEMAN: I assume to get the word to the nuclear medicine department in your situation, they submit a requisition or a -- is that what they do?

MS. ROBERTS: Yes, if it's an in-patient. Now, a lot of times we take the orders over the phone for out-patients, the doctor's office.

MR. WIEDEMAN: Does the out-patient bring a slip of paper in with them or do you require it?

MS. ROBERTS: Yes. The doctor usually writes on a little prescription pad what the patient is getting. Then they go down to out-patient registration and it's typed into a form, along with the written request from the doctor, and it's sent to us, and then we generate the order in our department.

MR. WIEDEMAN: So you get diagnostic referrals.

MS. ROBERTS: Yes.

MR. TELFORD: Who generates it within your department?

MS. ROBERTS: Whoever's working in the office that day.

MR. TELFORD: What sort of person is this? Is this the technologist or a resident or what?

MS. ROBERTS: Our secretary does it sometimes. I mean, they put it through the computer and it comes out on the request form.

MR. TELFORD: Does anybody check these requests, these referrals before the technologist administers? Say this is an out-patient.

MS. ROBERTS: If it's an out-patient, we go to our schedule book and make sure that order correlates with the order that's in the book. We do that.

MR. TELFORD: How about if it's an in-patient?

MS. ROBERTS: We have the chart with the patient when they come down to our department.

MR. TELFORD: But the chart is, in essence, a written directive anyway. What if you have something, a request that doesn't match your clinical procedures manual? It's what the referring physician asks for, but you look -- maybe they specified something extra and this something extra is not right. Maybe they said do a liver scan with so many millicuries of I-131, and you look in your procedures manual and it doesn't match. What do you do?

MS. ROBERTS: We would call the radiologist who is in charge of our department and let him take care of it.

MR. TELFORD: So you would let your nuclear physician prescribe the study to be done.

MS. ROBERTS: Right.

MR. TELFORD: Okay. Josie?

MS. PICCONE: When the patient is an out-patient and the out-patient goes to the out-patient clinic first, before you see the patient, if the patient presents to the out-patient clinic without a slip from a physician, do they write up the slip anyway and send the patient to you? Like the patient comes in and says my doctor so-and-so wants me to have a bone scan.

MS. ROBERTS: They would not do it like that. We send the out-patient department a list of our patients, out-patients for the following day and if they're not on that list, then they call us to find out why that patient is here.

MR. TELFORD: Gerry, how would you modify this No. 3 of having a written referral? How would you ensure that the right thing gets asked for?

MR. WHITE: We do a lot of what's in the standard and we do it a lot the same way that Jonette does. I'm not sure that qualifies as a diagnostic referral. The thing that I thought about when you were describing your method, which sounds a lot like our method, is that when you folks come to look and you walk into the department and say could I -- here's the scan you did on Mrs. Smith, could I please see the written request dated and signed by a physician, that includes the name, diagnostic clinical procedure and

clinical indication, she's not going to have that.

That piece of paper is down in out-patient someplace and maybe even been discarded.

MR. WIEDEMAN: Isn't your report typed on the requisition form itself? That's what I've seen in many cases. The requisition that is sent from the floor down to the nuclear medicine department, the authorized user in nuclear medicine uses that same form to dictate his report on.

MR. WHITE: But if I'm the inspector and I want to see a piece of paper that was signed by Dr. Family Practice that says Mrs. Smith is supposed to have a bone scan because she has a painful ankle, do you keep those? We certainly don't. That's a lot of paperwork, I think, and that's what this requires, I think. Doesn't it?

MR. TELFORD: Yes, yes.

MR. WHITE: And it's not even a reg guide requirement. It's a Code of Federal Regulations requirement. I have to have I would assume available for inspection that piece of paper.

MR. TELFORD: The question is what would you do with that?

MR. WHITE: First I want to be sure that that's what I need, because I heard you listen to her description and say, oh, yeah, that's okay. It sounds to me like that's

not even close to what this says. Am I assuming correctly that you have to have that piece of paper signed by the doc across town?

MR. TELFORD: That's what this says, yes.

MS. PICCONE: How would you change it?

MR. WHITE: Well, the first thing I would do is -- there a lot of things. Signed -- the signed part, the written I would change, first of all. I think that verbal orders need to be made. Signed would definitely have to go. We get a lot of stuff from the hospital now handled by computer. In the unfortunate event that you kept the written part, you'd have to allow for electronic transmission of data from the physician to the hospital. And we do that all through the hospital now for all sorts of orders, where the physician will enter a code into his computer and request a study, and only he knows -- it's just like writing on a prescription pad.

MR. TELFORD: That's his electronic signature.

MR. WHITE: Well, I think it needs to say something to that effect. At our hospital, the word they use for that is authentication. In hospital terminology, signature is something different, at least in our hospital. Signature is what we used to call a signature a couple years ago. A guy actually wrote it holographic.

The problem that we have with that is it generates

a lot of paperwork and it relies on the referring physician excessively to have a good idea of what it is the patient really needs.

The description that Jonette made for in-patients where the people in her hospital go up and look at the patient's chart and see if it all makes sense, I think, is an important one, and that's what we do for in-patients and we also do that for out-patients. When a patient comes in, the nuclear medicine technologist is responsible for talking to the patients about their symptoms and what doctor are you seeing and why are you here and what hurts, before they inject the patient.

We also do a number of other things. All our out-patient exams are scheduled through a central scheduling which is manned by a registered nurse who is familiar with these kinds of procedures. So if somebody orders something that seems appropriate, that's the first line -- inappropriate, that's the first line of defense.

MR. TELFORD: Does she write anything down when she gets the phone call?

MR. WHITE: She gets the phone call, she types it into a computer which generates a request to the nuclear medicine department, and that request includes the patient's name, referring physician, the test that's requested and the clinical indications for the study, all on that piece of

paper.

That, unfortunately, does not meet the requirements --

MR. TELFORD: Everything but the signed, it sounds like, signed by a physician.

MR. WHITE: No, because it may not even come from a physician. It may come from the doctor's nurse. In our hospital and I'm sure this is true in a lot of other places, there are regular pharmaceutical prescriptions that are not signed by a physician. In radiation oncology, if a patient needs low modal or demarol, a whole range of drugs, the nurses hand out prescriptions for those. That happens in doctors' offices, too.

The doctor will say to his nurse, Mrs. Jones need a bone scan at Penrose, take care of it. You're asking for a whole different level of interaction with the physician who, rightly or wrongly, value their time with an excessive --

MR. TELFORD: When your technologist gets this paper now that's generated within your department that the registered nurse typed into the computer, do they follow a clinical procedures manual for doing these studies?

MR. WHITE: We have a clinical procedures manual. One would hope that they're familiar with it. The clinical procedures manual has got to be ten inches thick. So they

don't go to it each time.

There are basically protocols for each study and we expect that the technologist know how the protocols are done. I refer to the manual as something that people generally don't do. An audit trail for that would be hard to find. When you go into inspect, how do you determine if they --

MR. TELFORD: Is that because they've memorized those procedures?

MR. WHITE: Yes. I think because they're sufficiently familiar with their profession that they can perform the procedures without reference to the manual; that's the way I would say that. Your original question, I would delete the requirement for a written prescription or written diagnostic referral signed by the physician.

To meet the intent of that, if I were writing it, I would say something to the effect that the person administering the radiopharmaceutical must be a trained nuclear medicine technologist, people who are familiar both with radiopharmaceuticals and illnesses and can put those two things together to determine if the appropriate study has been ordered.

I don't see any substitute for that.

MR. TELFORD: That's an interesting suggestion. I have two questions. One is what is sufficient training for

this trained nuclear medicine technologist? Secondly, what's the backup system that takes over when there's something that comes in that they're just not sure about, that they can rely on? What's the escape valve? Where do they go if they get something that --

MR. WHITE: I think that for the first question of what is adequate training, clearly if you are certified by either of the two bodies that do that, and, Jonette, you can -- our people go to take two different tests. One is the AART, subspecialty nuclear medicine, and then there's a C -- I don't remember.

MS. ROBERTS: NMTCB.

MR. WHITE: That's it. Thank you.

MR. TELFORD: What is that?

MR. WHITE: NMTCB. Is that it?

MS. ROBERTS: Yes.

MR. WHITE: There are two registries that do that for technologists. I think that's a good place to start. The second thing of what's the backup if, in fact, you get something -- if one of these trained people get something that they don't understand, I think that that's part of the training in medicine, is knowing how to deal with an array of diseases and, more importantly, even recognizing things that you don't know how to deal with.

It's that second aspect of the training that's

part of being a real nuclear medicine technologist, that a lot of the unqualified people don't realize, they don't realize that they don't know how to handle something.

So I think those two things go together.

MR. TELFORD: Well, where would you send that person? Would you have that person call the referring physician or would you have that person call the nuclear medicine --

MR. WHITE: Call the authorized user.

MR. TELFORD: Call the authorized user.

MR. WHITE: Yes.

MR. TELFORD: Okay.

MR. WHITE: Generally what happens is they'll call one or the other depending on what they think is going to be more productive. But if there's any residual doubt, they always call the authorized user. That's the guy that's responsible for the administration. I just think that that's the place -- that No. 3 is the best way to ensure that the patient's clinical condition and the study match up, is to have the person who is really doing the study, which is not the doctor, it's the nuclear medicine technologist, properly trained.

I just don't see any substitute for that, and you require that the physicians have appropriate training, require that teletherapy physicists have proper training,

but the guy that actually does the work, the guy that sees the patients and injects the dose, can be anybody off the street.

MR. TELFORD: How about for I-131 at your place? Who actually does those injections or administering the pill or whatever?

MR. WHITE: For diagnostic studies, the technologist does it. For the 100 millicurie therapies, the physician does it. For the ten millicuries, I can't remember. Two different hospitals, I can't remember which is which. One, the physician does it; one, the techs do it.

MR. TELFORD: All right.

MR. WHITE: When I say that, if somebody comes in for a ten millicurie therapy, the physician examines the patient that day, but may leave the room when the pill is administered. For the 100 millicurie therapies, the physician hands the patient the drug, basically.

MR. WIEDEMAN: I want to ask a question in your situation. When your referring physicians make their rounds to see their patients, how do they get the word to the nurse up on the floor that they want to order a bone scan or a liver scan? Don't they write it in the patient's chart?

MR. WHITE: Sure. For in-patients that's easy. They write it in the chart. That's easy.

MR. WIEDEMAN: The only thing I see where in your

situation you may have some difficulty is with out-patients.

MR. WHITE: Which is a lot of what we do. I would just guess 80 percent.

MR. WIEDEMAN: Because you were concerned that an inspector would come in and say, well, where is this paper trail, where is the signed directive by the physician, and with all those good things. I think an easy way is just to refer back to the patient's chart.

MR. WHITE: For in-patients that's easy. For out-patient -- I have to tell you guys. I've already been cited for failing to meet that regulation.

MR. TELFORD: This one, No. 3?

MR. WHITE: Yes.

MR. TELFORD: By the state?

MR. WHITE: Yes. Not at Penrose, but at another hospital.

MS. PICCONE: In the same state, though?

MR. WHITE: Yes.

MR. TELFORD: It was an out-patient?

MR. WHITE: This is in general. The guy came in and said let me see the prescriptions and they didn't have written prescriptions from the referring physicians.

MS. PICCONE: Is this a current state requirement?

MR. WHITE: It doesn't seem to be to me.

MR. WIEDEMAN: Are we talking about therapy or

diagnostics?

MR. WHITE: Diagnostics.

MR. WIEDEMAN: And the inspector asked for a prescription for this diagnostic procedure.

MR. WHITE: Yes.

MR. WIEDEMAN: And it was not an in-patient, it was an out-patient.

MR. WHITE: Right. It was all patients. He just wanted to see some of them.

MR. WIEDEMAN: You couldn't refer him back to the chart and say there's the chart signed by the doctor?

MR. WHITE: You could for in-patients, but we couldn't for out-patients.

MR. WIEDEMAN: Okay.

MR. WHITE: Again, I keep saying the inspection process is an important part of this. But, again, I think that's the place to put qualifications. That's where the people are really important. The person sticking the needle in needs to know what they're sticking in.

MR. TELFORD: Good points. Dr. Wu, do you have anything to add? Does your department follow a procedure that's basically like what Gerry's describing?

MR. WU: I'm not really qualified to comment on that because I'm not involved in the day-to-day referral procedures.

MR. TELFORD: Okay. Jonette, do you have anything else to add to No. 3?

MS. ROBERTS: No. I don't really know what the solution would be with out-patients. It's always worked the way we're doing it. I don't know you could word it, though.

MR. TELFORD: All right. Shall we move to No. 4? This one just says that -- this is sort of Gerry's point that he just made. Make sure that the people doing it understand what they're supposed to do. That is they're going to either follow the clinical procedures manual, or they're going to follow it plus the referral, or they're going to follow the prescription.

What would you do with Objective No. 4? Would you delete, modify or retain it?

MS. ROBERTS: I think it's okay like it is.

MR. TELFORD: Retain it. Dr. Wu, would you delete this one or retain this one? Would you modify this one, Gerry?

MR. WHITE: I'd just delete the part about diagnostic referral because I don't think that's a good idea from the No. 3.

MR. TELFORD: Let's see. What if we took No. 3 and we had a referral system that you described.

MR. WHITE: Yes, that would be fine.

MR. TELFORD: Whereas you took phone orders for

out-patients, but you took the other things, like the diagnosis and the clinical history and you got it somehow validated before administering. So think of this as a referral process, then, or some sort of -- not always written referral.

MR. WHITE: Again, I think that's another mom-and-apple-pie statement. It's sure hard to disagree with that.

MR. TELFORD: All right. Let's go to No. 5, then. This one just says that now that we've created a directive over here in No. 2 or No. 3 that tells the person what to do, No. 5 says ensure that the administration is in accordance with that.

Would you delete, modify or retain No. 5? Would you modify that one, Gerry?

MR. WHITE: No, not in the objectives. Subsequent to all the other caveats I've had.

MR. TELFORD: Okay. Jonette?

MS. ROBERTS: I'd leave it.

MR. TELFORD: You'd leave it. Okay. Dr. Wu, delete, retain or modify that?

MR. WU: I would retain it.

MR. TELFORD: Okay. I think we're ready to move to No. 6. No. 6 is the one about let's make sure we have the patient identified, and that's one that we've seen a lot of errors occur in. What we're probably really going to do

is we're going to ask for redundant identification because that's what you've heard Darrel Wiedeman talk about. When the QA team went to the sites, what it was really looking for was a redundant identification.

By that, in the reg guide we would say pick two of the following ways to redundantly identify your patient; ask them their name, check their wrist band if they have it, ask them for their address, their age, their social security number, some set of those such that you would be able to positively identify them twice.

So having said that, what would you do with No. 6? Would you delete, modify or retain?

MR. WHITE: I'd keep it.

MR. TELFORD: Jonette?

MS. ROBERTS: Retain it.

MR. TELFORD: Dr. Wu, retain it?

MR. WU: Yes.

MR. TELFORD: Okay. No. 7. This says identify deviations, meaning any deviation from what was supposed to happen, the diagnostic study or the therapy study. No. 7 says identify and evaluate. What would you do with that one; delete, modify or retain?

MS. ROBERTS: I'd retain it.

MR. TELFORD: You'd retain it. Okay. Some folks have objected to the word "unintended." Does that bother

you, Gerry, saying unintended deviation? Do you understand that means any deviation?

MR. WHITE: This is only for diagnostic studies?

MR. TELFORD: Also therapy, because it has the prescription. For any therapy, you need a prescription.

MR. WHITE: Well, the problem that we had with that is that the diagnostic clinical procedures manual is very large.

MR. TELFORD: Okay.

MR. WHITE: You may have a patient -- you either have to make the diagnostic prescription -- diagnostic procedures manual so vague or include so many eventualities as to be less than really useful, it seemed to us, or you're going to have a lot of problems with doing a procedure on somebody that doesn't quite include all that stuff.

Like, there may be a set number of views for a bone scan and you get in there and the guy doesn't really need that. I don't know who decides that, maybe even the authorized user would decide it. You have to document that somehow. If the procedures manual says three views on a lung scan and the physician comes in and says, gee, that's enough, I've seen what I need to see, then he's got to sit down and write out some documentation of why that actually happened, or if a spec study is supposed to be a 180-degree spec study and they do a 360 or vice versa.

I think there's a lot of stuff. This doesn't have to do with manuals just for you, and we have a joint Commission inspection coming up and we've got manuals coming out the wazoo. You just know that people aren't really familiar with everything that's in those manuals.

To say that if a patient's procedure somehow differs from what's written on that page, you have to write a documentation that can be inspectable.

MR. TELFORD: You're talking about different views. That's after the byproduct material is administered. That's not what we're asking about, is it?

MR. WHITE: I think it is, yes. That's part of the clinical procedures manual, which is as important as anything else in the manual.

MR. TELFORD: Let's go back to the definition, Page 1447. Let's look at the referral. The clinical procedure, it says patient's name, diagnostic clinical procedure and clinical indication. What we're interested in is what's the byproduct material to be administered, what's the activity, what's the route. How many pictures you take afterwards is not our business. So it's not all the information contained in the clinical procedures manual. It's just -- we're just paying attention to that information which tells the technologist what radiopharmaceutical --

MR. WHITE: Well, it says to administer. The

things that you said are part of the clinical procedures manual. That is it includes pharmaceutical dosage, route of administration. It also says that it describes each method and other instructions and precautions by which the licensee performs clinical procedures.

It sounds to me that once we have this clinical procedures manual, the stuff in there counts. It has to include, as a minimum, the things that you mentioned, but it may also and will also include other things. There is no indication here that it's limited to that subset. It just says other instructions and precautions.

MR. TELFORD: Maybe you put your finger on a problem with our techs, then, because that's certainly not our intention. Darrel?

MR. WIEDEMAN: I was just going to say that was not my interpretation. If you took three views and your procedures manual calls for four views, to me that's a medical decision. Your doctor says, hey, three is enough, I can see what I want to see.

MR. WHITE: But what you're saying is if he makes that medical decision, he has to document it. How is that different from the doctor coming in and saying I want Mrs. Jones to have 30 millicuries instead of 20 millicuries.

MR. WIEDEMAN: Now, that's a little different. Now we're talking about dose and -- well, of course, he's

intended to give 30 millicuries. Now, I assume that he will have a report that he's going to be sending to the referring physician saying I gave Mrs. Jones 30 millicuries of technetium sulfur colloid for a liver scan. To me, that's acceptable because he's the authorized user. He's the one that decides what dose to give.

MR. WHITE: He's got to document it.

MR. WIEDEMAN: Yes. He's giving guidance to the staff by the way of a clinical procedures manual.

MR. WHITE: It just looks to me like the definition of clinical procedures manual includes what we would normally call a clinical procedures manual, and that includes a lot of stuff.

MR. TELFORD: Okay. We didn't fix that.

MS. ROBERTS: Ours is total scan procedure manual. It's different. The scan procedure manual has how you do the scans, the positions and how many views to make.

MS. PICCONE: Does it have dose information, as well?

MS. ROBERTS: Yes, it does.

MS. PICCONE: The isotope you would use and the dose information, and then it has all that additional information.

MS. ROBERTS: Yes.

MS. PICCONE: That's not something that we

considered or we thought we would look at, but I can certainly see the point.

MR. TELFORD: That's a good point. Like for a liver scan, if your technologist looked in your clinical procedures manual, the part that -- it says how many millicuries of technetium sulfur colloid, for instance, would be used, either that or it's specified by the authorized user. How many scans they take and what angles, that's not our interest.

Let's say in the case of the authorized user decided 30 millicuries of technetium sulfur colloid. If 30 millicuries gets administered, fine. We're happy. If four views get taken instead of three, it's not our concern. It has nothing to do with the administration of the byproduct material. The byproduct material has already been administered.

I think you've got a good point and we'll have to fix that, because we're not after that at all. The deviations we're looking at here actually then are -- okay -- 30 was prescribed, but 32 were administered or it said the route was one way, but the route really given was the other way, something different. Those are the kinds of deviations we're looking for here, not how may scans are done.

So having clarified that, what would you do with No. 7? Would you delete it, modify it or retain it?

MR. WU: Let me ask a question to clarify. In terms of, let's say, teletherapy, prescriptions are -- any unintended deviation from the prescriptions are identified. That means you have to document everything, any deviation from the prescriptions.

MS. PICCONE: No. Unintended.

MR. WU: Unintended.

MS. PICCONE: Unintended.

MR. WU: Whether they are significant or not.

MR. TELFORD: Yes. Whether they're significant or not. Like, you're going to give a fraction, a daily fraction of 200 rads. You give 210.

MR. WHITE: 201.

MR. TELFORD: 201. You do chart rounds how often, every week?

MR. WU: Every week.

MR. TELFORD: So at chart rounds, the authorized user in this case says, okay, here's the column that says 200 were supposed to be given for this fraction, administered was 201, it's identified right there, you can see that it's -- you can see the difference between 200 and 201, so it's been identified. And the guy looks at, the authorized user looks at the cumulative total to date and says that's fine, it's been evaluated.

He may turn around and say give him 199 the next

day.

MR. WU: The problem is whether -- the key word is significant, whether they are significant. We give the patient -- it creates a lot of paperwork. We are checking this anyway. Every week we check on this. But every time we double-check the dose calculation, then there's some monitor unit, a couple monitor units out of 300 monitor units or something like that. We decide it's not significant.

MR. TELFORD: Therefore, you've evaluated it.

MR. WU: Yes, we evaluated it. Also, our user doesn't have to sign it. You require the authorized user to sign that.

MR. TELFORD: No. We didn't say that. We just said it's been identified and evaluated. If that's chart rounds, it's been done.

MR. WU: They have to be documented.

MR. TELFORD: Right. You have your chart already of the administered dose for each fraction. You're keeping track of it. You've already done that.

MR. WU: What I'm saying is do you need a piece of paper every week and write down patient so-and-so --

MR. TELFORD: No. No.

MR. WU: Okay.

MR. TELFORD: But what we're supposed to be

talking about is this objective of identifying and evaluating unintended deviations as you go along. In the case of radiopharmaceutical therapy or even diagnostics, as you do them. In the case of diagnostics, you would write a report to the referring physician and you would say this is the dose administered and a bunch of other information and that's your identification of what was done or any deviation from what was called for in either the manual or the referral.

The idea is should we do that or not.

MS. ROBERTS: Isn't usually dictated and reported if there's any deviation from the dose? Our radiologists do that.

MR. TELFORD: In the report back to the referring physician or to the floor, yes. So the question is what would you do with No. 7? Would you throw it away, delete it, retain it, or would you modify it?

MR. WHITE: I think you need to clarify that diagnostic clinical procedures question. What is that?

MR. TELFORD: Agreed. Restrict all of that just to the byproduct material, the administration of byproduct material. So if we did that, how would you modify this?

MR. WHITE: I think aside from that it's something that we already do. Again, like so many of these, I'm not sure it relates to the original first paragraph we started

out with this morning. But I don't think it's an unusual paperwork burden, but I'm biased because we already do it and it seems easy. I'm biased toward stuff we already do.

MR. TELFORD: Let's go back to that Paragraph A. Paragraph A talked about prevent, detect and correct the cause. Two and three tell us what to do, Objectives 2 and 3. Objective 5 says we do it, we do what we were supposed to do here. No. 5 says we have administered the byproduct material in the way that was prescribed.

No. 7 says we identify unintended deviation; that is something that was done that was not in accordance with the way it was prescribed. So this is the detection of the error. So Paragraph A talked about prevent, detect and correct. So this is one of the three, No. 7.

Do you agree that it relates to Paragraph A?

MR. WHITE: Yes.

MR. TELFORD: You do. Any other comments on No. 7?

[No response.]

MR. TELFORD: Shall we go to No. 8? All No. 8 says is that the treatment planning should be in accordance with the prescription for brachytherapy and teletherapy. For purposes of our discussion here, for brachytherapy, a prescription could be the pre-plan. Let's use a pre-plan for the brachytherapy, and you said that the prescription to

teletherapy was okay, there was no problem there.

So for No. 8, would you delete, modify or retain?

MR. WHITE: Again, I hate to be a hard guy, but I frequently prepare treatment plans for physicians that are not in accordance with their prescription, because I think that the prescription ought to be modified and when they see my treatment plan, they will modify it.

What we call treatment plan may not be what you have in mind there.

MR. TELFORD: Planning.

MR. WHITE: Why don't you tell me what you had in mind with that?

MR. TELFORD: I think what you're telling me is for brachytherapy, the physician, a nuclear physicians says to you they'd like to treat this case, and what you do is develop some alternative treatment plans.

MR. WHITE: Teletherapy is really what I was thinking of.

MR. TELFORD: Teletherapy?

MR. WHITE: Yes.

MR. TELFORD: So the treatment planning includes your set of alternate treatment plans.

MR. WHITE: Which may be different than the prescription.

MR. TELFORD: Which may be different than the

prescription. But before, prior to treatment, what happens? Does the nuclear physician select one of your alternatives and say, yeah, do that one instead of the prescription and sign off?

MR. WHITE: Sometimes they look at it afterwards. The patient will get started, a couple of days for teletherapy.

MR. TELFORD: Okay.

MR. WHITE: I think this is a better way to do it. Again, I'm not sure what -- for teletherapy, for example, what particular process do you mean by treatment planning?

MR. TELFORD: Calculations.

MR. WHITE: Teletherapy, you could do all kinds of changes to the computer-generated plans

MR. TELFORD: When you look at the isodose curves and you're trying to capture the tumor with a 90 percent line, 100 percent line, you don't want to go too much over here in this spot or you don't want to dose the organ that's outside this --

MR. WHITE: That's not in accordance with the prescription.

MR. WU: That's before the prescription.

MR. TELFORD: Let's see.

MR. WHITE: I'll get a physician who will write -- just take an extreme example. He'll be a little sleepy in

the morning, he'll write and want to treat somebody's -- some organ to a depth of seven centimeters with the single posterior field. So he writes that out, treat them that way the first day. It'll come to my desk and I'll say, gosh, when he sees what the skid dose is going to be, he's not going to want to do that. So I'll prepare a bunch of alternate treatment plans that don't treat the patient that way at all. It doesn't relate to the prescription, and I'll bring that in and say here's what you're doing and here are some other ways you could do it, one of which follows the prescription and four which don't.

Then he can pick from among those.

MR. WIEDEMAN: Does he rewrite the prescription?

MR. WHITE: Yes.

MR. WHITE: He likes Option No. 3 you've given him.

MR. WHITE: Right.

MR. WIEDEMAN: He turns around and writes a new prescription. Option No. 3, so many rads to the tumor, volume, field size of so big.

MR. WHITE: But that's not how -- what I read that is if I -- to me, treatment planning is preparing options for the physician which need not generally relate to the prescription. Maybe if you explain for teletherapy what that objective is, what that is supposed to accomplish, what

you envision me doing to meet that objective? Or better yet, what would I do that would not meet that objective? What would be wrong?

MR. TELFORD: The way we've defined the prescription for teletherapy is we want to talk about the total dose, number of fractions and treatment site. So if your authorized user said they wanted to give 200 rads to the center point of this tumor, please prepare some alternative treatment plans or treatment --

MR. WHITE: Why should my treatment planning be constrained to that?

MR. TELFORD: That's a good question.

MR. WHITE: The problem there is if the guy or woman knew what they wanted to do when they wrote the prescription, we wouldn't need to do treatment plans. We could skip them.

MR. TELFORD: We thought that in your attempts to carry that out, in order to capture the tumor with the 90 percent line or the 100 percent line, that you may have to change some wedge angles or different blocks. So the calculations that you have to do when you change those angles or put in a block or not, then that planning was certainly in accordance with the prescription.

You were attempting to do what the authorized user wanted you to do, but there were some --

MR. WHITE: That's different than doing what they write in the prescription. When you deal with physicians a lot, sometimes what they want to do is different than what they write. One of the things that we do for them is to show them that -- a guy will write he wants to treat two brain fields, weighed two-to-one on one side, and he writes that in the prescription.

Well, that rule, it would seem to me, means that if I do treatment planning, I'm constrained to follow that, when, in fact, what my job really is is to do other things, do things that he didn't prescribe oftentimes and show him the options.

Again, I'm asking what is it -- what would be a violation of that? I'm just searching for the purpose for that particular part.

MR. WU: I think what we're talking about is essentially the execution of the treatment plan, dose calculation. But usually the physician consults with the physicist before they make up their r . They say, well, how am I going to treat this. Therefore, the physicist works out two or three different plans.

If you do that, you can -- the kidney, you can treat the spinal cord, something like that. The physician looks at it and says, fine, let's take this particular plan. Now, that's a prescription after the treatment plan, what we

call the treatment plan.

Then once the physician decides on which plan he or she wants to use, then you do the dose calculation. I think that's probably what you mean by treatment planning; dose calculation according to the plan which the physician already chose.

MR. TELFORD: Yes, because the definition of prescription talks about total dose.

MR. WU: Total dose --

MR. TELFORD: Fractions.

MR. WU: How to treat the wedge angle to oblique fields.

MR. TELFORD: That's the treatment plan.

MR. WU: Eighty percent line.

MR. TELFORD: Yes.

MR. WU: Otherwise, when we do the treatment plan, the physician doesn't know how the 80 percent line covers. We do that for the prescriptions.

MR. TELFORD: That's what we mean by this.

MR. WU: That wording has to be changed.

MR. TELFORD: We may be overly restrictive. Darrel, did you have something to say?

MR. WIEDEMAN: No.

MR. TELFORD: Okay. Gerry, how would you modify this?

MR. WHITE: Suppose that you came to my facility and said you're violating No. 8, we're going to site you for that. What would I have done? That's my question. For the other ones it's pretty clear. For No. 1, I could think of something I could do wrong, but I'm not sure --

MR. WIEDEMAN: It's simple. If your physician wrote a prescription or a treatment plan and he said he wanted to give 200 rads per day to the lung and you were giving 400 rads per day, we would say that that was not in accordance with the prescription.

The next question, I assume, is why were you giving 400 rads. The physician prescribed 200 rads.

MR. WHITE: So I'm giving 400 rads not because the technologist just turned on the machine for too long, but because I did a calculation that was incorrect.

MR. WIEDEMAN: If you have a calculation that shows that 400 rads is better and your physician has reviewed that and said, yes, I like 400 rads, I think that is much better than the original prescription of 200 rads, and as long as he has a piece of paper saying --

MR. WHITE: I understand that, but just because a patient -- the physician writes 200 rads to some point and what you're saying is if we make a calculation error that results in the patient getting 400 rads to that point, that's a violation of No. 8.

MR. WIEDEMAN: Yes.

MR. TELFORD: Yes.

MR. WHITE: I think maybe what you mean to say instead of treatment planning is dose calculations.

MR. WIEDEMAN: Not always. We had a case where the technologist went on vacation and they brought in the x-ray technologist to cover it. She had done this before. However, she wasn't familiar with decibels of minutes. So when the treatment plan called for 1.5 minutes, she wasn't sure if that was one minute-fifty seconds, one minute-five seconds, or one-and-a-half minutes. So she was giving them one minute and fifty seconds.

Now, that was not in accordance with the prescription.

MR. WHITE: I think treatment planning as used in radiation oncology departments is different than what you intend there. I think you're referring to a broad process that relates the physician's prescription to some kind of time or monitor unit setting. You get a doc who writes 400 rads to a depth of seven centimeters and at sometime removed in time and space you get another piece of paper that says set 1.5 minutes.

I think what you guys are referring to is all that stuff in between, which is different than treatment planning, I think.

MR. TELFORD: Is your word for it --

MR. WHITE: It sounds to me like dose calculation. Maybe dose calculation and delivery.

MR. WIEDEMAN: How about field size? Doesn't your physician say I want to treat the chest with a ten-by-ten centimeters.

MR. WHITE: Never.

MR. WIEDEMAN: No. Who determines this?

MR. WHITE: That's not in the prescription, I should say.

MR. WU: It's not part of the prescription. The field size, sometimes the physicist has some input about the field size and angle of the delivery sometimes.

MS. PICCONE: But then the physician buys off on your plant, does he not?

MR. WU: Right.

MR. WHITE: Correct.

MS. PICCONE: In one way or another, he --

MR. WHITE: I think it's important that that not be part of the prescription. As I'm interpreting this, the prescription is dose to a point. If you're going to include field size and isodose curves and computer plans in prescription, I think you have a much bigger fight on this because I don't think there's any way in the world a radiation therapy department can meet that definition of a

prescription and meet these regulations at the same time.

MR. WIEDEMAN: I wish I'd have brought my example I picked up at one hospital where they have -- on the therapy treatment chart, it says therapy prescription pre-treatment plan, and that's what the physician writes out. Then when you open it up it's got all the daily fractionated doses and the total and the weekly chart checks. It has a spot for the medical physicist or the dosimetrist to put his calculations in. It covered everything. A beautiful job they did.

MS. PICCONE: Well, they're pretty much standardized forms that we've been seeing for teletherapy. Everyone uses sort of a variation of the same thing.

MR. WU: I think that treatment planning, the wording should be changed. This is not the same kind of treatment planning that Gerry and I talk about. The treatment planning is before the prescription is written. At our institution, like you said, we have a P/P, per plan. We look at the plan and the physician has 200 rads at 80 percent, circle, signed and dated. This is part of a prescription.

Now, on the plan you have the field size, angles, whatever, everything. But that's the treatment plan we're talking about. We give a lot of input to the physician on how to treat this particular disease. That's before the

prescription.

MR. TELFORD: Before the prescription?

MR. WU: Yes. We do all these computer plans before the prescriptions.

MS. PICCONE: They come up with three or four choices and then the physician decides which is the way that he wants to go.

MR. WU: You give them three choices, the physician picks one of the three, they circle I want 300 rads delivered at the area encompassed by the 80 percent. That's a prescription. But the treatment planning was done before that. We gave them three choices. That part of the work we call the treatment plan.

It's not possible for us to do treatment planning in accordance with the prescriptions.

MR. TELFORD: So we've used the term that means something specific to you.

MR. WHITE: I think it means something different to me than it does to you.

MR. TELFORD: So we should say something like treatment calculations or dose calculations or something other than treatment planning.

MR. WHITE: I think that's what you mean by that. You're saying, no, that --

MS. PICCONE: How about it's planning was just

removed from there.

MR. WHITE: Again, I'm still at a loss for what happens with No. 8. I don't think it's meant to restrict the options that I present to the physician, but I think that quite literally that's what that says.

MR. TELFORD: Okay. Therefore, we should not say treatment planning. We need to say something different, like dose calculations or treatment calculations or --

MR. WHITE: You did just make the point, and I hadn't thought of it. That sure seems a lot like what No. 5 says.

MR. TELFORD: Yes. This says that the plan is in accordance with -- the says the administered dose is in accordance.

MR. WHITE: One of the things that is important to us is that we can plan stuff as off-the-wall as we want to. Not that we necessarily do it, but you need to explore a lot of different options, and I'm sure it's not your intent to limit the options that we explore.

MR. TELFORD: You're right. Somebody had their hand up over here?

MR. KAPLAN: I'm just wondering. Would the word process help? Treatment planning process?

MR. WHITE: I think the treatment planning process often differs from what the original prescription was. We

do a lot of treatment planning after the original prescription. The physician will start out with a simple field arrangement, two fields, front and back, for some amount of time, with the intent of modifying that with something significantly more complex later on.

Again, I think it's your intent to see that what he writes in the chart, in the prescription, is what actually happens to the patient. As John pointed out, that sure seems to be No. 5, as well. So maybe that's already covered. I don't know.

MS. ROBERTS: Could you say treatment plan and modification is in accordance?

MR. TELFORD: Gerry, I think you have a good idea here. We'll have to look at treatment planning. We'll have to change it to something that doesn't cause you restrictions, because it's the calculation of the dose or the site or something, all that goes into calculating how to get that 80 percent line or 90 percent line to the tumor. We don't mean at all to restrict your alternative planning.

Any other comments on No. 8?

[No response.]

MR. TELFORD: Shall we move to the third paragraph of the proposed 35.35? This is the audit paragraph. What we had in mind here was that there is an annual review of your program, of the quality assurance program, that

management makes an evaluation of the audit findings, and then the management makes a determination that the program is still effective, and, in the spirit of the prevent, detect and correct paragraph, here's where they make the corrections and make modifications to prevent recurrence of problems they see or of the conditions that they see in the audit which would very likely lead to an error that they don't want to occur.

So what this is is an annual correction of your program, make an improvement each year. So that if you start off with something, a QA program which you think meets the eight objectives, but it turns out that it's got a flaw in it, this is your chance every year to potentially improve.

What would you do with this paragraph? Would you delete, retain or modify? Gerry?

MR. WHITE: Is there some way to combine that with all the other audits? It seems to me we've got a requirement for doing sort of a general radiation safety audit periodically.

MR. TELFORD: Yes, I think there is. Which review are you thinking of?

MR. WHITE: It just seems to me we're always making reports to the Isotope Committee every quarter about things that we've audited, things that we've checked,

personnel dosimetry, the technical QA program, misadministrations, all this sort of stuff.

MR. TELFORD: Then you audit your QA program quarterly.

MR. WHITE: Well, we report -- we review the -- maybe QA is not the right word. I'm talking about maybe looking at the dose calibrator records and the gamma camera and stuff like that. The physicist reviews those regularly, and then quarterly we report to management through the Isotope Committee if there have been any problems, like dose calibrator was not working right for three days and nobody found it, we need to fix it, that sort of thing.

Does this have to be separate from that or is there some way we can --

MR. TELFORD: If your quarterly review included those procedures that make up your quality assurance program and you had an evaluation, maybe you took it to some committee and there was an evaluation and you made a determination that the QA program was still effective, and then the same people had the authority to require modifications to prevent recurrence of problems, and if you're doing that quarterly, you could just stack those four up at the end of the year and you've got your annual audit.

So the intent of this requirement here is not to do something twice. If you already do it twice a year

already, then you're already exceeding what we have in mind. This is just at least once a year look through your -- do an audit, do a review of your quality assurance program.

You already may have this requirement from JCHO for your nuclear medicine department. Let's ask Jonette. What do you do for audits in your nuclear medicine department?

MS. ROBERTS: Well, our nuclear physicists quarterly audits, and then I think we have a Radiation Safety Committee meeting twice a year. I guess they're the audits.

MR. TELFORD: So twice a year you get an audit, that's number one. And, number two, you go to the Radiation Safety Committee twice a year. Number three, they make a determination that the program is effective. Number four, they say fix something if something needs fixing. So you already exceed this.

Gerry, are there some words that we need to put in here on Page 1449 where we pick up C? Is there something that we need to say there, such as if you're already doing this four times a year, you've exceeded the requirement?

MR. WHITE: No, no. I'm just curious as to how you guys viewed that.

MR. TELFORD: Okay. Josie?

MS. PICCONE: I understood your question to be

does this mean you have to have an audit separate and totally different from ongoing audit programs. This audit requirement doesn't say that. If you have an ongoing audit program that you have where you audit other things, you want to add the audit of this quality assurance to that ongoing audit, there is nothing in here that prohibits that.

MR. WHITE: There is nothing in here that requires the audit be done by specific people.

MR. TELFORD: In the regulatory guide, it will say by --

MR. WHITE: That was in the reg guide.

MR. TELFORD: -- by qualified folks.

MR. WHITE: But we're not talking about that now.

MS. PICCONE: No.

MR. TELFORD: We'll get there. Any comments?

[No response.]

MR. TELFORD: What I'm hearing is you would make no modifications to this audit requirement.

MR. WHITE: It makes sense if you're going to do all this, the current NRC philosophy to have an audit requirement, it would be easier for us if we didn't have an audit requirement.

MR. TELFORD: Okay. What would you do instead?

MR. WHITE: I'd read your inspection report when you came. Let you guys audit it when you come.

MR. TELFORD: So if we inspected your hospital once a year, if you were the department chairman, you would look at our findings.

MR. WHITE: Yes.

MR. TELFORD: From the inspection report.

MR. WHITE: Yes.

MS. PICCONE: Wouldn't you like to identify breakdowns yourself and try to take care of them?

MR. WHITE: There's a lot of this stuff I would like to do and I may do this, but this is different than me doing it. This is you requiring me to do it and keeping records of that, putting it in the minutes and all that kind of stuff. I think that that's different. If you drop the requirement, I could still do it, but wouldn't have to worry about the form and explaining it to inspectors and all that kind of stuff.

Again, the difference between doing something for clinically appropriate reasons and doing something to meet a regulation. It's always easier not to have the regulation, even if you do it.

MR. TELFORD: Your the department chairman and what if, unbeknownst to you, there's some parts of your program that really aren't so good and you don't know that. The inspector comes and finds that out and gives you a citation. Would you rather have done the audit yourself and

found it and fixed it or would you rather get the --

MR. WHITE: I'd rather find it and fix it, but, conversely, if I didn't have any problems and you came and audited me and didn't find any problems, I would hate to be cited because I didn't do the audit that said I didn't have any problems.

[Laughter.]

MR. WHITE: That's what we're talking about here. We're talking about another thing I can screw up on and probably will. Again, that's the difference between regulations and just doing it because it's the right thing to do.

MR. TELFORD: All right. Any other comments on this audit business?

[No response.]

MR. TELFORD: Would anybody object to about a ten-minute break? Let's come back at 3:15.

[Brief recess.]

MR. TELFORD: Everybody's got some coffee, something to drink, let's go back to work. I'd like to start by briefly showing you the current requirements that are in 35.2. The agreement states now have to report these misadministrations as of April 1 of this year. So if a licensee in an agreement state commits one of these -- makes one of these six mistakes, they have to report currently.

The first one is you have the wrong source and use the wrong source. The second one is you have the wrong patient in the administration. The third one is you have the wrong route of administration. The fourth is you have a radiopharmaceutical administration that the administration is 50 percent different from what was prescribed.

The fifth one is a therapy radiopharmaceutical administration where what was administered is ten percent different from what was prescribed. Number six is both the teletherapy and brachytherapy administration where what was administered was ten percent from what was prescribed.

The reason I'm showing you these is that we have retained several of these in the proposed reporting requirements. We'll cover the reporting requirements in two parts. The first part is just for diagnostics and the second part is for therapy.

The current reporting requirements just covers misadministrations. For these proposed reporting requirements, there is a new idea here. The idea is to have things called events that you would capture internally. You would detect these types of events and report them internally and correct them before they become bigger problems, like misadministrations.

But the A events go internally. The words that I have n the screen are cryptic descriptors of the actual

words. So for the actual words for the proposed 35.33 reporting requirements for diagnostics, they begin on Page 1447. If you want to check the specific words, just look on that page.

Now, let's take the A events and let's look at these. We have diagnostic use not authorized in your license. We have a diagnostic use without a prescription or a referral. For the prescription here, you're always allowed to use a prescription for diagnostic cases. What we expect is that you would use a referral.

For the purpose of this discussion, let's say that this referral here is not the written referral, but whatever formalized referral procedure we come up with based on your comments. Three is a diagnostic use or a diagnostic administration without daily recording of the administered dose or doses.

Would you like to delete, modify or retain these A events?

MR. WHITE: What is the daily recording, what does that mean?

MR. TELFORD: Well, in the case of radiopharmaceutical diagnostics or even therapy, you would have recorded -- if you have a dose calibrator, you would have recorded that dose, measured it in the dose calibrator, made a record of it before you gave it. That's a daily

recording.

MR. WIEDEMAN: That may not be a requirement in your state.

MR. WHITE: To do what?

MR. WIEDEMAN: For diagnostic nuclear medicine, to enter in a utilization log the -- Mrs. Jones' liver scan, five millicuries sulfur colloid.

MR. WHITE: I think it's a requirement. We sort of follow the NRC. Actually, since Bob Quillen came, we're following the NRC stuff. It's a lot easier to figure out what we have to do now. I don't understand. Does the daily mean anything special?

MR. TELFORD: That's the requirement, daily, each day that you use material. This is sort of a relaxation, if you will. We could have said upon measurement, but we didn't, or we could have said upon administration.

MR. WHITE: Just write it all down once a day.

MR. TELFORD: This just says whatever you do in that day, write it down.

MR. WHITE: I see. Okay.

MR. TELFORD: Would you modify this, Gerry, any of these in any way?

MR. WHITE: [Indicates no.]

MR. TELFORD: Jonette, would you make any modifications?

MS. ROBERTS: Would you explain No. 1 a little bit? What do you mean?

MR. TELFORD: Maybe there's a new brachytherapy source on the market but you don't have it on your license yet.

MR. WIEDEMAN: An example would be if you're authorized for -- I assume you go by the groups, groups one and two, three, four. If you're authorized for groups one and two, which is imaging and uptake and dilution, and you have to mix up a reagent which is covered under the Group C or Group 3 or 35300, you're not authorized for that. So that would be a diagnostic use, unauthorized.

Or let's assume that you're authorized for only thyroid uptakes and you end up doing a thyroid scan with iodine.

MR. TELFORD: This first one is kind of a real gross mistake. It's something that you're not authorized to do.

MR. WHITE: Aren't the groups now structured so that the use is not regulated by -- I just remember in the past having trouble injecting somebody with a certain radioisotope and wanted to image a different organ.

MR. WIEDEMAN: That's years ago.

MS. PICCONE: Yes.

MR. WIEDEMAN: That hasn't been around for 15-20

years now.

MR. WHITE: I'm too young to remember that. My dad told me about that.

[Laughter.]

MR. WIEDEMAN: I can remember looking over NRC inspection reports from the 1970s and 1960s where they cited a licensee for putting the scanner over the chest and doing a lung scan when they were supposed to have it down at the liver doing a liver scan. We did away with that because it's none of our business where you put the scanner. But they were cited in the past.

MR. TELFORD: Gerry, would you make any modifications to this, the first --

MR. WHITE: No. It looks reasonable to me.

MR. TELFORD: Dr. Wu?

MR. WU: [Indicates no.]

MR. TELFORD: Okay. Let's see what happens to these -- let's see what you have to do if you have one of these. We'll skip to Paragraph C here. If you have one of these events, you have the RSO investigate and make a record of what happened here and report to the licensee management.

Would you change any of that? Visualize that if one of these things occurred, would you want the RSO to investigate it, make a record and report to the licensee management?

[Pause.]

MR. TELFORD: Jonette, in your case, let's say that you've got a thyroid scan, but somehow there was no referral on this patient, none whatsoever. What would happen at your place? Would you RSO or somebody else investigate and make a record of this?

MS. ROBERTS: If we had a thyroid scan to do and we had no referral, we wouldn't do it.

MR. TELFORD: That's a good answer.

MR. WIEDEMAN: How about if you had a new technologist that wasn't 100 percent sure that the prescription was required and they went ahead and did the study? John's question is should the RSO investigate that and make a report.

MS. ROBERTS: I don't think so. I think he'd just call the referring physician and verify the order and be sure that he gets one over there.

MR. TELFORD: Okay. Let's pick another problem. Let's say that we have a new technologist and it was a thyroid scan. What if the technologist got busy and didn't use the dose calibrator and didn't record the dose given? Is there a person that's designated at your hospital that would go investigate what happened and make a record?

MS. ROBERTS: The technologist would be written up.

MR. TELFORD: By whom?

MS. ROBERTS: The department manager. They would probably be warned one time and then written up if it happened again. They're real particular about that.

MR. TELFORD: Where would that report go to?

MS. ROBERTS: In the personnel file.

MR. TELFORD: Is there a department chairman that it would go to or would it go to the authorized user or where?

MS. ROBERTS: It would just be kept in the records in the technologist's file, the personnel file, as far as the written up part.

MR. TELFORD: What I'm really asking here is for these events, do they warrant having an RSO or somebody like that to go investigate and make a record and report it entirely to the licensee management? Is that called for?

MS. ROBERTS: If they made a habit of doing it, I think it would be. I don't know really. I don't see where it would be necessary, really. I mean, if it's done all the time -- because we keep good records and we always keep our dose book up.

MR. TELFORD: Gerry, do you think that those actions are warranted?

MR. WHITE: I think that if they're going to be in the regulations; that is assuming that diagnostic events, in

fact, require a record or report, then I think the way to do it is as you've outlined; to have the RSO notify the management. I think that that's the only way to do it, really.

MR. TELFORD: Let me ask a more general question. How would you handle these events in your department?

MS. ROBERTS: Are you asking me or him?

MR. TELFORD: Both of you, everybody.

MR. WHITE: It's a little hard to know because I'm not 100 percent sure how we, except in our random audit, would pick up whether a diagnostic test had been done without a referral. Assuming somebody discovered that or assuming when I was going through the records and I saw a bunch of isotope slips with no patient's name attached or something like that, then that's something I think the RSO -- what we do is the RSO takes note of that and then at the next Isotope Committee meeting, at which management attends, we bring that up and describe what happened and describe what we did to fix it.

That's the way we do it. I assume that that sort of procedure is acceptable for this.

MR. TELFORD: So the RSO would find out what happened. Would they make a written record of that?

MR. WHITE: Yes.

MR. TELFORD: But the report to management would

be in the form of the verbal description at the Isotope Committee meeting.

MR. WHITE: And it would be in the minutes of the meeting.

MR. TELFORD: It'll be in the minutes.

MR. WHITE: Yes. Every time something like that happened, I wouldn't send them a letter.

MS. ROBERTS: Our nuclear physicist goes through our records and if he found something like that, he would report it at his meeting.

MR. TELFORD: Dr. Wu, is that what happens at your place?

MR. WU: No. 2 and No. 2, there are different kinds of -- the gravity of the problem. No. 3, just not recording every day, is that warranted to have the RSO involved. No. 2, there's a possibility that you -- I think No. 2 is over there because you try to avoid to keep diagnostic radiopharmaceutical -- the wrong patient or the patient is not supposed to have.

It seems to me that presents a much more serious problem than No. 3.

MR. WHITE: You bring up a good point that I hadn't thought of about informing the RSO. At our hospital, I'm the RSO and it's a small place and I think you'd be hard pressed to call the RSO of the University of Pittsburgh to

tell him that you had failed to write in the book what somebody's dose was. That had never occurred to me.

MR. TELFORD: Who would you call, then?

MR. WU: Usually, those things are solved internally in the department.

MR. WIEDEMAN: Assuming that it's recognized and identified. As it stands right now, if you, on a day-to-day basis, were not recording the daily doses, that would be a Severity Level 4 violation because that's a requirement right now. This gives you a little advantage because right now you can identify it and correct it, and I'm sure no NRC inspector would cite you for identifying and correcting the problem, especially if you only missed a couple of days.

But if it was an ongoing problem, now we've got a violation.

MR. WU: I don't have any problem with that, except I think some management has to be notified, then that's probably the right way to do that.

MR. TELFORD: Okay. Well, let's move to B, which are the misadministrations. Now we're going to talk quantitative things about the errors. No. 1 is something like the wrong patient or the wrong radiopharmaceutical or the wrong route.

No. 2 is you have a diagnostic administration that's 50 percent different from what was prescribed.

That's it for the misadministrations. This one is a current requirement, No. 2, and No. 1 is also.

Would you delete, modify or retain any of those?

MR. WU: How did you get the 50 percent, that number?

MR. TELFORD: It's equal to a half.

[Laughter.]

MR. TELFORD: It's a significant departure from what was prescribed.

MR. WU: Why not 60 percent? Why not 40 percent?

MR. TELFORD: Which of those numbers do you like?

MR. WU: You decide a specific number and my question is is there any rationale behind it.

MR. WIEDEMAN: No. I know where that number came from.

MR. TELFORD: It's a large enough difference that you can say, by golly, that wasn't like an oops, that was a mistake. You can't just say it was close. That's not even close. That's the only rationale that's behind it.

MR. WU: I would ask the same question on the teletherapy and brachytherapy, where you set limits. To me, if you're talking 100 percent over; to me, 100 rads to 200 rads, the fact that the patient -- it's very different from 1000 rads than the 2000, 100 percent over.

I'd just give you some examples. So I don't know

that this 50 percent is arbitrary or you have some reason.

MR. TELFORD: Let's look at the rest of this because since you've talked about the 50 percent, if the administration is 50 percent over what was prescribed, then you notify the NRC. If you get an organ dose that's greater than -- you've got 50 percent and you get an organ dose greater than two or around the whole body greater than half.

Would you modify 50 percent or would you modify these thresholds over here or would you modify all of them?

MR. WU: Say 50 percent and this.

MR. TELFORD: If you're greater than 50 percent different, you have a misadministration. You would notify the NRC -- you have an occurrence B, you have a misadministration if you have an unauthorized byproduct material, five-fold dosage or an organ dose greater than two rem or a whole body dose greater than half-rem.

MR. WIEDEMAN: As an example, your typical, say, liver scan are -- the physician prescribes two millicuries technetium sulf colloid. The technician draws up four millicuries and injects it. Well, that's more than 50 percent, that's the 50 percent. But now if you look at it om the standpoint of was it greater than two rem whole and greater than a half-rem -- two rem organ dose or lf-rem to the whole body, the answer would be no. Therefore, it would not have to be reported to the NRC.

But now in the case of iodine-131, you meant to give five millicuries and we gave ten millicuries, then you're going to go way over those numbers. That would have to be reported to the NRC.

MR. WHITE: It's a two rem incremental that is the erroneous dose, gave two rem or the whole shizole together?

MR. WIEDEMAN: Two rem to the target organ.

MR. WHITE: From the dose that was administered or the difference between what they would have -- two rem extra?

MS. PICCONE: No. Not the difference. Two rem.

MR. WIEDEMAN: Two rem total. And I might add that just about everything that we do in nuclear medicine will go over that, except for sulfur colloid, even ten microcuries of I-131 will go over those limits. So even if you make an error on a thyroid uptake, you will exceed the two rem organ dose or the .5 rem whole body.

MR. WHITE: When I go back to my shop and I say -- I put these up here and say, yeah, I told them this was okay, I'd sure catch a lot of flack. The first thing that people would ask me is -- they would say, yes, if we did this kind of thing, if we gave them 50 percent more than we should have or a dose more than two rem, we want to fix that, we want to know about it, we want the Isotope Committee to know about it, do we want to send letters to

the NRC, and we want that to be illegal. No, we don't.

The question is the one that we keep hearing, what does it really mean to the patient. It's not a lot of dose.

MR. WIEDEMAN: You're looking at it from the legal liability, though, aren't you?

MR. WHITE: No. I'm looking at it from what's really wrong here, what has really been the harm. We've done something sloppy, we've made a mistake, how wrong is that, what's happened to the patient.

MR. TELFORD: Do I interpret your remarks to mean that the things that do get reported to the NRC, they should be things that cause harm to the patient?

MR. WHITE: Have the potential to cause harm in some -- I mean, have some potential to --

MR. TELFORD: Some biological effect.

MR. WHITE: Yes. You know, the range -- Andy keeps saying it's the range that we're talking about here. The range for reporting overlaps significantly with the range of ordinary changes in the prescription. An example is you've got a clinic that buys iodine-131 caps for thyroid uptakes. I won't tell you what they used to do. What they do now is they keep them for two weeks at a time.

Well, the guy that comes in the first day and the guy that comes in the last day both get very different doses of iodine-131. If you come in on Monday and get the last

cap of the old batch and your brother comes in on Tuesday and gets the first cap of the new batch, you've got a difference in dose that exceeds significantly the NRC reportable dose for an error, even though it's ordinary --

MR. WIEDEMAN: Those are the prescribed doses, though.

MR. WHITE: That's what I'm saying. If everyone agrees that these differences in the prescribed doses are negligible, they're so unimportant that we're not going to bother to order iodine once a week, we're going to order it every other week, they're so negligible that the doctor doesn't really care, then they ought not be sufficiently significant to have to write a letter to Washington about it. They happen intentionally.

They are so trivial that intentionally you don't care about the. It seems silly that if they happen accidentally you have to make a lot of reports.

MR. TELFORD: These are diagnostic cases?

MR. WHITE: Yes.

MR. TELFORD: Andy, is what you're after here you would like somehow to have these thresholds mean something, mean that there are some biological effects and harm to the patient?

MR. WU: I have been saying that the whole purpose of this reporting system, if I understand you correctly, is

to try to protect the public, to have the possibility to get any biological harm. If the harm doesn't exist, why are we doing this? I keep asking myself why are we going out of our way to -- we can't regulate everything. But if it doesn't matter, then why are we doing this? You put yourself in the perspective that because we want to protect the public.

MR. TELFORD: Let's take an example. I want to make sure I understand what you're telling me. We have a diagnostic administration. It was supposed to be a diagnostic administration. It was supposed to be ten microcuries of I-131, but they got 20 millicuries of I-131. It's greater than 50 percent different, but this 20 millicuries resulted in about 20,000 rads to the thyroid. So that's significant harm to you.

MR. WU: Right.

MR. TELFORD: So if I started at 20 and I dropped down to 10,000, then 5,000, down to 1,000, at some point you would say or somebody would say 500 rads to the thyroid, no big deal. So it's at that point I think you're telling me we ought to have a threshold here that says that's no big deal, don't cause a report to go to the NRC.

MR. WU: You had to accept certain risk thresholds. It's impossible to have a zero risk world. I got out and can be hit by a car or something. But you

calculate the risk and under that threshold, what kind of misadministration which would cross over that threshold, then we have to report and we try to prevent, try to protect, try to eliminate.

MR. TELFORD: That's over the threshold.

MR. WU: Over that risk threshold. If we don't know what that is, then we're just talking about a few numbers which don't mean anything to me. The 50 percent, why 50 percent? Why not 50 percent? Why not 100 percent? It doesn't mean anything because you can report this or report that -- I mean, my wife is cleaning the kitchen floor every week. I said to her you can clean every day, twice a day, five times a day, you have to accept a certain threshold.

Under this situation, you define it as clean. You can mop 100 times a day. What is the threshold that you accept it as cleanest, accept it -- is it a risk about which is not acceptable. If you establish that, then you can have all this reporting system set and everything will work and be placed in the right perspectives.

But to just throw out a number, pull a number out of a hat, it does not mean to much.

MR. TELFORD: So you would like the reporting requirement to list the definitional requirement of what a misadministration is, but this is a reporting requirement

here of you would like a meaningful threshold to put in here.

MR. WU: The organ dose greater than two, that means much more to me than 50 percent.

MR. TELFORD: Okay.

MR. WU: Whatever you calculated, whether it's two rem, or whatever the risk is involved. But at least it means something to me.

MR. TELFORD: Okay. Any more comments over here?

[No response.]

MR. TELFORD: Did we get any recommendations of what those numbers should be?

MR. WU: That's a hundred dollar question. Nobody knows that. Particularly, some low dose level, whatever, but it's a risk. I think there -- I'm not an expert on that. There are many people who are expert in the field who can calculate the risk.

MR. TELFORD: Okay. We'll be talking to the experts in subsequent meetings, but I think I've got the spirit of your idea. You would like a meaningful threshold above which you would be causing harm to the patient.

We're down through D. Any more comments on A, B, C, or D?

[No response.]

MR. TELFORD: Let's look at E. This says you will

keep these records. You will keep each prescription, each referral, and a record of the dose or dosage for three years; keep the old pages of your clinical procedures manual for three years before you throw them away. For each occurrence, event or misadministration, you will keep that report for ten years. That's what E says.

MR. WHITE: That's in the CFR?

MR. TELFORD: That's probably Page 1448, in the middle column, under E, each licensee shall retain the following records. I have distilled all those words to this cryptic descriptor here.

MR. WHITE: I'm sorry. There's something in the lefthand that I meant to ask you about.

MR. TELFORD: Okay.

MR. WHITE: This sometimes happens in regulations with disastrous effects, or's and and's get switched around. There is an "or" in the CFR and B, No. 1, any diagnostic use other than the ones stated in the prescription or procedures manual is what that should be.

MR. TELFORD: On the viewgraph, the "and" is incorrect

MR. WHITE: Yes.

MR. TELFORD: Okay.

MR. WHITE: Because a physician -- one of the things that we try to do with prescriptions is if he wants

to do something differently, he writes it in the prescription.

MR. TELFORD: You're correct.

MR. WHITE: Back to the other one, though, it says kept in an auditable form.

MR. TELFORD: Yes.

MR. WHITE: Again, to a civilian that sounds a little scary. You never know what people are going to find easy to audit.

MS. PICCONE: It doesn't say easily audit. It just says auditable. If you can produce the record, it's auditable.

MR. TELFORD: The records may be in central files, but you ought to be able to retrieve them within some reasonable amount of time.

MR. WHITE: I would think from a practical point of view we would find it difficult -- again, speaking for us -- to keep the records of the clinical procedures manual for three years after it was last used.

MR. TELFORD: Okay. That's E(2). How long would you keep those?

MR. WHITE: First, we don't revise the whole manual all at once. These are real thick documents that are kept for a variety of purposes. We try to satisfy a lot of requirements with the same big book. There are a number of

facilities that try to make those books reflect reality, as well; that is not only do we have a procedures manual, it's a procedures manual that reflects what we actually do.

So they're constantly being updated. Pages come, pages go, pages get updated, pages change. To have to keep each page for three years after you change that page, I think, is an unpleasant burden.

MR. TELFORD: Here's the problem, though. You have a misadministration, let's say, that occurred last year, a diagnostic misadministration -- not last year -- eleven months ago. The inspector comes and the procedure was conducted in accordance with the old page of the clinical procedures manual, and you threw that away ten months ago.

Now the inspector is at a loss as to what was the technologist following. He obviously was not following the new page, but rather following the old page.

MR. WHITE: I can see the point, but I think this is another prime example of the difference between doing something because it's good clinical practice and doing something because it's a regulation. That's a whole area there that impacts significantly the amount of time we spend shuffling papers for no clinical benefit but just to make it easier for regulatory processes.

What I would say is, gee, if you didn't -- if you

just left us care for our patients and dropped all these regulations, we wouldn't have to hassle with that. I think that's an interesting problem. But I think that it ought not to be the hospital's problem or not to be the user's problem.

I'm not sure how you solve it, but I just think that that's -- I don't think that that's trivial. I think that's real hard. It's really hard now to keep all these manuals updated, let alone keep all these old pages. Finding them is the other part, too.

MR. TELFORD: How about your records of the doses or dosages that you give to your patients? How long do you keep those?

MR. WHITE: That's a lot easier. We generally keep them until a state inspector comes and looks at them. But that's easier because you don't have to keep track of what's current and what's not, and we just have these books and when they fill up, we take the book and throw it in the closet. But with the procedures manual, we don't take the whole procedures manual when it's done and throw it in a closet. We change pages; short of having a big box where you throw all these old pages and then you have to date each page when you put it in the box.

I know it may not sound hard, but that's a lot of hassle.

MR. TELFORD: How many pages do you think get replaced each year?

MR. WHITE: I just have no idea. These books are big, though. Are yours big?

MS. ROBERTS: Not really because we have a small hospital, small department.

MR. WHITE: We have a whole bookcase full of these things. I know that because we're going through a joint Commission inspection now. People are pouring over -- I mean, now is the time to buy stock in three-ring binder companies, people who make those little plastic page covers, because we're sure using a lot of them.

I think it's a burden.

MR. TELFORD: Okay. How about the other ones, the first requirement on the records of the dose and dosage, prescriptions, referrals. Do you keep those for three years? Like, you get an out-patient, you send a report to the referring physician that would have what was requested and what was administered. Do you keep those for three years?

MR. WHITE: We don't have referrals, so we don't keep those.

MR. TELFORD: But you've got a record of your telephone referral.

MR. WHITE: We don't keep those now, but we could.

We keep all that stuff, the record of dose or dosages in the physician's dictation and we keep that for five years after the last patient contact. If they keep coming in for bone scans, we keep them. If you haven't been there for five years, they throw the films away.

MR. TELFORD: That's greater than three years, so you're okay there. How about records of misadministrations? Do you have a requirement from the state as to how long you keep those records?

MR. WHITE: Well, an inspection period is an inspection period, basically, is the way that works right now. Is that how it is for the NRC, a certain number of years?

MR. TELFORD: It's proposed.

MS. PICCONE: That's also current, record retention for misadministration. I wonder if that was an item of compatibility, as well, with the agreement states.

MR. TELFORD: Only the reporting of the misadministrations is an item of compatibility currently. Okay. Any other comments on the proposed 35.33?

[No response.]

MR. TELFORD: Let's move to the therapy, then. These are probably of more interest to you. Now, similarly to 35.33, in 35.34 we have four items that we call events. The first one is an administration without a prescription

and a prior review of the patient's case. The second is without recording of the dose or dosage. The third is single fraction where it's 20 percent different from what was prescribed. Fourth is therapeutic not authorized. Now I can use by brachytherapy example.

What are your suggestions on these events, delete, modify or retain?

MR. WHITE: Well, of course, it's a lot easier to say what's wrong with them than to say how they should be written to make them right. Nice thing about being on this side of the table.

MR. TELFORD: We can start with what's wrong with them. That's all right.

MR. WHITE: I had a couple of notes about these. One is that for brachytherapy, the language in the CFR about daily recording is confusing. One might infer that to mean that a patient who was being treated for a multiple-day brachytherapy needs to have something updated each day, how many rads today, how many rads received so far. I don't think that's what you intended.

Now, unless somebody is getting 30 rads an hour, I don't want to have to go up there every 24 hours and say, well, now, we're up to 1,875. But that sure looks a lot like that.

MR. WIEDEMAN: I think the intent was for

fractionated dose for teletherapy.

MR. WHITE: I think it would be good if you could clarify that, especially because it's not in a reg guide or interpretation. It's actually in the Federal Register, it says daily recording.

MR. TELFORD: That's a good point. We'll fix that.

MR. WHITE: A question that came up -- and one of the things that we check for in chart checks each week is addition errors and copying errors, 180-180-180-150, and although the patient still got 180 rads, the dose has not been recorded correctly. We don't necessarily view that as something that needs to be reported to the RSO and the Radiation Safety Committee and the management, although it seems to me to be included under that.

MR. TELFORD: Ten percent is 18, 20 percent is 36.

MR. WHITE: In cases where the dose was administered correctly, but the recording was in error. Clearly inferred there is if you're going to record the dose, it's got to be the dose that the patient got, and that would seem to me to be a therapy event under this definition.

MR. WIEDEMAN: Yes.

MR. WHITE: And I don't think it ought to be.

MR. WIEDEMAN: It says daily recording of

administered dose, but you said that it was just an error in the way it was entered.

MR. WHITE: Copying error. Yes. So it was recorded that the patient was given 180 rads and the technologist writes down 150 rads.

MR. WIEDEMAN: To me, that would not meet that, that they were not administered 150 rads.

MR. WHITE: But they recorded the wrong -- to me, the way I read that is the dose you give to the patient and the dose you write in the charts have got to match. There are times when that doesn't happen.

MR. TELFORD: What do you do with errors like that?

MR. WHITE: I fix them. I determine, first of all, if it was really a copying error, something wrong. If it was a copying error, whatever the problem was, we revise the chart to reflect our best estimate of what the patient got that day. But we don't feel that ought to be even an internally reportable --

MR. TELFORD: Do you do that daily?

MR. WHITE: No. We do it weekly. I mean, if somebody sees it --

MR. TELFORD: Whenever you see it, you fix it.

MR. WHITE: Yes. But at least weekly.

MR. TELFORD: But you check it weekly.

MR. WHITE: But I think that that's -- one of the differences between therapy and diagnosis here is that we do a lot more things. Even in the busy nuclear medicine department, we might do 20 injections a day. We did an estimate in our therapy department of how many things a therapy technologist does per month, because the hospital wanted to base job performance, raises and things on how many mistakes the techs made.

For one to four mistakes was this many points off from your job rating. And we figured that the average tech did somewhere between 10,000 and 15,000 items each month; collimator setting, wedge setting, monitor units, writing things on which they could make a mistake.

If you do 15,000 things a month, the chances of doing a couple of them wrong are pretty high. And if you've got to do all this stuff every time somebody does one of those wrong, we're going to spend a lot of time doing that.

MR. TELFORD: That's an interesting question, but if we didn't require that the correct dose be written down, then you could just write down any number and say, well, I tried.

[Laughter.]

MR. TELFORD: The patient got the right dose, but I just wrote down a number. But what would you do with it?

MR. WHITE: I'd drop that from events requiring

records, reports and notification.

MR. TELFORD: Let's see. There was a C part to this that's just like the one in 35.33. Let me put it up for you. If you have an A event here, and we go back to the RSO, but you're saying you would do something of a lesser nature.

MR. WHITE: Yes.

MR. TELFORD: Than that.

MR. WHITE: Yes.

MR. TELFORD: Could you describe that?

MR. WHITE: I'd just fix it.

MR. TELFORD: Who would you allow to fix it? The head technologist?

MR. WHITE: Anybody.

MR. TELFORD: Anybody?

MR. WHITE: I mean, anybody who is allowed -- there are only certain people who are allowed to write in the chart, certain people do certain things, but certainly the machine technologists are allowed to do that.

MR. WIEDEMAN: It sounds like you're doing exactly what the proposed requirements are, because if you look under C, any occurrence of A, which we're talking about recording inaccurate recording of a daily fractionated dose, above shall require the RSO to take appropriate actions, and your appropriate action --

MR. WHITE: The RSO may never even know about it. In fact, there's no need for he or she to know about that.

MR. TELFORD: Let me see if I understand this. You're taking the special case under A(2) where a copying error was made, the wrong number was written down. The correct dose was given to the patient and there was an attempt to record the dose, but they just made a mistake.

You would treat that to a lesser degree than you would not writing the number down at all. Is that what you're saying?

MR. WHITE: No. Sometimes that happens, too. Sometimes they'll treat four fields and only write three of them down, the dose. For each field, the technologists typically write on a linear -- well, I'm thinking about Cobalt therapy. They'll write the time the machine was on and then the dose from each field. If you have, say, four fields for a particular treatment point, there will be four entries and then they'll write the summation for that day, and then we write the summation, the running total.

Well, sometimes they'll treat four fields and they only write three of them down, but they'll write the total of 180 and they'll add 180. So it's clear what happened, but there will be one blank space in there. So when I go through and check the chart, I'll walk back to them and say, gee, it says you treated two minutes for each of these four

fields, but you only entered three of the doses, did you really treat that fourth field; yes, we did, because we wrote down what we treated.

Then let's write that dose in and add it to the summation. To me, that's not something you need to report to the RSO, report to the Radiation Safety Committee or report to the management. I think that's overkill. Maybe we're just sloppy. Does that ever happen in your shop?

MR. WU: I have to agree with you. That's the purpose of the chart checking every week, because when you go through the charts and going through everything, some mistakes like this happen. The RSO, they're really not the expert who understands the day-to-day operation in the therapy department. So we just make sure the chart is in order and we fix it and that's it.

MR. TELFORD: Maybe what you're saying is if you do weekly chart checks or have weekly chart rounds, then you don't need No. 2, or am I putting words in your mouth?

MR. WHITE: I just think that No. 2 ought not to be a therapy event.

MR. TELFORD: Okay. MR. WHITE: And the reason is that you do a chart check anyway on a periodic basis.

MR. WHITE: My reason is that it's just a trivial error -- I guess that's right -- trivial error if caught, if recognized.

MR. TELFORD: If you already have a mechanism to catch these events, then you don't need the RSO to --

MR. WHITE: That's right.

MR. TELFORD: I think that's what you're telling me.

MR. WHITE: And management and all those other folks.

MR. TELFORD: Let's look at No. 3. Surely you want to make some suggestions on No. 3.

MR. WHITE: No.

MR. TELFORD: Dr. Wu?

MR. WU: I have a very difficult time here to support that No. 3 because, again, 20 percent is an arbitrary number and 20 percent, it depends on the fractionated dose, the size of the fractionated dose. If the size of the fractionated dose is very small, like we sometimes --

MR. TELFORD: Hundred rads?

MR. WU: Even smaller than that.

MR. TELFORD: Fifty rads?

MR. WU: Fifty rads.

MR. TELFORD: Okay.

MR. WU: Fifty rads, sometimes we treat like an enlargement of the spleen. Fifty rads, sometimes you're escalating to 75, I don't know about your institute, 75 and

100. So some magic radio-biological effect and the screen begins to shrink. At 20 percent of 50, that's 60, but you ask yourself, well, does it make any difference to the patient; no. If you mistakenly treat a 60 the first day, there is nothing -- no harm done to the patient.

MR. TELFORD: Okay.

MR. WU: And the same thing. The first fraction like that, if you say 5000 rads, 25 fraction, 200 rads per fraction, and the first treatment you treated 300, 20 percent of 240, and compare that 40 rads compared with overall 5000 rads. It's totally insignificant.

MR. TELFORD: Okay. Let me give you two alternatives here. One is you could delete No. 3 entirely. Another alternative, you could say the administered dose is 20 percent greater than what was prescribed and the difference is greater than 100 rads.

MR. WU: My choice would be to delete No. 3.

MR. TELFORD: Okay. Is there a level, if I had said X percent in Y rads, is there a level here in percent or in rads -- say in the case of the spleen. You're going to give 50 rads, 50 rads is prescribed. Now, 20 percent doesn't mean anything there, but what if 200 had been given?

MR. WU: It depends on the overall dose. If the deviation from the dose is really inference the biological consequences. Of course, it's also one of the factors of --

like people used to treat breast at 300 rads per day, now they treat with 180 rads per day for various reasons. First of all, less the dose, less the long-term complications. From the financial point of view, they kept more fraction out of it and that doctor is making more money.

There is no definite unique dose, fraction of dose that's the golden rule, that's a Bible. You should not go over 20 percent or something like that. But it's very, very -- it's a recognized fact that if the overall dose is deviated, then you know -- try to add 4500 rads to another ten percent to 5000, mistakenly treat them to 5000, in terms of complications that the -- that makes sense to me, but deviation 20 percent from one of the 25 fraction doesn't make that much difference.

MR. TELFORD: So your choice is to delete No. 3. Any other comments on the A events?

MR. WHITE: I would agree with that.

MR. TELFORD: You would agree with deleting No. 3.

MR. WHITE: Yes.

MR. TELFORD: Or would you agree with something else?

MR. WHITE: I agree with -- I just think it's too complex.

MR. TELFORD: No. 3.

MR. WHITE: Yes.

MR. TELFORD: Okay. Let's get more complex, then. Let's look at misadministrations. What should we do? Let's take these one at a time. No. 1 is administration is different from the prescription; that is, you get the wrong patient, the wrong source, the wrong site. Any comments on that?

[No response.]

MR. TELFORD: Any proposed modifications there?

MR. WHITE: Yes. I think that treatment sit concern because of the questions that you raised earl. about things like blocks, angle. I think it's -- in the cases that we read about in the Federal Register where the problems with treatment site -- you know, the patient comes in to be treated at their spine and their leg gets trea d; they come in for a brain treatment and their lung gets treated. That's the wrong site.

What about a four-field oblique plan where instead of if being at 230 degrees, it's at 235 degrees. Is that the wrong site? What about a block that's misplaced or put in backwards or something like that. Is that the wrong site? I think that some sort of guidelines need to go along with that to exclude things like that.

MR. TELFORD: Meaning that you pick out the obvious --

MR. WHITE: No, not obvious. You pick up the big

ones.

MR. TELFORD: The blatant wrong site.

MR. WHITE: Again, one of the things that -- as users, that we struggle with in regulations is that a guy who is doing a good job and makes a small mistake doesn't get penalized more than a guy who is doing a lousy job that's worse to begin with but does it the same way every time.

An example of that might be a clinic that spends a lot of time doing custom blocks and one day puts a block in backwards and ends up having to report a misadministration to the patient and the NRC and all that kind of stuff. The guy in the clinic down the street doesn't use any blocks. He doesn't have to do that. We see that in x-ray all the time.

An x-ray machine doesn't have a light field. So it doesn't have to have any brightness requirements. The guy next door has got one that's not quite bright enough and he gets cited. I think that sort of thing is important to avoid here, and I think that mistakes in custom blocking, collimator setting, gantry rotation, collimator angle, those are all things that happen and we try to avoid.

When it happens in our clinic, it's a big deal. People get called on the carpet and technologists feel bad and it's gloom-and-doom, but we're not sure it's an

appropriate thing to make a regulatory concern, especially when there are so many of these items that people have to do everyday.

MR. TELFORD: So those things that you just listed you would exclude as not being the wrong treatment site. You would just capture those wrong treatment sites that are lung instead of brain or left instead of right, things like that.

MR. WHITE: What I would do, and we've talked about this before, is I would define the therapy prescription in real specific terms. That is a physician prescribed a certain number of rads per day, certain number of fractions, to a certain point, like mid-plane pelvis. If that gets done, even if the blocks are backwards, then it's not a misadministration.

If you prescribe 180 rads a day to the mid-plane of the pelvis and the guy gets his shoulder treated, then that's a misadministration.

MR. WIEDEMAN: Is it just the wording "treatment site" that's bothering you? Maybe if we said treatment area, treatment location --

MR. WHITE: I think that's all the same.

MR. WIEDEMAN: All the same?

MR. WHITE: The ICRU has a set of very rigorous definitions for treatment volume and treatment -- I can't

remember all of them all. Tumor volume, treatment volume, it's real carefully defined. And treatment site is not one of those. I'm not sure any of those would really fit.

I think that's more complex than the regulation --

MR. TELFORD: Would you rather see treatment site or treatment volume?

MR. WHITE: I don't think either of them are appropriate.

MR. WIEDEMAN: How about treatment area? That's pretty general and vague.

MR. TELFORD: How about center point?

MR. WU: I think that treatment site is okay provided that you -- you can't prescribe the treatment site very generally. You said it was a pelvis. Okay, a pelvis. Now you have the four corner blocks. What is it you're blocking? Well, part of the blocking is blocking the radiation exposure to testicles or to inguinal nodes.

Now, one day the technician forgot the block. If the treatment site is the whole pelvis, these inguinal nodes are part of the pelvis, it's the area you're not supposed to treat, but you treat it. It seems to me that's pretty much the same as the treatment of the wrong site, wrong area.

These things happen more frequently than you'd believe. Is that reportable every time that the technologist forgot the put a corner block? If we just say

-- took the treatment site as half of the body, then it doesn't really matter. So we don't have to report it.

MR. TELFORD: Darrel?

MR. WIEDEMAN: My impression when I first looked at this requirement is that -- it's like Gerry said earlier. We meant to give the lung treatment and, misunderstanding, we treated the hip, not that the gantry angle was different or the blocking devices were not in or the tray wasn't attached, or all the different --

MR. WU: Well, if it was a different gantry angle, you may treat the kidneys which you do not intend to treat.

MR. WHITE: I think you need to think of some -- what you're saying that you wanted to do, it sounds reasonable to me, but I don't think that that's what you wrote.

MR. TELFORD: What's a good word that we should put in there?

MR. WHITE: I'm not sure.

MR. WIEDEMAN: Wrong anatomical area of treatment?

MR. TELFORD: That's pretty general. Basically, it's an anatomical area of the body where we're not talking gantry angles.

MR. WHITE: The other solution that comes to mind to me is to describe in a narrative fashion what you said to me someplace, and I don't know where that would go, but I

don't see a two-word phrase to stick in there that would say that. Maybe there is one.

MR. TELFORD: Okay.

MR. WHITE: Did anybody at another meeting suggest something like that? Any magic phrases? But I think that would be a big problem if we had to do that.

MR. TELFORD: We were looking for gross mistakes, like left hip versus right hip or lung versus brain, because the quantitative things where you would change the dose by an amount, like -- pardon me?

MR. WU: Has it ever happened before?

MR. WU: Wrong site.

MR. TELFORD: Of course.

MR. WIEDEMAN: Sure. Got one right in the State of Indiana not more than three months ago, I think I said earlier, where the patient is the one that identified it. He said why do you keep pointing to the left hip, it's my right hip that's bothering me. Then after they checked the files, sure enough, it was the right hip that had the lesion in it and the authorized user was standing there when they did the simulation on the patient.

But the patient was an anterior position when they marked the hip and when they put the patient on the treatment table, they were in a posterior position. So everyone had it in their mind that it's the closest to one

end of the table. So that was where the error was caused. But they later came back and said the other hip needed it, also.

[Laughter.]

MR. TELFORD: So that the things like the wrong wedge or leaving out a block, you would be treating -- if you left out a block, maybe you're treating -- or the wrong angle -- and you might be overdosing the kidneys. And if you put the wrong wedge in, you might be having a difference in a quantitative sense.

So that's why we were looking for just gross mistakes up here for this treatment site.

MR. WU: I think this is a current requirement.

MR. TELFORD: Yes.

MR. WU: We are not reporting, in other words, the wrong wedge, wrong angles and put the block backwards. We're not reporting those, with the understanding that you mean that the gross anatomic structures. We interpret it as gross anatomic structures.

MR. TELFORD: No. 2 is radiopharmaceutical therapy, administration ten percent different from what was prescribed. That's a current requirement. Does anybody have any modifications to make to that?

MR. WHITE: The only problem we have that even comes close to that is when we do iodine therapy, sometimes

the patient doesn't slurp out quite as much as we had hoped. We don't discover that until we go back and re-assay the empty vial. Generally, we don't make another trip upstairs to give them that last two millicuries.

I assume that the physician -- can the physician change his prescription then, even after the administration?

MR. TELFORD: Well, the physician can make the choice. If they want that patient to have the extra two millicuries and that's important, then they give it.

MR. WIEDEMAN: Say they order ten millicuries and only nine millicuries arrives. Well, you can say if they go ahead and give the nine millicuries, that may be a misadministration. Well, you go to the authorized user and say, Doctor, we have only nine. He can make that decision, no, I want to give that patient ten and I'm going to stick to my guns and use ten, or he will say, no, I think nine will be sufficient to treat the patient with the type of treatment that I'm prescribing.

This happens all the time.

MR. TELFORD: No. 3 is all about teletherapy and (i) is ten percent difference in total, where the total administered is ten percent different than what was prescribed. Two is you have a single fraction that's off by a factor of 2 and (iii) is a running total where the window that you're trying to go within is ten percent of the total

prescribed.

For instance, if there's 5000 that's prescribed and you're going to give 200 rads per fraction, this would be the fractions, the total accumulated to date would have to be within 500 rads. We put in No. 3 so that since we were putting a limit on each fraction, this would allow some adjustment.

So what modifications would you like to make to No. 3?

MR. WHITE: I guess I'd want to know dose to where? What dose?

MR. TELFORD: We're dealing with the prescription in here, so this is to the treatment site.

MR. WHITE: There's a wide rating of doses within the patient, some of which are easier to predict the actual dose than others. I'd be concerned about that from a regulatory point of view.

MR. TELFORD: Well, if you're looking at the 80 percent of 90 percent isodose curve or the center point, however you define your -- like your prescription of 180 rads to the midline, that's your site.

MR. WHITE: Suppose you have that prescription and then you've got a set of isodose plans, four or five plans. All those plans and all their points have to be within that criteria or just one point?

MS. PICCONE: The prescription is to one point, right?

MR. WHITE: Yes. I looked real hard for that in there.

MS. PICCONE: This is teletherapy. So the prescription is 180 each fraction to a total of such-and-such.

MR. WHITE: To --

MS. PICCONE: To wherever you're treating. Whatever the site is. If it's to the midline, to the -- whatever your prescription identified, not every little dot point on an isodose curve. How could we do that? There is no way in the world we could look at that?

MR. WHITE: That's my question. Sometimes a physician will write a prescription the way you've described and which I hope is the way you will interpret prescription, that is to one point. But in point of fact, in our clinic, that's not the way prescriptions - that's not the way things really get done.

What we'll do is we'll generate a treatment plan that's fairly complex with blocks and wedges and things like that. The physician will look at that and say, yeah, I want that. What he's looking at is, for one thing, the point that you described and he's looking at a lot of the other points, dose to critical structures, gradient across the

tumor. If any of those things chang[illegible] of them are wrong, they get mad at me. They vi[illegible] problem. I just want to be sure that you won't [illegible] as a problem, as well.

MR. TELFORD: We're looking for t[illegible]e dose to a point, like the center point or whatever isodose curve the prescription is written to. It's just that single point. We're not going to look for all possible points. But, surely, you got more confident than that on No. 3. Dr. Wu, how would you modify this?

MR. WU: I would get rid of No. 2 and No. 3 altogether.

MR. TELFORD: Okay. Why?

MR. WU: I accepted No. 1 because it's occurring now, a current regulation. First of all, like Gerry described, when you do a very complicated treatment plan and the physician traces a target, not necessarily a tumor. It's a target volume you want to treat.

They sometimes accept the more than ten percent homogeneity. In their mind, in their mind, the target is he's going to treat, the dose delivered to the target, he will accept somehow more than ten percent. In his mind, ten percent variation of his prescribed dose doesn't really matter.

MR. TELFORD: You mean for a fraction?

MR. WU: No. For a fraction or for the total dose. But No. 1 says greater than ten percent of the total dose, it's reportable. It's a misadministration. It's an error.

MR. TELFORD: Yes.

MR. WU: I'm saying that even though in the planning stage, the homogeneity in the target region is more than ten percent. So obviously there's a contradiction there. The regulatory point of view is that you made your decision, ten percent is harmful to the patient. In reality, physicians, the dose of variation across the target volume is more than ten percent he has accepted.

MR. WIEDEMAN: I don't think we've said that ten percent will cause harm to the patient, nor did we imply that. We just said that's the limit, like the speed limit, 55 miles an hour. If you go over a limit, you have to set the limit somewhere. Maybe the limit is too low. Maybe the limit is too high. I don't know.

MR. WU: I'm just telling you that in the physician's point of view, the dose, total dose ten percent over is very frequent.

MR. PICCONE: Dr. Wu, the ten percent is current, as well.

MR. WU: I know that. I'm just giving you a reason. If you start from scratch, I would throw that away,

too.

MR. TELFORD: If you started from scratch, what would you put here?

MR. WU: Again, it depends on the site or the disease you're treating. Sometimes the spinal cord -- we never allow the spinal cord to be over 4500, not ten percent, not even one percent. If you're treating some other site where the biological radio-sensitivity is not that great, we can accept a 20 percent variation.

MR. TELFORD: So in some cases you would say it would be one percent and in other cases you'd say it would be 20 percent.

MR. WU: Yes.

MR. TELFORD: Depending upon what's the organ that's not in the treatment volume, but, yet, vulnerable.

MR. WU: Right.

MR. TELFORD: Okay.

MR. WU: Again, going back again, how much -- the spinal cord, we have a paper, we have the technical experience, there's a risk factor involved that if you treat the cord over 4500, that's the standard practice. But in terms of other organs, we don't know the respect. It's current law, we accept it. But if you added two more, to me, you just add the extra burdens and you're monitoring for no purpose at all.

MR. TELFORD: I understand about some percent of total.

MR. WU: No. 2, I think, give you the example that if you treat 5000 or sometimes, the prostate you're coming up to 6000, then you -- one misadministration, for 200, you treat it 400. This is twice as much. Okay. You treated 400 rads. One fraction out of 25 fraction or 29 fraction, biologically it doesn't make any difference.

MR. TELFORD: If you delete No. 2 or (ii), you could give 2000.

MR. WU: Again, you're going by the prescription. The prescription said that 200 rads, how many fractions, total of how many. When you come back to the previous slide, if you're not going according to the prescriptions, then you're in violation. To me, it makes sense to monitor the total dose if you want to. If you want to monitor, it makes sense to monitor the total dose.

It has more significance to monitor the ten percent over the total dose than the fractionated dose.

MR. TELFORD: Darrel?

MR. WIEDEMAN: How about, Dr. Wu, with high dose hemibody therapy where you're giving a range of 400, 500 rads per day for three days.

MR. WU: Right.

MR. WIEDEMAN: You're saying that you can go ahead

and deliver --

MR. WU: We have inhouse QA program. Anything over 500 rads, they have to be double-checked before the treatment to make sure that it's correct.

MR. WIEDEMAN: In this case, a factor of two error would be very significant, wouldn't it?

MR. WU: Well, it depends.

MR. WIEDEMAN: Hemibody, we're talking half the body.

MR. WU: We're doing brain radio-surgeries. We can't allow -- but I'm thinking of overall consequences, if you will, say harm to the patient. I'd rather to think ten percent overall dose would harm the patient much more than your first fraction of 400 rads when you're supposed to deliver two, then everything else afterwards you did correctly. Only 200 rads over the 5000. It's not significant.

MR. WIEDEMAN: But, once again, hemibody, when you start talking 400-500 rads for three days --

MR. WU: Of course. We're not doing hemibody. We're doing bone marrow transplant.

MR. WIEDEMAN: You have a dual verification system, but there's probably -- I know there's other licensees out there that do not have a dual system in place, and this is what I think this regulation is trying to catch.

If you make an error in the fractionated dose, even though we're not talking about -- well -- the ones that we're doing the many fractionated doses, it's not all that significant.

It's a reportable event under the proposed rule, but, biologically, we're not going to see a big problem, but the high dose hemibodies, that could be very significant.

MR. WU: So it depends on the site. It depends on what you are treating. You can't just arbitrarily say that if it's greater by a factor of two, it's reportable.

MR. TELFORD: Would you recommend that the wording be changed, factor of two error and, say, large dose hemibody?

MR. WHITE: I think the implication is that there is acceptable wording, but I'm not sure that that's the case.

MR. TELFORD: You don't think the wording is -- the wording should be removed?

MR. WHITE: I think that the implication in at least this part of the discussion is that someone can't, in two paragraphs of fine print, set up a regulation that would be appropriate for reporting or defining what might generally be called serious misadministrations in radiation therapy. I'm not sure that can be done.

It's a very complicated set of circumstances that come together for that. It's a lot like the Holy Grail. It

may not be there to be found. I understand what you're trying to catch, but it's like catching that one big fish in the pond by throwing a stick of dynamite in. You get a lot of the little fish at the same time that really you didn't want. I'm afraid that's what we're looking at here.

There are clearly instances that have been terrible mistakes in radiation therapy that need to be addressed somehow, but I think we need to avoid doing that by catching all these little trivial things and generating a lot of paper. Basically, what I see this sort of thing leading to is not reducing errors, but just getting rid of Cobalt machines.

If we had a Cobalt machine and this became law, the first thing I would want to do is dump it, send it to Mexico or Brazil.

MR. TELFORD: Gerry, is a factor of two a little fish?

MR. WHITE: Yes. Well --

MR. TELFORD: How about a factor of three?

MR. WHITE: See, let me again talk about clinical problems that they're going to get caught in that net. Mrs. Jones comes down for brain treatment, is real sick. She can't hold still. She's having seizures. We treat the left brain, but the right brain can't be treated because by that time, she's just uncontrollable. We send her back upstairs

and have to send a report to the Nuclear Regulatory Commission that she was supposed to get a 200 rads that day. No?

MR. WIEDEMAN: No.

MR. WHITE: Why is that?

MR. WIEDEMAN: Once again, as we said earlier, the patient cannot tolerate a treatment for some reason or another, as long as it's documented. Patients die before the treatment is completed. We don't expect a report because they didn't get all the radiation dose.

MR. WHITE: How about if a machine breaks?

MR. WIEDEMAN: That's beyond your control. You have no control over that. We wouldn't hold you responsible.

MR. WHITE: I have a hard time reading that in here. I just don't see it.

MR. WU: As long as the physician makes a note that the left brain is not treated, acknowledge it, that should satisfy the regulation.

MR. WHITE: There must be some conditions under which the physician can't acknowledge that. Otherwise, it would never be in misadministrations if the doc could just say, yeah, it's okay.

MR. TELFORD: Well, let's hear those conditions that they can't do that.

MR. WIEDEMAN: Errors in calculations, wrong part of the body.

MR. TELFORD: You intended to give 200 rads to the brain, but you gave 500 rads to the brain. It didn't exceed ten percent of the total yet because you haven't given all the fractions.

MR. WU: Again, you have to assess the harm.

MR. TELFORD: All right.

MR. WU: There are incidents that, yes, of course, hemibody or total body or radio-surgery or external to the spinal cord. You can't allow that kind of error to occur. But in most of our regular fractionated treatments, I'm not defending the techs made a mistake by twice as much dose delivered. They have some excuse, I'm not saying that.

I'm saying that we have internal QA and a managerial -- some sort of action taken within the department. It's not really necessary to report to the NRC because the physician can assess the harm, does that really harm the patient. The physician says, oh, it doesn't really matter because instead of 200 rads, you gave 40[illegible] I'm going to give 5000 anyway.

So the physician makes an assessment that it doesn't really matter. But a regulatory agency, you're required to report to NRC, but to me there's no harm done to the patient.

MR. TELFORD: So if we have a requirement to report, an error in fractional dose, you would like it to be above the threshold that would cause harm to the patient for that treatment.

MR. WU: It would have to be very specific.

MR. TELFORD: It would have to be very what?

MR. WU: Specific.

MR. TELFORD: Specific for the specific treatment.

MR. WU: Yes.

MR. TELFORD: Okay. You would delete them.

MR. WU: I would delete No. 3, too.

MR. TELFORD: All right. Any other comments on --

MR. WHITE: I still have concern that people are going to be looking at multiple dose points, not just the single one.

MR. TELFORD: So we need to put clarifying words.

MR. WHITE: I think so. We're carrying eight different dose points. Later on, we change one of them because of a calculation change.

MR. WU: Like the Hodgkins, we carry seven points. You're treating several different sites.

MR. WHITE: Irregular field or spinal cord dose is another one. We do sagital cuts for our spinal cord doses. I just think that the dose specification problem is a lot more complex than these regulations are set to deal with.

MR. TELFORD: So we should say pick one.

MR. WHITE: But then the question rises, well, why did you pick that one.

MR. WU: We do pick one. We usually pick central access, the midline central access. But the question is you monitor that point -- this point has absolutely zero therapeutic anatomic rationale at all. It happens to be a geometric point. The other points which dose to the cord, those are related to real anatomic, that you want to treat where the diseases are.

But if you said ten percent error on total dose over a point which doesn't have any meaning in terms of treatment, that's also a lack of --

MR. TELFORD: So you're looking for a level of harm there, as well; exceed a level that would cause harm.

MR. WU: At least in No. 2. No. 3 it doesn't create --

MR. TELFORD: How about No. 1?

MR. WU: No. 1, yes. But I can justify to myself much more under No. 1 than the other two.

MR. TSE: I'd like to make a point. I was listening on your discussion. I think those misadministrations, first, you have to have an error or a mistake or something. It doesn't say ten percent exactly, how does prescribed dose compare with actual dose received

by the particular point. Somebody had to make an error or mistake.

Then as a result of that error or mistake, that wrong calculation or picked the wrong part, and then you've got the wrong calculation if the dose exceeds or wrong execution, the dose exceeds the prescribed dose by a certain percent. Then it would constitute a reportable.

If somebody has a problem and you discontinue this, that's not a mistake, not an error, and that's the first point. The second point is that we did discuss some of your suggestions in the Federal Register Notice. It's on Page 1444.

We talked about somebody, a physician did make suggestions like what we said. We discussed a little bit why we did not adopt that in the proposed rule. However, we still would like to consider that you can provide some good suggestions like that.

If you want to read that a little bit, perhaps you can give us more suggestions on why you think it's a problem and suggesting a solution to that problem.

MR. WU: We've spent a lot of time discussing it today. I think we constantly struggle with the problem that one tried to arrive at a regulation to cover everything. In reality, it's much more complicated than that. For instance, this morning we talked about whether the

brachytherapy should be applied to the medical use during or after.

If you have the liberty to write this for various cases, then you don't have that problem. If you try to write one single line that says greater than a factor of two should be reported, in many cases, as Darrel pointed out, it's justified and there are other cases that are totally insignificant.

If you say, well, for half-body and some fractionation less than five fractions or four fractions or half-body, total body or whatever, then if it's over, twice as much, of course it's significant. But if you have 25 fractions or 30 fractions, that's totally insignificant.

MR. TSE: That's why we're here to see what suggestions like this morning's sessions would be very useful to us.

MR. WU: I am not claiming that I know the answer. I know it's very difficult to write one line to cover all those possibilities of all the cases. That's difficult.

MR. TSE: So would you suggest that you use an overdose to describe each organ, dose to each organ --

MR. WU: That may be a good suggestion. In this orange book, published by the University of Rochester, it lists all the organs tolerances. It may be something that one can use. If the dose is over this point, you have to

have some sort of explanation, the physicians. We use that a lot.

But physicians still overrule. There are cases that the head and neck, the patient's being treated with 6000 rads three years ago, then recur, coming back, and he wants to treat with another 6000 rads. I say, my gosh, 12000 rads, you're going to burn a hole in him.

As physicists, our position is that we bring to the physician's attention, hey, this patient has been treated before, the same area, you're going to treat it, the dose is going to be over the tolerance dose. They frequently come back to you that do I have any options. Zero. Either you treat or not treat.

MR. WIEDEMAN: That's a medical decision.

MR. WU: That's a medical decision.

MR. WIEDEMAN: And we wouldn't get involved in that.

MR. WU: No. As physicists, we don't get involved either. But we do bring it to the attention -- that's our responsibility. Like I said, it's not that simple. It's very complicated. In order to have a one-line statement that is to cover all the possibilities, it's difficult.

MR. TELFORD: Any other comments on No. 3?

[No response.]

MR. TELFORD: Let's have a look at B-4. Here

we're capturing leaking and lost brachytherapy sources. Any comments there?

[No response.]

MR. TELFORD: How about No. 5? This is we're capturing brachytherapy administration that's 50 percent different than what's prescribed. Twenty percent, not 50. The current requirement says ten percent. We've increased that t 20 in recognition of the difficulty of calculating the doses, because of the difficulty in locating exact source.

MR. WHITE: I think I said before I still think that's overly optimistic.

MR. TELFORD: Twenty percent?

MR. WHITE: Yes.

MR. TELFORD: Okay. How would you modify it?

MR. WHITE: I think you might consider 20 percent in excess of errors induced by unavoidable calibration -- unavoidable uncertainties in the calibration of the sources and the spacial distribution of the radiation intensity, combined with some way to quantify unavoidable errors in geometric localization of the sources. Those are the two big things that combined produce errors.

MR. TELFORD: The spacial distribution of the sources, as you've tried to apply them in the OR.

MR. WHITE: That or just -- I'll use the example

of dose calculation.

MR. WIEDEMAN: But the one thing we were looking at originally was the calculations show that the source was supposed to be removed on Tuesday evening at 6:00. They forgot. It didn't get removed until Wednesday morning at 8:00.

MR. WHITE: Unfortunately, if it said something about Tuesday morning at 8:00 up there, I wouldn't have a problem with that. One of the things that gets caught on this is a point that I think is ten millimeters away from the source and is really eleven millimeters away from the source on a blurry radiograph.

If somebody came to me, if one of my colleagues came to me with certain kinds of implants that we do and said did you calculate this dose to within 20 percent, I'd have to look them in the eye and say, no, uh-huh, I didn't, couldn't. If you're a centimeter away from a cesium source or another point source and you're off by one millimeter, that's 20 percent.

MR. WIEDEMAN: But if the State of Colorado inspector came in and said to you, did you calculate that dose to be removed Tuesday evening at 6:00 to get the total dose of 3500 centigray, you would say probably, yes, I did, 6:00 Tuesday evening. And then the next question is, well, when did you remove them, and if you said 6:00 Tuesday

evening, then everything is clean and clear. But if you say, no, we forgot to remove them, we didn't get around to it till Wednesday, morning, then we have a problem.

MR. WHITE: I think that's true, but I think it's important when you're writing stuff that goes in the Federal Register that it mean what it says. If it says 20 percent, then I ought to be able to look you in the eye and say, yeah, that was 20 percent. I think that both the brachytherapy and teletherapy sections presume the true accuracy that is better than is available.

The preface to the section in the front part of the Register talks about being able to calculate teletherapy doses to within two or three percent. Under some conditions, you can do that. When I say to the radiologist, yeah, I calculated that to within two percent, he understands the limits. He understands what's within two percent and what's not.

When you say that to a lawyer, he expects that to be within two percent. We're going to be talking to you guys about this. We're going to be talking to inspectors. We may even be talking to lawyers in court, saying, well, my client, the NRC said 20 percent and you're telling me that wasn't true, that the vaginal apex received 35 percent more.

That's 150 percent in excess of the NRC allowable dose limits. You laugh about that, but I counsel a lot of

people who come to me in panic because their houses have 50 percent more radon than the EPA allows. Those numbers assume incredible importance to people and if you're going to put them in the Federal Register, I think they need to be related to reality.

When a manufacturer sells me a source that says we guarantee that we won't give you the source unless it's within 20 percent, but we don't know how close, I sure am not going to -- I think it's wrong to ask people to be able to -- it's just -- it can't be taken seriously.

If you're going to put regulations in here that can't be taken seriously, then I think the whole program suffers, and that happens to be one of them.

MR. WIEDEMAN: You're saying that the 20 should be raised to what, 40?

MR. WHITE: I'm saying it ought to reflect your intention, which is to exclude certain errors, such as reasonable errors in placement of sources and it ought to exclude reasonable errors in calibration of sources. That's not to mean that you take a 20 milligram source and it's really a 40 milligram source. But there are some sources whose spacial distributions are known better than others and I think that's the sort of thing you need to take into account.

Again, it's an example of a complex situation.

It's difficult to squeeze it into a ten-word phrase. You may not be able to get it in ten words. But I think those are -- given a certain set of assumptions, we can calculate a certain dose. But if the assumptions are wrong, the dose is wrong.

I think what you guys are saying is that let's pretend the assumptions are right, will the dose then be correct. My hesitancy is pretending that the assumptions are right. If I really got the source right in the middle of that vaginal candle, then I calculate the dose to the vaginal candle.

But when I'm sitting there in my lab with a drill drilling out the center of these wax candles, I may be off by a millimeter or two. I think that for brachytherapy that's a significant difference between reality and the regulations that I think we need to think about.

MR. TELFORD: Okay. Any other comments on any of the B misadministrations?

[No response.]

MR. TELFORD: If we look at C, that simply requires someone like the RSO to investigate and make a record of a misadministration. D says you'll notify the NRC by telephone. E says you'll have a followup report within 15 days. F says you'll keep the records as you kept before in 35.33, prescription and record of the dose or dosage for

three years; record of a misadministration for ten years.

How would you modify these?

MS. ROBERTS: What does the NRC do with the records of misadministrations?

MR. TELFORD: We send an inspector.

MR. WIEDEMAN: What was the question?

MR. TELFORD: What do we do with records of misadministrations. This is a report here of a misadministration. I guess the question is what do we do with this report.

MS. ROBERTS: Right.

MR. WIEDEMAN: I'll tell you what we do. When we receive diagnostic or therapeutic misadministration reports, they come into the regional office, they go to the section chief in charge of inspection, and he reviews it. For diagnostic, he looks at is it a typical diagnostic misadministration; technologist grabbed the wrong syringe, wrong reagent kit was used to mix up a batch of DTPA; the typical things.

We enter it into a database program where we keep track of it. That way if a FOYA, Freedom of Information Act request comes in asking for all the misadministrations in the State of Missouri, we can go and pull that data out.

On the 15th of each month, we send a copy of that database program, plus the report itself, to NRC

Headquarters. NRC Headquarters receives those in an office called AEOD, Assessment and Evaluation of Operational Data.

MR. TELFORD: Analysis and Evaluation of Operational Data.

MR. WIEDEMAN: And they keep a running track nationwide of how many misadministrations. They look at generic problems. If all of a sudden we started receiving a bunch of reports on, say, leaking sources and it happens to be a 3M CD6C source, they look for generic problems and then they'll go back to the manufacturer and say, hey, we've had four reports in the last three months of a leaking source, have you looked into this matter. That's basically what we do with it.

With therapeutic, we inevitably, almost always send an inspector, unless there was some -- if it's a typical therapeutic misadministration, no major effect on the patient, we will normally get a hold of a medical consultant, NRC medical consultant, an MD and he will review the case to see if the patient, if he feels the patient is receiving proper medical care.

You will find that many of the hospitals, even though they treat patients in teletherapy, brachytherapy, they may not know how to properly treat the patient for biological effects of radiation and that type of thing. So we just make sure our medical consultants agree with the

proper treatment.

So a lot of things that we do with those reports.

MR. TELFORD: Okay. Let me see where we are here. That's Thursday. What we have covered so far on the agenda is we've covered the proposed rule 35.35; we've covered the reporting requirements, the diagnostic and therapy reporting requirements.

So we've covered the morning session and the feedback session. The only thing we have left is the discussion of the guide, which, if nobody objects, we can do tomorrow morning.

Are there any last comments before we adjourn for the day?

MR. WHITE: It's been fun.

MR. TELFORD: Let's adjourn for the day, come back tomorrow morning at, say, 8:30. Let's go off the record.

[Whereupon, at 5:16 p.m., the workshop was recessed, to reconvene the following day, Friday, October 26, 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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NAME OF PROCEEDING: Quality Assurance Workshop

DOCKET NUMBER:

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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.

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