OFFICIAL TRANSCRIPT OF PROCEEDINGS

Agency: U.S. Nuclear Regulatory Commission

Title: QUALITY ASSURANCE WORKSHOP

Docket No.

LOCATION: Atlanta, Georgia

DATE: Thursday, September 6,1990 PAGES: 1 - 207

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

U. S. NUCLEAR REGULATORY COMMISSION

- x

In the Matter of:)

)

QUALITY ASSURANCE WORKSHOP)

)

- x

Room London, Cluster 3

Marriott Marquis Hotel

Atlant , Georgia

Thursday, September 6, 1990

The above-entitled matter convened at 9:00 a.m.

ATTENDEES:

On behalf of the Nuclear Regulatory Commission:

JOHN TELFORD

ANTHONY TSE

DARREL WIEDEMAN

LARRY CAMPER

On behalf of Brookhaven National Laboratory:

EDWARD KAPLAN

On behalf of Pilot Program Participants:

NEIL CANADA	ASHOK DESAI	SANTIAGO GOMEZ
STANLEY GIPSON	JEAN RHODES	TAWFIG HAIDER
JERRY MORRIS	ROY LANDERS	SARAH KIRTLAND
LORI HANLEY	TOM CLARK	TONY PULCRANO
THOMAS A. WHITE	SURESH ARGAWAL	DAVID GARRISON
KENNETH FRYMAN		

I N D E X

PROCEEDINGS

MR. TELFORD: Good morning.

My name is John Telford. I'd like to welcome you back to the post-trial period workshop. Your faces are beginning to look a little familiar by now.

The first thing I want to do is go through the agenda this morning and let you introduce yourselves again, as we did before. Then we'll discuss the agenda for both days and along the way we'll have a few announcements and in just a few minutes I'll tell you what we're going to accomplish in this workshop and tell you that this meeting is really just for you.

So let's go to the first item on the agenda, which is sort of self-introduction of volunteers. During this self-introduction, I'd like you to tell us, as you did before, your name, the name of your hospital or clinic, its size, how many beds, its location and in particular the department or departments that participated in the 60-day trial period, for instance teletherapy, brachytherapy, nuclear medicine therapy or diagnostics. So let's start over here on the left. Are these name cards lined up correctly?

MR. CANADA: My name is Neil Canada, I'm from Dalton, Georgia, from the Hamilton Medical Center and we're about a 300-bed hospital. We just participated in the nuclear medicine services.

MR. GIPSON: Stanley Gipson from Forrest General

Hospital, Hattiesburg, Mississippi, south-central part of Mississippi. I'm in charge of the Nuclear Imaging Section and we're about a 450 to 500-bed hospital, general care hospital, community hospital.

MR. MORRIS: Jerry Morris from Forrest General Hospital, Hattiesburg, Mississippi. I'm in the Radiation Therapy Section, Nuclear and Radiation Therapy participated.

MR. TELFORD: Okay.

MS. HANLEY: Lori Hanley with Rockdale-Newton Tumor Center in Conyers, Georgia. It's a free-standing center and we participated in teletherapy.

MR. WHITE: Tom White, Baptist Medical Center in Columbia, South Carolina. I'm primarily in radiation therapy and I'm responsible for radiation therapy and nuclear medicine. We're a 450-bed hospital.

MR. DESAI: Ashok Desai, I'm from Houston, Texas, Hermann Hospital. We're a 500-bed hospital, primarily nuclear medicine and we participated in the nuclear medicine.

MS. RHODES: I'm Jean Rhodes, I'm from Valdez Hospital in Valdez, North Carolina. We operate 75 beds at our hospital now. Both our Radiation Therapy Department and our Nuclear Medicine Department participated in this project.

MR. WIEDEMAN: My name is Darrell Wiedeman, I am with the NRC Region II office in Chicago, I'm the Technical Assistant to the Director -- to the Division of Radiation

Safety and Safeguards. I'm also a member of the QA Medical Site Team.

MR. TSE: My name is Anthony Tse, I'm from Washington, NRC Office of Research. I'm the Program Manager of this program.

MR. KAPLAN: I'm Ed Kaplan from Brookhaven National Laboratory. I'd like to thank you for cooperating and sending me the questionnaires and other material in a timely fashion. Thank you.

MR. CAMPER: I'm Larry Camper, Section Leader for the Medical and Academic Section, NRC Headquarters. My shop is responsible for policy and technical issues related to the medical and academic uses of materials that NRC regulates. My group is working with the Office of Research in writing the proposed quality assurance rulemaking.

MR. ARGAWAL: I'm Suresh Argawal, I'm the Director of the Radiological Physics Division at the University of Virginia. University of Virginia Hospital is 400 beds and we are participating in teletherapy, brachytherapy and nuclear medicine.

MR. TELFORD: Thank you.

MR. LANDERS: I'm Roy Landers from Sarasota, Florida. I represent several free-standing facilities run by the same group of physicians and we do radiation therapy for three hospitals, altogether having about 1000 beds. This covered the

therapy parts; teletherapy, brachytherapy and nuclear medicine.

MR. CLARK: Tom Clark, Southeast Alabama Medical Center in Dothan, Alabama. We're approximately 400 beds. We participated in all phases of nuclear medicine and radiation and brachytherapy.

MR. GOMEZ: I'm Santiago Gomez from San Juan, Puerto Rico, University of Puerto Rico which is a cholemic and chemical institution and we participated in nuclear medicine.

MR. TELFORD: How large is your facility, how many beds?

MR. GOMEZ: Twenty thousand students, it's not the hospital.

MR. TELFORD: Not the hospital, okay. How many -- patient load or beds?

MR. GOMEZ: Well we have a university hospital with 300 beds.

MR. HAIDER: Tawfig Haider, Columbia, Tennessee. It's a 400-bed hospital. And radiation therapy and brachytherapy, we participated in.

MR. TELFORD: Okay.

LT. KIRTLAND: I'm Sarah Kirtland, I'm from the Naval Hospital in Bethesda, it's a 500-bed hospital but when I left there were only 120 patients due to a loss of personnel. We participated in brachytherapy, teletherapy and nuclear medicine.

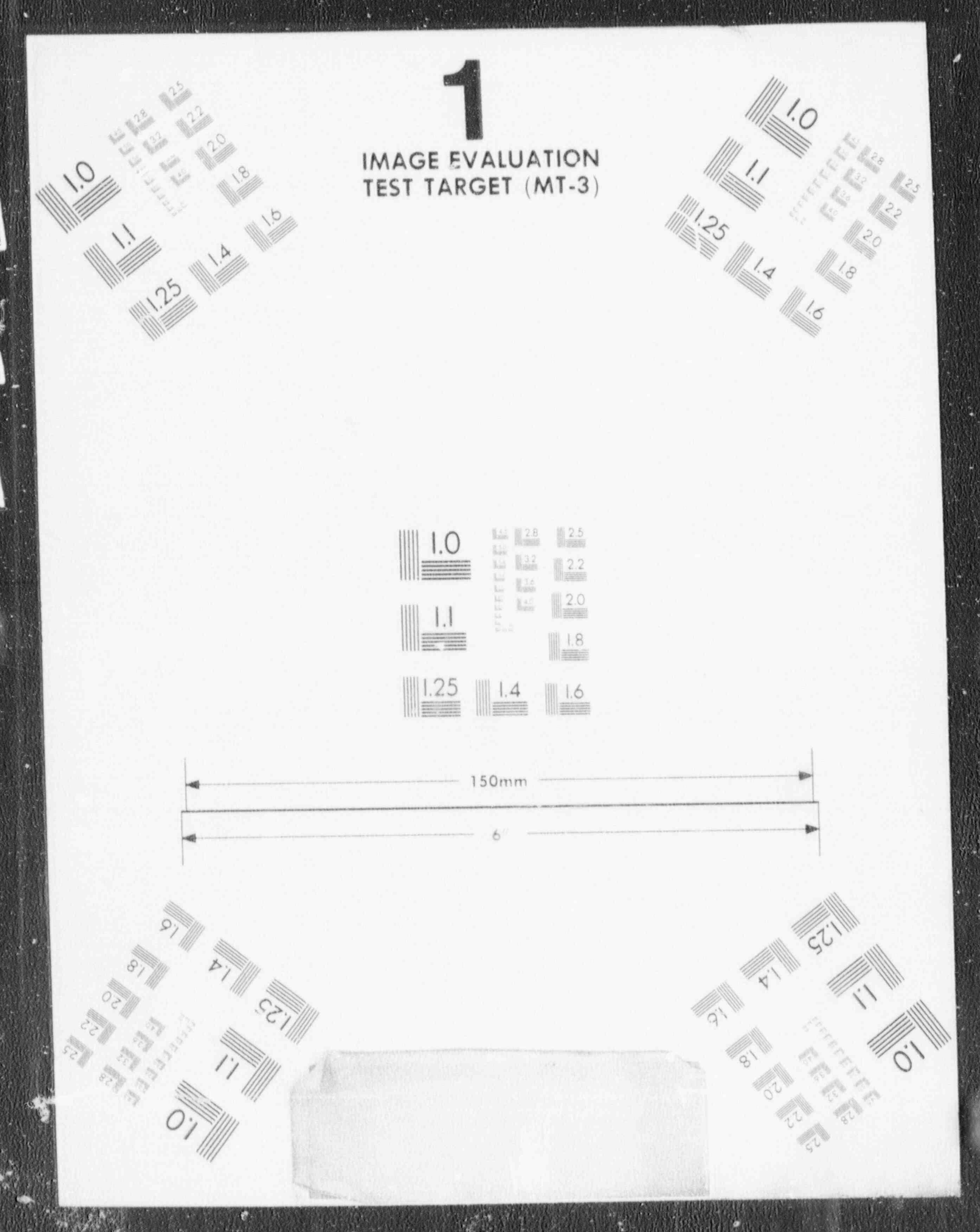
LT. CMDR. PULCRANO: Tony Pulcrano, I'm from the Naval Hospital at Portsmouth, Virginia. We're about a 500-bed hospital and we had all three fields participating in the program.

MR. GARRISON: Dave Garrison, I'm from Arlington, Virginia, Arlington Hospital, it's 350 beds, right outside of Washington, D.C. We participated in nuclear medicine, diagnostic and therapeutic.

MR. TELFORD: Great, thank you.

Let me direct your attention to the agenda. We're going to cover these first two items here rather quickly, then I'll show you both days. But I want to go to the second item on this agenda because you'll recall at the pre-trial period workshop what I told you that you could expect and I told you that we would confess to you the criteria that we would use for your program evaluation and we would confess to you the criteria that we used for the site visit, if your site was one of the 18 chosen. But obviously those two sets of criteria would be helpful to you to understand in a licensing sense or inspection sense what this might be like if this were the final rule.

So Mr. Wiedeman is going to discuss those two sets of criteria with you this morning and we're also going to have your evaluations for each program, because each program got evaluated, so we'll have sort of a checklist of results that


1
IMAGE EVALUATION
TEST TARGET (MT-3)
1.0
1.1
1.25
1.4
1.6
1.8
2.0
2.2
2.5
2.8
3.2
150mm
6"

we're going to give you. We're going to do that -- we'll hand that checklist to you right before lunch so that you'll have ample time to catch some of us to ask questions about anything you don't understand. Mr. Wiedeman will make that much more clear.

Now we also told you during the pre-trial period workshop that we would listen to you to understand your suggestions as to what you would do with the proposed rule, Part 35.35, just the QA rule. We will also listen to you on the Regulatory Guide, we'll go through each section of that, and the reporting requirements, 35.33 and 35.34.

So what we have personnel-wise is at least three of the five people that will be writing the final rule. So we have come to you to listen to you to find out your suggestions for what we should do with the rule, the Guide, reporting requirements. Okay?

So seriously, this meeting is for you.

Now, ground rules. Ground rules are simple. Volunteers get to talk, we get to listen. We have some observers here. I will show you on the next day's agenda, when I get to it, where they get to ask questions. But we're here to listen to the volunteers and we will have sort of a tow-way dialogue and that's what this is all about. So any observers will have to hold their comments and questions.

Now basically we've taken everything we want to cover

was in the 60-day trial period. I jokingly say this is your passport to go to lunch.

MR. WIEDEMAN: Well good morning, everybody, welcome to Atlanta, Georgia.

This morning, I'm going to go over with you, and I'm going to go quite quickly, through the background, the evaluation criteria, the program evaluation and what we found at the site visits. Now I can only recommend that don't try to write all this down because I'm going to give you copies of the evaluation, both the site and the program evaluation for your particular facility.

Now there's two things to keep in mind, the program evaluation is very similar to a licensing review. This would be the criteria that we established for the licensing reviewers to go over to make sure that we have consistency throughout the agency in reviewing an application for a medical QA program. The site evaluation criteria is basically what the inspectors would use to evaluate your program during an on-site inspection.

And to give you sort of an idea of what we were looking at, we selected 18 licensees, 11 from NRC and seven agreement states, which consisted of 15 diagnostic nuclear medicine programs and less than 30 microcuries of I-131 or 125; and 12 therapeutic radiopharmaceuticals consisting of iodine P-32 and gold and iodine greater than 30 microcuries; five

brachytherapy and eight teletherapy programs.

Now geographically, they were distributed quite wide, all the way from French Camp, California; Spokane, Washington; Sarasota, Florida; a lot of the corn belt, Cleveland, Ohio; Indiana; Iowa and of course down in Texas. So you can see it was pretty well geographically distributed.

And as I said earlier, we reviewed the various different types of programs and both as an on-site evaluation and a program evaluation.

Now the breakdown from what we're looking at here is the NRC facilities and the agreement states. There were some questions that the various people were asking -- well how many agreement states will be represented and how many of the NRC. The diagnostic nuclear medicine, in this case we looked at nine hospitals, NRC hospitals. PP is private practice, we saw one. Agreement state hospitals, four, and one private practice, and so one down.

Now starting off with the diagnostic nuclear medicine, what we did is when we review for the program evaluation, the first objective - ensure that the medical use is indicated for the patient's medical condition. Now you say well how is that interpreted. What we would do is we would look at (1) does the authorized user review the case and are procedures ordered by a physician. We wanted to make sure that we don't have emergency room nurses or leave that

we're going to give you. We're going to do that -- we'll hand that checklist to you right before lunch so that you'll have ample time to catch some of us to ask questions about anything you don't understand. Mr. Wiedeman will make that much more clear.

Now we also told you during the pre-trial period workshop that we would listen to you to understand your suggestions as to what you would do with the proposed rule, Part 35.35, just the QA rule. We will also listen to you on the Regulatory Guide, we'll go through each section of that, and the reporting requirements, 35.33 and 35.34.

So what we have personnel-wise is at least three of the five people that will be writing the final rule. So we have come to you to listen to you to find out your suggestions for what we should do with the rule, the Guide, reporting requirements. Okay?

So seriously, this meeting is for you.

Now, ground rules. Ground rules are simple. Volunteers get to talk, we get to listen. We have some observers here. I will show you on the next day's agenda, when I get to it, where they get to ask questions. But we're here to listen to the volunteers and we will have sort of a tow-way dialogue and that's what this is all about. So any observers will have to hold their comments and questions.

Now basically we've taken everything we want to cover

and broken it up into four blocks of time. The first block is the feedback to you of discussions of the criteria and the results of our findings, both from program evaluations and from site visits.

Next we will go through the proposed rule, the 35.35, and I'll be going through it in this fashion, each objective at a time. We'll give you a couple of times, opportunities, here and here on the agenda today, where you'll have individual time to say whatever you like.

Tomorrow, we'll have the Regulatory Guide and we'll go through each section of the Guide piece-by-piece, take it apart. In the afternoon tomorrow, we will go through the diagnostic reporting requirements and secondly, the therapy reporting requirements.

Now at the end of this, if any of the observers want to ask the NRC staff questions or make comments, we will make ourselves available for as long as they'd like to talk.

Oh, one last thing on these times, let's just say they're approximate. We will go at your speed. If you want to go faster, we will; if you want to go slower, we will.

So I'm going to get the show on the road and let Mr. Wiedeman come up here.

Oh, yeah, one more thing. Dr. Kaplan has some forms that he would like to pass out and we would like you to fill these out so that we'll know for sure what your participation

was in the 60-day trial period. I jokingly say this is your passport to go to lunch.

MR. WIEDEMAN: Well good morning, everybody, welcome to Atlanta, Georgia.

This morning, I'm going to go over with you, and I'm going to go quite quickly, through the background, the evaluation criteria, the program evaluation and what we found at the site visits. Now I can only recommend that don't try to write all this down because I'm going to give you copies of the evaluation, both the site and the program evaluation for your particular facility.

Now there's two things to keep in mind, the program evaluation is very similar to a licensing review. This would be the criteria that we established for the licensing reviewers to go over to make sure that we have consistency throughout the agency in reviewing an application for a medical QA program. The site evaluation criteria is basically what the inspectors would use to evaluate your program during an on-site inspection.

And to give you sort of an idea of what we were looking at, we selected 18 licensees, 11 from NRC and seven agreement states, which consisted of 15 diagnostic nuclear medicine programs and less than 30 microcuries of I-131 or 125; and 12 therapeutic radiopharmaceuticals consisting of iodine P-32 and gold and iodine greater than 30 microcuries; five

brachytherapy and eight teletherapy programs.

Now geographically, they were distributed quite wide, all the way from French Camp, California; Spokane, Washington; Sarasota, Florida; a lot of the corn belt, Cleveland, Ohio; Indiana; Iowa and of course down in Texas. So you can see it was pretty well geographically distributed.

And as I said earlier, we reviewed the various different types of programs and both as an on-site evaluation and a program evaluation.

Now the breakdown from what we're looking at here is the NRC facilities and the agreement states. There were some questions that the various people were asking -- well how many agreement states will be represented and how many of the NRC. The diagnostic nuclear medicine, in this case we looked at nine hospitals, NRC hospitals. PP is private practice, we saw one. Agreement state hospitals, four, and one private practice, and so one down.

Now starting off with the diagnostic nuclear medicine, what we did is when we review for the program evaluation, the first objective - ensure that the medical use is indicated for the patient's medical condition. Now you say well how is that interpreted. What we would do is we would look at (1) does the authorized user review the case and are procedures ordered by a physician. We wanted to make sure that we don't have emergency room nurses or leave that

responsibility up to the technologist to make that decision. And I might add, we didn't find any case where it wasn't ordered by a physician or the authorized reviewer -- authorized user did not review the case.

Are prescriptions made or a diagnostic referral? Now of course remember in the diagnostic nuclear medicine program, it could be done either way, but normally you would think of the prescription when you get into therapy.

Now what we were looking for -- instructions were understood by responsible individual. If you had committed to -- if you used the wording, we will follow the guidance in 35.35(a)(4) or Reg Guide 2.1, 2.2, then basically our program evaluation would be over. We'd just basically say they've committed to the Reg Guide and the regulation.

So when we would get out to do our site evaluation, we would look in and personally instruct on the importance of accurately and clear records, and that would be by simply asking the technologist do you have procedures in place? If you don't understand or if you see an order that does not fit into your procedures manual, what would you do? And once again, personnel instructed to match the medical use with the diagnostic referral, in every case this is where you would look at the requisition of the diagnostic referral, compare that with the chart and see if it's covered in the procedures manual.

Here were key examples of things that we would look for. Are they using the clinical procedures manual? Do they have a diagnostic referral system in place? Are telephone referrals -- this was kind of a very touchy subject because some facilities would not authorize telephone referrals, they had to have it in writing or in several cases, the authorized user would contact the referring physician and get the referral over the phone. But it was not always left up to the technologist, but in several cases we did find where the technologist did the follow-up.

Patient identification was another area we looked into, trying to find a redundant system, see if you have a redundant system in place, and in a few minutes I'll explain some of the creative things that we found.

Patient's identify verified. We found out with this redundant system there were several creative ways -- most of the most of the military hospitals didn't really have much of a problem, such as I believe Madigan and Bethesda, I believe they have a patient photograph identification. So it was very easy to look at that. However, in the private practice facilities, it was a little more difficult. Some key examples of how this was handled is the out-patients where the technologists would go up and ask the receptionist "where is Mrs. Jones" and the receptionist would point to Mrs. Jones. Then you'd walk up to Mrs. Jones and you'd say, "Excuse me, what is your name?" And

then if she said "Mrs. Jones", you'd be verified -- dual verification system. And once again, they would cross reference the diagnostic referral or the prescription with that patient's -- and the identity of the patient.

Unintended deviations -- we were looking to see if you had a system, if you confirmed that you would follow 35.35(a)(7) or the Reg Guide, then basically it was all over with. There was nothing else to review during the review criteria.

Personnel instructed to terminate the medical use if a discrepancy was identified -- we found that in almost, probably 75 percent of the cases, the licensee didn't have procedures in place for what the technologist is supposed to do when he finds a discrepancy in the order, the referring physician's order, such as an order for a thyroid scan. What does that mean, is that with technetium, is that with iodine. Or a cancer scan, what does that mean, metastatic scan? However, most of -- well all of the technologists that we talked to, they had this sort of an understanding that what they would do is they would go to the authorized user and show him or her the request and it was decided between the authorized user and the referring physician what type of study to do.

Treatment planning in accordance with the prescription -- this really would not apply for diagnostic

nuclear medicine.

Any questions on the diagnostic program?

(No response.)

MR. WIEDEMAN: Okay, now on the radiopharmaceutical therapy, one thing that we found out from our previous workshops is the use of iodine 131 Hippuran, we were told that this would be impractical to have the physician write a prescription for every time that they get a requisition or a prescription for a kidney study using Hippuran. So the site team decided that what we will do is we will not require or even look for a prescription because we found that some facilities do as many as 20 to 30 of these studies each morning, or each day. And so to have the physician have to sit down and write out a prescription for every one of those cases may be somewhat impractical.

In our review of this particular subject, authorized user reviews the case, we found that in almost all cases the authorized user would go through each case, examine the patient, talk to the referring physician and determine the proper therapeutic amount to use.

Now what we were looking for when we get to the prescription is did it talk about the isotope, the dosage, the chemical form, route of administration and physical form. Now we found that, oh, I'd say a good 75 percent of the cases, it did not include the route of administration and the physical

form. We looked into this matter and it was somewhat of an understanding that everyone had that if they always used capsules, they never used liquid, then we would put down on our form that it was not included; however, everyone understood that it was -- they always used the same physical form of iodine and it was always by oral ingestion.

Diagnostic referral, this would not really apply to therapy. Once again, if you made the statement in your QA program that you -- we just confirmed that you had followed 35.35 or the Reg Guide when we would look at our site evaluation, we would look for this type of personnel instructed on what to do, clear and accurate records. Once again, procedures were not in place in many of the facilities, but everyone seemed to understand exactly what to do.

We found, probably in a good 75 percent of the cases that the physician, the authorized user, is the one who would administer the dose. The other 25 percent, it appeared that the technologist would administer the dose, following the prescription of the authorized user.

The things that we would look for -- the procedures manual, content of the prescription, telephone referral. We found in many cases they do not have telephone referrals for therapeutic use of iodine. It requires that the referring physician would consult with the authorized user before the dose is given, and the authorized user would almost always

examine the patient before the dose was given.

Patient identification -- once again, when it came to in-patients in the hospitals and clinics, it wasn't a major problem because you always have the name band of the patient, calling of the patient's name, that type of thing, but when it gets to out-patients it gets a little touchy in that area because it's hard to come up with a creative way other than the ways that I explained earlier in diagnostic where the receptionist would point out Mrs. Smith and you would ask "what is your name?" and she would say "Mrs. Smith". Once again, the physician that examined the patient would also be the one who administered the dose in many of the cases. So that was once again a somewhat redundant system of patient identification.

We would look at, once again, instructions to terminate the medical use of a discrepancy as identified -- many times the authorized user examines the patient and administers the dose and there was very little to look into. The one thing -- we looked at the record of prescribed and measured, this is already required under Part 35. Many of the cases it was not stated in the program itself that you do that, but when we looked at it from the site team side, we found that every single one of them was doing it.

Treatment plan in accordance with the prescription -- once again that wasn't a major problem. It really is not applicable for radiopharmaceutical therapy.

Any questions on radiopharmaceutical therapy?

(No response.)

MR. WIEDEMAN: Next, on brachytherapy, this is what we would look for when we review your program. Keep in mind, ensure that the medical use is indicated for the patient's medical condition.

Brachytherapy, this was not a major problem -- authorized user always reviewed the case and went over with the patient and examinations and conferred with the referring physician.

Once again, this is what we would look for when we'd go out to our site team -- to see if the prescription included the isotope, the treatment site, total dose or treatment time, number of sources and combined activity. Now we found in our review of this particular situation that many times the initial prescription would say -- I'll give you an example -- intracavitary therapy, cesium 137, sometimes the prescription would talk about milligram hours. And then after the dummies are loaded, the calculations would be made and a total treatment time would be evaluated, and then another prescription would be written outlining everything, that there were so many ten milligram, five milligram sources -- radio-equivalent -- and describe in more detail. And that was acceptable.

Diagnostic referral made -- this would not apply to

brachytherapy.

Once again, when we would look at your program on paper, we would try to confirm these statements or either the statement that you would commit to the Reg Guide. In many cases it wasn't addressed, and you may see on your form, it'll be checked off "needs more information".

Now this is what we would look for when we got out there -- a procedure to verify the radionuclide source and strength with the prescription. There was the color-coding system that we would look at. There was also various different unique systems that licensees were using. There was one facility I can remember that was using the dose calibrator to verify the doses -- or the sources, the brachytherapy sources.

Examples of key procedures that we would look for -- requirement for the content of the prescription; exceptions due to the patient's emergency condition. Now we found that there are occasionally cases that come up where there is an emergency in brachytherapy, or the physician has decided this would be considered an emergency. In all cases, the authorized user is always consulted, he always has direct input into this, and it didn't appear to be a big problem.

Patient's identity verified -- we're looking for redundant procedures, and with brachytherapy, we found that there's quite a few things. Almost always, brachytherapy is done as an in-patient, except for high dose after-loaders. We

have once again the patient's chart, we have the name -- arm band of the patient, many times we have photographs of the patient inside the chart. In military hospitals, they have the photo identification type system.

Unintended deviations -- we looked into how personnel are instructed to terminate the entire procedure if they don't understand. And there weren't a lot of facilities that had any written procedures per se, but once again, everyone seemed to know what to do, and they'd go back to the authorized user and discuss it.

Current practices that we would look at -- after the sources are inserted into the patient, we were looking for various different ways that the people come up with the proper dose to the patient; taking radiographs, CT, nomograms, dose tables and procedures for confirming the dose calculations, making sure that they're accurate.

Once again, this is what we would look for. We would try to determine how you do your dose calculations, computer generated calculations, proper input, proper output, QA on who rechecks the numbers. Is there a procedure in place that describes how this is done; who does it, technologist, dosimetrist, who checks the dosimetrist, who rechecks the physicist's calculations.

Remote after-loading, I think we had one facility that had a high dose remote after-loader and they're unique and

different. However, a lot of the criteria in the objectives would apply.

Any questions on brachytherapy?

MR. LANDERS: Yeah.

MR. WIEDEMAN: Yes?

MR. LANDERS: Termination of a brachytherapy procedure if things were not clearly understood or something like that. I didn't understand what you were after there. You're talking about not doing the implant if something was unclear?

MR. WIEDEMAN: If the prescription was written and the physicist or dosimetrist did not quite understand what the prescription called for -- we were looking for, does the licensee have a procedure in place to get that prescription clarified, like go to the authorized user, discuss this with him -- it's usually the authorized user that wrote the prescription. And sometimes the handwriting is a little illegible.

MR. LANDERS: You were not talking about removing implant.

MR. WIEDEMAN: No. Now keep in mind that many times in brachytherapy, there's things that are above and beyond the control of the licensee, such as the licensee -- or the patient has pulled out the brachytherapy sources. Now the original prescription may have called for 3000 centigrade and the

patient pulled the sources out after day one. Well then we would expect to see some kind of documentation trail to show us that the treatment was terminated or we reinserted the sources -- you know, that type of thing.

Now the interesting thing was one of the facilities -- I won't mention their name -- we asked to see three recent cases of brachytherapy and they brought us three cases and we went through them. One of them was a therapeutic misadministration that went unreported. I thought at least they'd pull three good cases.

(Laughter.)

MR. WIEDEMAN: Medical use indicated -- once again, this is what we would look for. Does the authorized user review the cases, each one of the cases, prior to teletherapy. And of course that was not a major problem, except for one facility. The oncologist worked out of another town and they came over once or twice a week, and sometimes I couldn't quite understand how the authorized user reviewed the case on Monday when the patient was treated on Monday, when they didn't show up to the facility until Wednesday. But they said they have a computer system that sends data back and forth.

Prescription -- we would look for total dose, number of fractions, treatment site, prescription changes -- are they written and dated and signed.

Diagnostic referral -- this would not apply in

teletherapy.

Once again, instructions understood -- in our review of your program, if we saw these words, that you would follow 35.35(a)(4) or commit to Reg Guide 2.1, 2.2, we were finished with our review.

When we get out to the site team, personnel instructed on importance of accurate and clear records or requests, instructed to clarify unclear records or requests. We were looking for procedures, procedures that would describe what you would do if you don't understand the prescription or it's illegible or doesn't quite make sense, it's out of the ordinary, you've never done it before, such as hemi-body -- hemi-body teletherapy treatments are somewhat rare in some facilities. We wanted to make sure, if you've never done one before, who do you go to, who do you talk to, who do you get all the answers from.

Some of the things that we found in previous experience current practices -- we had in there "industry practices", it's not really an industry practice -- weekly chart checks. How do you determine that the patient had the proper setup, the fractionated doses are correct, the total dose is correct. And this is done by, in many cases, weekly chart checks by the dosimetrist, the physicist and/or the technologist.

When we got to individuals understand the current QA

program, if the authorized user described the program to us, the we talked to the physicist and everything the physicist said was basically the same as the authorized user, and when we talked to the technologist, it was still the same -- we marked that off as an excellent program, that everyone that was involved in the program totally understood how the program worked. Now if there was a discrepancy on what we were told by one, one or two discrepancies, it was marked as good. We had no fair -- everybody, I think, pretty well understood how the program ran.

Once again, we were looking for redundant patient identification procedures -- teletherapy, many cases for in-patients, we have review of the chart, the arm band. We many times have photographs of the patient, we have photographs of the tattoo area, we have verifications of the tattoos versus -- compared to the photographs. And so there were many redundancies. And once again, in teletherapy the patient is usually a patient that comes back and back and back and you see them many times, and after awhile the technologist knows them on a first name basis. So after about the third or fourth treatment, it's highly unlikely to get the patient mixed up unless you have two patients that look a lot alike.

We were looking for personnel instructed to terminate the medical use if a discrepancy is identified -- we were looking for procedures, and in many of the cases we didn't find

those procedures but everyone had a good understanding.

When it came to the treatment planning, we were looking for these areas -- full calibrations, beam modifying devices, does your procedure include these things, a complete calibration before the first use or after a source change.

Now to give you some statistics from the site visits -- I'll let you look that over. As you can see, we had a good sampling of hospitals, all the way from 150 beds up to 1000 beds. Workload in the diagnostic nuclear medicine program, 180 procedures per year all the way up to 7500. I might add that the facility that had 180, they also had a pharmaceutical therapy program that I think they said they do two a year -- two iodine therapies. They said when this happens, this is a big thing, everybody in the hospital knows about it and people want to come down and watch. And it's no big deal because, you know, they bring the patient in and hand them a little pill, give them the instructions and they go home. So it lost some of the excitement.

Now let me explain what you're looking at. We have 15 facilities, nuclear medicine, so therefore, you're not going to see anything above this line. Now the facilities that met the objective -- this line is your program evaluation. This is what you sent us to evaluate. We went through your program and if it met all the objectives, then you're right up here. The dark line is what we found at the time of the site evaluation.

So in this particular case, objective number one, you told us how you were going to handle this program -- I think that was on medical use indicated -- and when we went out to the site, this is what we found. Every one of the objectives were met -- every facility met that objective. In this particular case -- number two, I believe that was with a prescription for a diagnostic. There were several facilities that told us that they were going to use a prescription for the diagnostic nuclear medicine program; however, when we got out there, we didn't find that they were really using the true prescription, they were using a diagnostic referral form -- and all the way across. Number eight, that was the audit program. So you'll see this one always blank. And number three, this did not apply to pharmaceutical therapy. For brachytherapy and for teletherapy.

Now the interesting thing, you can see like in teletherapy, this was the information that was given to us to evaluate or else you didn't address it. However, when we went out to the site, we found that every one of the facilities met that particular objective. Objective number three did not apply in teletherapy.

Any questions?

(No response.)

MR. WIEDEMAN: Okay, thank you very much.

Later on, I'm going to pass out copies of your

program evaluation and site evaluation.

MR. TELFORD: Okay, the next item on the agenda will be the individual air time, in which you tell us about your experiences or any comments or conclusions you came to while you were trying out this proposed rule for 60 days. So that takes a little bit.

So prior to that, why don't we take a break for about ten minutes and come back around ten o'clock.

(A short recess was taken.)

MR. TELFORD: Let's go back on the record.

Dr. Kaplan has one announcement he would like to make, I guess it's in the form of a request.

MR. KAPLAN: Yes. This time, for reimbursements, it's absolutely necessary that we have only original receipts. So please don't send us copies, we need the originals. And if you need -- you should have gotten this in the mail, if you haven't gotten this form, just feel free to come up and ask me for one. Send it in as soon as we can, because if we can process your forms and your bills before the first of the year, we'll get it out very quickly. If it goes after the first of the year, it'll take more time.

Thanks.

MR. TELFORD: Okay. I notice that Mr. Wiedeman is passing out your checklists for both program reviews and site reviews, if you were one of the 18.

Let me just repeat a little bit of history for you. You'll recall that in our original sampling, we solicited participation from 24 NRC volunteers and 48 agreement state volunteers, and out of those, we randomly selected 18 for the site visits. And you'll recall when Mr. Wiedeman was showing you the map of the U.S. and how the volunteers are sort of geographically distributed across the country, you noticed a goodly number in the northeast and a goodly number in the central. That's because in the northeast, that's NRC's Region I and Region III is around Chicago, so that's sort of the central. And those two regions contain the vast majority of all NRC licensees. So that's why you see a lot of them there. We were sampling in proportion to those in a region or those in an agreement state. Likewise for agreement states, we have volunteers from New York, California, Texas, Florida -- well those five I want to mention, because those five states have a large number of licensees in each state. So that's why you see that.

Now I'm going to move to the point on the agenda, which is the 11:00 item, where it says "Volunteer's Summary of". Now you're the folks that tried out the proposed rule for 60 days and just to get started, before we start discussing the rule, proposed rule, objective-by-objective, we'd like to hear from you. We'd like to hear some comments, anything you want to say about your experience. Just tell us something about

your experience. You can include any comments on work or costs that you like, or whether one in particular gave you a lot of trouble, or anything you'd like to say.

And you can have about five minutes approximately each. We're in no rush here. Last time I started on the left, this time I'll start on the right.

David.

MR. GARRISON: I was reading, Mr. Chairman.

MR. TELFORD: Ah, you were reading your program -- your evaluation. You don't have to say anything, if you don't want to, or you can say just a few words, but you tried the proposed rule for 60 days. What do you want to say to us after you tried it -- you tried it, you liked it; you tried it, you hated it; you tried it, you think it's a waste of time -- anything you want to say.

MR. GARRISON: Okay. Yeah, I got a lot out of it. I think the majority of the stuff we were doing, we didn't have it written down. The technologists sort of were following it, but they weren't really tuned into it, it was just a day-to-day thing. I think once we got going on it, everybody just kind of -- I don't know if they were afraid because I told them we were probably going to have someone come in and inspect us, but they just seemed to be more aware of what their responsibilities were as far as knowing that we were doing the right patients, the right procedure. I think more questions were directed

toward our physician than before, that kind of thing.

I think basically it's a good idea. Like I say, it makes them aware that there's a program that they should be following. It's documented, it's written down and they're part of it, and that -- you know, it just makes them more aware. At least that's what we got out of it.

MR. TELFORD: Okay, good.

Tony.

LT. CMDR. PULCRANO: I met with a lot of mixed emotions about this thing. The nuclear medicine people had very, very little trouble accepting the rules basically as written. They only had a few questions, which I'm sure we can clear up. But they were able to make a few semantic changes to what they already had in writing, and pretty much, without skipping a beat, continue on with normal procedures.

Oncology, however, had some major problems with it, which I'm sure we'll get in and discuss later on. But I kind of got the feeling that the major problem here was "oh, my God, one more set of people to look over our shoulders. And there was a lot of gnashing of teeth about should the NRC really be looking at this.

Other than that, I got a lot of good cooperation out of everybody, I think overall we made it work.

MR. TELFORD: Good.

Sarah.

LT. KIRTLAND: I think my comments kind of reflect what Lt. Commander Pulcrano said. The feeling I had was that it was kind of like a honeymoon and now you have to -- now comes the marriage, and whether or not the Navy is particularly concerned about how it will be enforced when things actually get going. And the Navy is very sensitive to embarrassment and if there is any kind of penalty. It's true that would be a very motivating factor, but the Navy also considers itself a mature organization that is able to handle -- would rather handle it in-house, than have an outside organization come in.

But there's certainly no question about the need for standard operating procedures and the training of personnel, and w hat the program does I think has reflected what's actually going out in the industry or in the field. So we don't have any problem with that.

MR. TELFORD: Okay.

Tawfig.

MR. HAIDER: Well our therapy center is relatively new and we didn't really have a very good program, it was just borrowed from here and there, hodge-podge and all that. So this program has really gave us opportunity to look hard really at what we have and what we were lacking. And we found that we were lacking in some of the places. There were no errors but we just had a whole new program that we've written. I don't know, maybe without this, we wouldn't have looked into that. So

we got a lot out of it.

MR. TELFORD: Okay.

Santiago.

MR. GOMEZ: We are trying to improve because the quality assurance program for countries that the Joint Commission regulates. So many of those suggestions we are accomplishing, but we are trying to improve the instruction of the personnel. It seems to me that this is the best way of controlling and avoiding any misadministration.

MR. TELFORD: Okay.

Tom.

MR. CLARK: We found that some of the prescription requirements and things like that were a bit -- I don't know, they were in all cases not necessary. Many of these things we were already doing, but we aren't necessarily -- didn't have a written procedure, but a lot of it we felt like were common sense things that -- you never administer anything to anybody without first finding out who they are, just things like that.

Again, it helped our program as far as having our procedures written down. All of our techs are certified and fortunately we don't have any misadministration or anything like that, or haven't had one in two years. There's only myself and two other techs. Everybody makes a conscientious effort to see that things are done correctly.

Any time that you have any kind of question

whatsoever about what you're supposed to do -- we never do anything without checking with an authorized user first, in any case. And like I say, a lot of times that was not written down as a procedure, but with only three people involved, it's a lot easier to maintain a good quality working atmosphere and make sure everything is done correctly.

And as we go through these things piece-by-piece, I'll probably have some more comments.

MR. TELFORD: Good.

Roy.

MR. LANDERS: First let me say that in my estimation, the incremental work and cost involved in implementing this was small relative to what we're already doing. It was not trivial, but I would estimate somewhere in the neighborhood of eight to ten percent.

One of the things that I found onerous, that I knew I would, is having a second person required to quickly check what someone else has already done. That can cause a problem. another specific example is we have two physicians who will not always write down their prescription, sign it and date it. They have 15 to 20 years of experience of telling someone to write it down and they continue to do that sometimes.

Changes in prescriptions are not always written, signed and dated by the physicians. They are again related to people who do it.

Brachytheraphy requirement of a second independent person checking everything is particularly difficult sometimes for short, quick procedures. No deviations or errors were found because of this pilot study. Some were found and would have been found without it.

This applies to something we'll get into later on, but I think the biggest concern that the physicians voiced was the misadministration and reporting requirements.

MR. TELFORD: Okay.

MR. ARGAWAL: At the University of Virginia, we are committed to these QA rules, most of them we have been following, some even more than what we have here. So there was no problem in implementing these regulations.

We had some difficulty in some specific elements, which we will discuss later on, in brachytherapy or teletherapy, but overall we had no problem.

MR. TELFORD: Okay.

Jean.

MS. RHODES: Oh!

MR. TELFORD: These are not volunteers over here -- sorry.

MS. RHODES: We didn't have any problem at all in nuclear medicine. We're like the University of Virginia, we have had quality assurance programs in place. But really weren't yielding anything. It was just a paper exercise. In

nuclear medicine, they feel like this gives them a lot better information for other regulatory agencies.

Down in radiation therapy, we had somewhat of a different experience. They didn't much like the idea of anyone looking at what they did. They set up the program and they're monitoring now, but I can't say they're happy with it.

But it cost us no more than our previous program.

MR. TELFORD: Okay.

MR. DESAI: We basically meet all the criterias that we are discussing here at Hermann Hospital. We have been doing it, although I think this will increase some documentation that we had not been doing.

Our physicians are upset basically because of the prescription and the form of radio-isotopes that we use. Usually they know it, but they do not want to put it down on the prescription, saying that we want you to use sodium iodide. A lot of administration, we already discussed that. It's given IV or it's given PO, it's a general understanding -- they do not want to put that down on the prescription. I think it will increase some documentation of that kind.

Auditing was another issue and we all feel at Hermann that auditing should be done by the regulatory agencies and not by -- I mean it is going to create some problem for us getting an outsider to audit my department without paying any fees.

Management can do the auditing but the qualification

of the managers is questionable to the physicians. I think all the physicians in my department feel that the regulatory agencies should be doing the auditing and not the next door physicist come to my department and do the auditing.

Unintended deviations, that also would create some problems. It's a general understanding, like everybody else is saying, we all go to the authorized user and ask him why are you prescribing 30 millicuries of MDP when my protocol says 20 millicuries. He says the patient is too old or it's required by the medical history of the patient. So there is a deviation from what the set protocols are, and we do document after we administer the dose to the patient, that 30 millicuries is given to the patient, but the physicians do not want to do the documentation of the prescription at the time, so we discuss all these things. So I think documentation, creating extra documentation is going to create some problem for me at Hermann Hospital.

MR. TELFORD: Okay.

Tom.

MR. WHITE: My experience was quite similar to Lt. Commander Pulcrano, in that the people were quite cooperative with the program.

I find that the auditing is most time-consuming that helped me develop an appreciation for what NRC people have to do.

In the case of diagnostic quality assurance, we have a central pharmacy service that would prepare the unit dosage for our patients and the technologist is supposed to assay the dosage each time to see if there's agreement in the reading. And in my auditing, I found that the agreement was quite good. Occasionally the tech would be in a hurry and would fail to record the dose and they would tell me it's in the patient record. So I'd have to dig up the patient record and I did not find it. So I found that to be a problem.

Another interesting experience, particularly in radiation therapy, occasionally -- not frequently -- we have an initial dose check before we begin radiation therapy treatment. Sometimes the physician will give the verbal prescription and the technologist will have the calculation sheet to present to the dosimetrist or the physicist. And later on, it'll be found that the written prescription will be different. This does not happen often. So we have a policy now that we have to see the written prescription before we will check the initial calculation.

MR. TELFORD: Okay.

Lori.

MS. HANLEY: Overall we had no problems, none other than have already been discussed.

MR. TELFORD: Okay.

Jerry.

MR. MORRIS: I think we pretty well were able to abide by these guidelines. I guess brachytherapy was the weak point in getting a second check over the computer calculation. There was some question of what constitutes a prescription on brachytherapy. Is a consult a prescription.

MR. TELFORD: Okay, we'll go over that.

Stanley.

MR. GIPSON: Basically no problems with the program. Maybe I saw some areas where we needed to clarify a few procedures in our procedures manual or in our QA program. Our QA program is being reviewed, being developed over the past couple of years in radiology in general, and they're addressing some of the areas that we've spoken about with this pilot program as far as the patient -- procedural indications, verification of these indications by the user, by the technologist, who does what documentation of these indications. But basically a little housecleaning in our procedure manual and our QA manual to address these specific points that y'all have brought out I think is what we will spent more time with.

No major problems, no extra expense really pertaining to our existing QA program.

MR. TELFORD: All right.

Neil.

MR. CANADA: We didn't have very much trouble. There was only a few of us in the department, we only participated in

nuclear medicine. Most of it I felt like we were already doing, just you know, again like everybody said, not writing down, like when you check with the referring physician or, you know, the radiologist.

We basically didn't have any trouble even though we didn't do any I-131 therapies, I did create a prescription form for the radiologist to fill out when they administer the dose. And that was helpful so we have some documentation for them.

One of my main troubles was in getting a written referral from the out-patient physicians. During the first month, I only got about 30 percent of those, I was wanting one for each patient, and the second month that dropped off to 23 percent. We're used to being able to call up and talk to the receptionist and take the information that way.

MR. TELFORD: Okay.

Okay, let's move on to the next item on the agenda, which is a discussion of the proposed 35.35 in detail.

The first item we want to look at is what you see called a Purpose on your agenda, but the actual words that describe the purpose is in the first paragraph of the proposed regulation as it appeared in the Federal Register. Now we have copies of the proposed rule, reporting requirements and the Guide, if anybody needs them. So from here on, what you'll see on the screen will be sort of concise cryptic descriptors of those words. So if anybody needs that copy -- you may have

this left over from the pre-trial period workshop, but if you don't, we'll get you one.

Now the Purpose paragraph just says to each licensee that you shall have a written basic quality assurance program. It is a performance-based requirement in that this is -- there are only a few prescriptive requirements, like you must have a QA program. It's to detect errors, prevent errors and correct the cause if you have errors in medical use. And its objective is to prevent errors.

So by the item on your agenda, it says -- it asks the question "Do you want to delete, modify or retain" these pieces. So I want to entertain suggestions on whether you'd like to delete, modify or retain.

Now this is going to be a little bit for you to get used to here, but if you would like to make some suggestions for modifications, just speak up. If there are none, I'll move along, but I want you to understand that we're here to listen to your suggestions. So if there are some words, particularly in that paragraph, that you would like to improve on, then I'd like to hear it.

MR. MORRIS: My impression is that it really doesn't leave much room to write a QA program, it seems to be pretty rigidly spelled out as to what is going to be required.

MR. TELFORD: You mean in total?

MR. MORRIS: Yes.

MR. TELFORD: Okay, let's -- the first paragraph, yes. The first paragraph that you see just says -- it's a fairly rigid requirement, you should have a QA program.

Now by performance-based rule, what we really mean is that we don't want to dictate to you what the program shall consist of. What follows of course are the eight objectives. Now by listing all of those, that may give you the impression that that doesn't leave much room for negotiation or wiggle. But we wrote these eight things down as the eight good things to do because it sort of follows the straight-forward approach that if you have a written directive from the authorized user, then these are the intermediate steps that will occur on the way to administering the byproduct material. But these eight that we'll talk about in detail are not prescriptive. You can do these any way you like, or in fact you could propose a QA program that you thought was just as good, that met the intent of the first paragraph and maybe you didn't address these specifically. But these are meant to be the eight good things to do, they're not meant to be eight prescriptive requirements. So that the only part that you could really call prescriptive would be the first paragraph. And perhaps the third paragraph for audit, but we'll get to that.

Does that help at all, or --

MR. MORRIS: Well I don't know, I'm thinking about all these steps in say, teletherapy or brachytherapy.

MR. TELFORD: Oh, you must be thinking about the Regulatory Guide.

MR. MORRIS: Yes. This is a different thing.

MR. TELFORD: Okay. Now the Regulatory Guide is there for your use. You see, we're kind of caught because if we go out with a regulation, then we don't want to hear the criticism that this is such a hard problem that we don't know how to solve it, so we just gave it to you -- that's not fair. So we said look, we'll write a Regulatory Guide, this is our best shot at it, it'll get improved I guarantee you before it goes final, but that's the guidance that we could help you with at this point in time. However, it's optional, you know. You may have the hospital that's the national center for excellence in teletherapy or brachytherapy. Our guide is certainly not going to tell you anything if that's the case. It's completely optional, so please don't look at the suggestions in the guide as requirements.

Now at other workshops, let's see -- I believe it was the workshop in Dallas, the pre-trial period workshop, there was a gentleman from Colorado that said he had a suspicion that his state -- and I believe it's an agreement state -- would use the guide as a prescriptive rule. So we said gee, we don't like the sound of that, we're going to see if we can beat that. What we're going to do is in the guide, we're going to list alternative ways to do everything and say you can do A or B or

C or D or whatever else you want to do that still meets the intent. So we're going to do our dead level best to make sure that the guide is not used by anybody as prescriptive requirements. But obviously something has to be done. If you look for these eight objectives in other programs, like the JCAHO or sort of "standard hospital programs", you'll probably find them, but that's just sort of by coincidence. We did these independently.

But I think I'm getting a little ahead of myself. Let's drop back to this first paragraph. For instance, it has the sentence in there that the objective is to provide high confidence that errors in medical use will be prevented. Do any of you have any inclination that you would like to quantify "confidence"?

MR. LANDERS: As long as y'all don't.

(Laughter.)

MR. TELFORD: Or is this qualitative approach sufficient for you?

MR. LANDERS: Let's leave some judgment in it.

MR. TELFORD: Okay. Anybody else?

MR. ARGAWAL: Why should we have high confidence, why not just confidence? I mean, what is the difference between the two?

MR. TELFORD: What's the difference between just confidence and high confidence?

MR. ARGAWAL: And high confidence. You are making a quantification rather than qualitative?

MR. TELFORD: No, I'm asking would you like us to replace a qualitative statement with a quantitative statement. That's a question open to you. I think it's sort of an obvious difference. If we just asked for confidence, it sort of begs the question of how much or what do you mean by confidence. If we say high confidence, it has the implication that, you know, it's up there someplace. It's not 100 percent but it's kind of up there. It's just a qualitative statement.

Sarah.

LT. KIRTLAND: Well I know one of the things that the Navy, in its nuclear program, in trying to implement the ALARA concept, is they look at errors kind of as a trend and what they want to see is a decrease. And that's been maybe the past 25 years, they've been doing that. And I would not like to see that.

MR. TELFORD: Okay.

LT. KIRTLAND: Because I think it can sometimes bring a mentality that -- I don't think you can achieve zero and some way you need to be able to tell what your base level should be.

MR. TELFORD: All right.

Tony, do you have anything you want to say?

LT. CMDR. PULCRANO: Well I know what I would like to say --

MR. TELFORD: Hey, I'll listen to you, go right ahead.

(Laughter.)

LT. CMDR. PULCRANO: Remembering that, you know, as was already stated, you're not going to catch every error, it's just humanly impossible. I would just like to say provide assurance that most errors in medical use would be prevented.

MR. TELFORD: Okay.

LT. CMDR. PULCRANO: Just an assurance that, hey, you know, we're not going to forget about these things. We're going to work toward zero, realizing we're not going to get there.

MR. TELFORD: If I'm hearing you correctly, you're embodying the idea of minimization, but without saying that zero -- you're certainly saying that zero is not the target, but minimization of errors is. Okay.

Anybody else?

(No response.)

MR. TELFORD: All right, let's not dwell on that too long. Let's go to the first objective now. I'll refer you back to the agenda and show you where we are. Let's go through each objective. Let's take the first objective. What would you like to do with this objective, do you want to delete it, modify it, or retain it? If you don't find it useful, you'll tell me to delete it. If you think it's of value but you'd

like to improve it, tell me how to modify it. If you like it just like it is, you'll say retain it.

Now the spirit of this one is that we would like for somehow -- remembering this is one of the eight good things to do -- let's get the instruction to be given, the directive to be given, let's let it have some sort of a basis. Let's make sure that the authorized user who is on the license has made the judgment that this person ought to get byproduct material. Okay?

Now would you like to delete this?

MR. LANDERS: I would just like to say that I'm not aware of any case of it never being done. From that point of view, it's both a waste to have that requirement and easy to satisfy. So we could either delete it or retain it and it would make no difference.

MR. TELFORD: Because it's already being done, to the best of your knowledge. Okay.

Tom, would you like to delete that?

MR. WHITE: I believe we should retain that statement.

MR. TELFORD: Retain it, okay. Stanley?

MR. GIPSON: I think we should keep it.

MR. TELFORD: Keep it, okay.

Any modifications to it?

(No response.)

MR. TELFORD: No? Okay.

Let's go on to the second objective then. Now what the second objective is all about is to establish a directive -- this is for therapy. Number three is for diagnostics and number two is for therapy. So what this says is that one of the eight good things to do is to have a prescription. Now recall that prescription is defined in the hand-out. Now that's a written directive, it's signed and dated by an authorized user and it contains certain information content, depending upon whether it's for teletherapy, brachytherapy, radiopharmaceutical therapy. But number two captures radiopharmaceutical procedures that involve more than 30 microcuries of I-125 or I-131.

So the intent behind this is to say if we're going to do something, let's have a clear instruction to begin with, or else how do we know what to do.

Now would you like to delete this?

MR. GARRISON: We had a problem with that.

MR. TELFORD: All right.

MR. GARRISON: That one and the next one kind of went together.

MR. TELFORD: Well could we address them one at a time?

MR. GARRISON: Our physician didn't like the 30 microcuries.

MR. TELFORD: Okay.

MR. GARRISON: He didn't understand why we came up with 30 for therapy of I-131 -- 30 microcuries. He said it was next to impossible that anybody would do that.

MR. TELFORD: Okay, anything else?

(No response.)

MR. TELFORD: What would your physicians do with 30 microcuries, what would they tell us?

MR. GARRISON: I think any therapy involving I-131 --

MR. TELFORD: Any therapy dose of I-131?

MR. GARRISON: -- the prescription.

MR. TELFORD: Okay.

MR. GARRISON: He just -- 30 microcuries just didn't suit him.

MR. TELFORD: Okay, well let me agree with the sentiment that it ought to be a prescription of a therapy dose of I-131. But what's a therapy dose? How many microcuries or how many millicuries constitute a therapy dose? At what point does that start?

MR. ARGAWAL: It's in the millicurie range, 10 to 100.

MR. TELFORD: Ten millicuries?

MR. ARGAWAL: Yes, in a therapy dose.

MR. TELFORD: In a therapy dose.

MR. CLARK: For a whole body iodine scan diagnostic

we use five millicuries. That's what we consider a diagnostic dose. As he stated, this 30 microcuries, I don't know -- where did that come from?

MR. TELFORD: Oh, okay --

MR. CLARK: That's weird.

MR. TELFORD: -- you'll recall that at the pre-trail period workshop, I told you that I was going to be the only one to say these were any good? I don't mean to defend the 30 microcuries, but I can certainly tell you our thinking.

What we see when we look at the mistakes that have been made is that people have a tendency -- I should say the mistakes involve the micro to millicurie switch. So if we ask ourself, could we pick a level, a microcurie level, such that if the switch were made, the mistake wouldn't be too terrible. That's one side of it. The other side is that could we pick this level such that below that level, almost all of the diagnostic procedures would be conducted at a dose less than that.

Now 30, maybe it doesn't do that, maybe it ought to be lower, if that's our intention. If you're going to worry about a micro to milli switch, maybe it ought to be ten. But if you pick it at ten microcuries, then there's probably a lot of diagnostic tests that get done at above ten. So it's somewhat of a dilemma but that's what we were trying to do.

MR. CLARK: You're saying substituting accidentally

30 millicuries for 30 microcuries?

MR. TELFORD: Sounds crazy, right?

MR. CLARK: Yeah.

MR. TELFORD: Well I could tell you about a lot of cases where exactly that was done. But --

MR. CLARK: Our main problem for that particular item right there is Hippuran studies, which you said that does not apply to Hippuran.

MR. TELFORD: Well we said in the pre-trial period workshop, almost all the workshops, we did discuss Hippuran procedures and we said do whatever you're currently doing and say that in the QA program. Now what Mr. Wiedeman said was when they went to these 18 sites, they weren't going to hold anybody's feet to the fire over the fact that they didn't write a prescription for number two, because that's the way we discussed it at the pre-trial period workshop.

So now a good question to ask here is what are we going to do with the final rule. We will probably not do a number two objective for Hippuran because it has a different chemical -- it's a different chemical compound and not taken up by the thyroid as preferentially as I-131. Correct?

So let me take your suggest as for number two you would like it to apply just to therapy and somehow define a therapy dose, and it's probably in the millicurie range, is what you're telling me. That's the way that you would like to

modify number two.

What else would you like to do to it?

MR. LANDERS: I would like to see it lightened up a little bit, in that I foresee many, many cases where the physicians are going to have to come back and write down "this was an emergency".

MR. TELFORD: Okay.

MR. LANDERS: And we had to start this before I wrote down, signed and dated the dose prescription.

MR. TELFORD: All right. Are you thinking of teletherapy?

MR. LANDERS: Yes. Brachytherapy generally not, and radiopharmaceuticals generally not. Teletherapy in particular. Part of the problem here is I see the agreement states applying this to x-rays, and when you bring medical accelerators in, you've got a huge patient load. And frequently things are clearly understood and done on the basis without the physician writing down the prescription ahead of time. And in order to require it, I can think of a quadruple handful of cases where it would cost an additional 30 minutes waiting for the physician to write that down.

MR. TELFORD: All right. When we get to the Regulatory Guide, we will probably come up with a term something like a preplan, particularly for brachytherapy. Now if we introduce that concept for either brachytherapy or

teletherapy such that it makes it a little bit easier prior to the first treatment in teletherapy, first fraction dose -- maybe that's what you're looking for, because once you start into a regime of 20 or 25 fractions, everything is set unless the patient doesn't tolerate the dosage, in which case you may terminate or alter. So for now could we just say that we have some sort of directive, a written directive, for teletherapy prior to beginning.

MR. LANDERS: Written by the physician?

MR. TELFORD: Well this is authorized user. I make that distinction so that we can talk about a referring physician when we get to number three.

MR. LANDERS: I don't have a problem with it myself, I think it's a pretty good idea to have written down what you're going to do before you do it.

MR. TELFORD: Yeah.

MR. LANDERS: But I see a large number of cases of inspections in the future, of them saying have you started a patient without have the prescription written down, and me either have to lie or say yes.

MR. TELFORD: Okay. How could we make that easier on you but yet have a written directive to begin with?

(Laughter.)

MR. LANDERS: That's the problem.

MR. TELFORD: Well what actually happens then? Is

there an oral directive?

MR. LANDERS: Yes.

MR. TELFORD: Okay, is it from the authorized user to the technologist, it's a direct communication where the authorized user says start Mrs. Jones at 250 first dose and I'll write it up later?

MR. LANDERS: Or 3012, one to one -- whatever, but a prescription is given orally.

MR. TELFORD: Okay.

MR. LANDERS: You say why can't the physician sit down and write this -- well sometimes they're back in the film viewing room and that's where they do it, you don't have everything with you.

MR. TELFORD: Well let me see, the definition just says it's dated and signed by the authorized user. So somebody else could actually write it.

MR. LANDERS: Correct.

MR. TELFORD: Isn't that an okay idea, that somebody else could write it and all the authorized user would have to say is I agree with this, I'll sign my name; therefore, the technologist --

MR. WIEDEMAN: Of course, it says if this is an emergency, you just go ahead and give them the treatment but you get it written and signed within 24 hours.

MR. LANDERS: Right, but I'm thinking about the large

number of non-emergency cases when it occurs. That would help I think, if it could be written by someone other than the authorized user and then dated and signed by the authorized user on a small piece of paper and attached to the chart -- that would be helpful.

MR. TELFORD: That would make it easier, okay, good.

MR. LANDERS: So as long as it doesn't have to be in the authorized user's handwriting --

MR. WIEDEMAN: Sure. And in the site visits, we found a case in a couple of places where the technologist would make out the prescription because the authorized user said hey, I want to start Mrs. Jones right now at 200 centigrade, she would write it up 200 centigrade, Mrs. Jones, and after that's made out, she would take it in, he would sign it and it would go into the chart, and then he would fill out the whole prescription at a later date.

MR. TELFORD: That's a pretty good idea because if I'm the technologist or the radiation physicist or something and I write it out, I pretty well know what it says, if I wrote it -- and get the authorized user to agree to it by signing it.

Tom.

MR. WHITE: What happens if he tell her the prescription with something like 200 centigrade and then he writes 180 or something like that? What happens --

MR. LANDERS: I'm sorry?

MR. WHITE: What happens if he orders 200 centigrade but writes 180, after the delivery is done?

MR. TELFORD: Oh, he's saying what if the patient gets a dose but the authorized user writes a different number after the dose is already delivered. The guy has created a problem for himself.

MR. HAIDER: Make it up the second day.

MR. TELFORD: Pardon me?

MR. HAIDER: Make it up the second day of treatment. I say we put a time limit of 24 hours that the physician needs to write it down. That'll take care of it.

MR. TELFORD: So you say all corrections or adjustments --

MR. HAIDER: Yeah, within 24 hours, whatever needs to be done.

MR. TELFORD: All right.

MR. HAIDER: The physician should be able to do it -- he may not be able to do it right at that time, but he can do it at night.

MR. TELFORD: Okay.

Stan, any suggestions on number two?

MR. GIPSON: This is therapy, right?

MR. TELFORD: Just therapy, this is only therapy.

MR. GIPSON: I just agree with what has been mentioned as far as looking at that as far as the physician

calling a nurse about an order, you know, a phone order, get a certain procedure where the technologist, physicist or whoever could write the prescription like has been mentioned on the user's phone order or communication, however, and he'll check it and initial or sign it, whatever, at a later date.

MR. TELFORD: Oh, at a later date, not prior to the first dose.

MR. GIPSON: Right. You want it prior.

MR. TELFORD: Okay. Any comments on number two?

MR. DESAI: Yeah, I think we have a problem with (D), if you want to continue having (D), because a lot of procedures that I do using 100 microcuries of I-125, that is more than 30 microcuries. You of course discussed about total body bone scan with I-131 with ten millicuries.

So if you are continuing to have (D), do you want to add "physician's referral" -- with prescription of physician's referral for radiopharmaceutical procedure with more than 30 microcuries of I-125 or I-131.

MR. TELFORD: Okay, so you would sort of second the motion that (D) be amended or modified to address therapy doses.

MR. DESAI: That is correct.

MR. TELFORD: Okay. Any suggestions on teletherapy or brachytherapy or radiopharmaceutical therapy in the concept of having a written directive prior to?

MR. DESAI: When we catch the physician before we do that -- I mean, we always make sure that he signs it, what he says. We write it down, but we make sure that before we give it to the patient, the physician signs it with the number, so we don't have any problem with that.

MR. TELFORD: Okay. Darrel.

MR. WIEDEMAN: John, I'd like to ask Ashok, how would we handle the situation where we're doing a diagnostic procedure, however we're using iodine in a therapeutic range, any therapeutic range, such as a metastatic scan of the thyroid, five millicuries I think is what was said. Shouldn't that be included in there? Wouldn't you want a prescription to know exactly what the physician wants, the dose, the procedure spelled out?

MR. DESAI: I think if we have a referral from the referring physician that this patient has a total thyroidectomy or he's looking for metastasis, then we already have a protocol to that effect, that we want to use five to ten millicuries of iodine. So I think we need to add "either a prescription for diagnostic exams or a physician's referral". That should suffice, just like number three, it says "either a diagnostic referral or prescription."

MR. WIEDEMAN: And you're saying the diagnostic referral would be more than adequate --

MR. DESAI: For diagnostic use, yes. I'll give you

an example. When I get a patient from an endocrinologist who already knows clinically the patient has advanced disease and the patient may get five to ten millicuries of I-131 therapeutic dose, in those cases, the radiologist is going to find out whether the patient has a nodular or uniform gland. In those cases instead of giving five microcuries of I-131 for uptake, we give 50 to 100 microcuries of I-131, so we can also take a picture of the thyroid gland to rule out whether it is nodular or non-nodular gland.

So I think that it is well justified by referring physicians to say that the patients may need a therapy and the radiologist says we'll give 100 microcuries of I-131. That's still a diagnostic dose and not a therapeutic dose.

MR. TELFORD: Okay, good point.

I just want to say that we're here to hear your ideas and if you have a rationale like you just stated, that's exactly what we want to hear because in my opinion, it's the rationale that's going to carry the day.

Let's move on to number three, that seems to be quite interesting to most of you. This is for diagnostics of course. You'll recall that the diagnostic referral -- now this says "or prescription" in parenthesis because you can always do that. So let's look past that. It says "diagnostic referral", now that's defined in the Federal Register notice as a written directive signed by a physician, meaning a referring physician,

meaning typically not a nuclear physician and not an authorized user, but typically for -- probably the hardest case to handle is out-patients. So you have a general practitioner in town that sends a patient to the nuclear medicine department via referral. Now as we said in the pre-trial period workshop, we thought the ideal case was a written referral. And we were told by almost all the volunteers with the exception of the military and the VA folks, that most of your patients were referred to you by telephone.

So what would you like to do with this objective? How would you like to modify it, or would you like to delete it?

MR. ARGAWAL: Can you think of any procedure done without a diagnostic referral? So what's the need of it?

MR. TELFORD: Okay. Let me say what the intent -- in many departments -- in many nuclear medicine departments, the receptionist or the nurse for the referring physician calls the receptionist or sometimes the technologist for the nuclear medicine department, and they say I'm going to send Mrs. Jones over for a liver scan. The way that we envisioned that this would work was ideally the patient would arrive with a written directive that says written for this person, a couple pieces of information on this -- couple of items of information on the referral such that the patient can be redundantly identified, but it says "liver scan".

The technologist would, upon getting this patient -- because typically we're told the authorized user just doesn't review these cases -- that we created this need for a clinical procedures manual, such that the liver scan procedure is defined in the clinical procedures manual, which would be approved by the authorized user. Therefore, we have got the authorized user into this loop by that mechanism.

Now the technologist then says I know what the clinical procedures manual says for liver scan, this patient is to get a liver scan, that's what I'll do. So we're just making sure that a clear directive is established at the beginning.

So that's really the intent and that's the mechanism that we envision.

MR. DESAI: We have a problem with the diagnostic referral being dated and signed by the referring physicians. Since we get lots of out-patients, I think we need to change the definition of diagnostic referral by including the verbal referrals rather than dated and signed by the referring physicians.

MR. TELFORD: Okay, let's say that we amend that definition and we include a verbal communique. Now between which two parties should this referral, this oral communication, happen? In other words, would it be okay with you if it's the nurse from the referring physician calls the receptionist in the nuclear medicine department and then the

receptionist talks to the technologist or talks to the head tech and then the head tech talks to the tech that's actually going to do it? I mean, we've got second or maybe third-hand information. Would that be acceptable to you?

MR. DESAI: It is acceptable because we are looking at objective number one where we always interview those patients before we start any exams.

MR. TELFORD: Even diagnostics?

MR. DESAI: Even diagnostics, that is correct -- even diagnostics.

MR. TELFORD: Okay, so you're saying -- let me see if I follow you here -- you say we can have an oral referral and if a mistake has been made, then the authorized user, following objective number one, will look at this patient and they will know if this patient should get this scan, this diagnostic test first of all, and if they're going to do it, they would be able to direct it be done according to the clinical procedures manual or any modifications that might be needed. So that's one way you would --

MR. DESAI: That is how we do it.

MR. TELFORD: Okay. Well gee, that's good.

MR. GARRISON: I was under the impression that our individual QA program was going to be tailored to our individual hospital.

MR. TELFORD: Yes.

MR. GARRISON: At the last meeting, I didn't have any feeling at all that every patient, for a diagnostic referral, was going to be required to have a prescription. Are we saying now that --

MR. TELFORD: No, I'm not saying that.

MR. GARRISON: See --

MR. TELFORD: As a matter of fact, you're correct, at the pre-trial period workshop, what we said was these are the eight good things to do, you build your program to meet these objectives. Now if currently in your hospital or clinic that's -- however you do business, that's how you should say what you're going to do for referrals. Now if that included written referrals, okay.

Then I said to put into your QA plan under what conditions you would use oral referrals. So I opened it up for you to do business the way you're currently doing business, because the strategy there is that if it turned out that it was problem, it was the source of 90 percent of your problem, you'd find that out. If it's not a problem, or a small problem like one or two percent, you'd find that out.

So what I'm now saying is that this is what the idea was originally, was to have a written referral. And that's what we have proposed in the Federal Register. Now before we go write the final rule and give it to the Commission next March, how would you like to amend it.

You've tried your method, in essence, that meets these objectives, for 60 days. We have a suggestion that we modify the referral to say that it can be written but it also can be oral. Now there's two or three cases here that might be possibilities. One would be that it would be any oral directive between any two parties, as long as the authorized user looked at the patient prior to administering the byproduct material. Now that seems reasonable.

But I'm sure somebody is going to speak up in a minute and tell me that that doesn't happen at my place. I mean you've got a really good program -- that's great. But somebody is going to tell me that look, patients come to my nuclear medicine department and my authorized user is not there and the technologist handles this patient.

So for those cases, what kind of oral referral would you think to be sufficient to get a clear message across to the technologist so the technologist would have a clear directive to know what to do. Roy.

MR. LANDERS: Even though I'm mostly therapy, let me go ahead and put my two cents in.

I think staff to staff, office staff to office staff, written on both ends. And I think in particular of a case where a radiation oncologist is away from the office, away from the patient concerned, receives information over the telephone from other physicians, wants to order a diagnostic test. The

physician who is overseeing the license where the diagnostic test is to be done is in a different city. I don't see how the authorized users -- I mean, it's not an emergency, but I don't see how the authorized users can be writing, signing and dating things before this test needs to be done. The only applicable way I think to do that would be for office staff to office staff.

MR. TELFORD: Okay. The suggestion was made that instead of -- or as an alternative to a written referral signed by the referring physician, you could have an oral referral provided you had your authorized user -- that it was that standard practice in that hospital to get involved in the loop.

MR. LANDERS: I don't see that.

MR. TELFORD: You don't see that happening in any hospitals you know about.

MR. LANDERS: No.

MR. TELFORD: But you said signed on both ends, signed by the referral and signed in at the nuclear medicine department. Now is that signed prior to, by the referring physician?

MR. LANDERS: No, I'm thinking in particular, a physician phones his office, has his office phone a patient, send them for a diagnostic procedure.

MR. TELFORD: Yeah.

MR. LANDERS: When they get there, they've never had

contact with anybody, they don't have written anything.

MR. TELFORD: Okay.

MR. LANDERS: The office staff of the referring physician should write down --

MR. TELFORD: What they said on the phone?

MR. LANDERS: -- what they are doing on the phone and the office staff at the diagnostic facility should write down what they are receiving over the phone.

MR. TELFORD: Oh, this would be like a telephone log at both ends.

MR. LANDERS: In essence.

MR. TELFORD: In essence, okay. And does the referring send written confirmation to the diagnostic department later?

MR. LANDERS: No.

MR. TELFORD: Just keep that log. Tom?

MR. CLARK: The way we're doing it is we have a physician/surgeon, that he has his patients call us and say it's time for my yearly bone scan. We accept that. I mean she shows up, we know she's Dr. Conner's patient, we do bone scans sequentially every year on her. You know, that's -- I can't see the confusion there. We know this lady's got breast cancer and she gets a yearly bone scan.

MR. TELFORD: Okay. What would you do if a patient showed up that you didn't know?

MR. CLARK: Call the doctor. We would not do it without -- nobody shows up at our facility, just boom, I'm here for a bone scan. It does not happen.

MR. TELFORD: Okay, so then you would call the referring physician to confirm.

MR. CLARK: Absolutely.

MR. TELFORD: Do you make any written record of that, like Roy is suggesting?

MR. CLARK: Yes, sir, we have a patient log. We have 8:00, 9:00, 10:00, 11:00 set aside for bone scans. Eight o'clock bone, they called Mr. Jones for CA of the prostate, we need a bone scan. He may or he may not present with a written order for that. A lady's kid was playing with the thing and it blew out the window on the way -- what do we do if we're required to have a written? Is she going to have to go back and get one? Do we refuse to do it?

MR. TELFORD: Okay.

MR. CLARK: There's a lot of problems t here.

MR. TELFORD: Okay, so you make a telephone call to the referring physician. Do you talk to the nurse, the receptionist or the referring physician?

MR. CLARK: Depends on what the problem is.

MR. TELFORD: Whatever the need is.

MR. CLARK: Yes.

MR. TELFORD: Okay.

MR. CLARK: It's standard procedure for us that it's the physician's nurse that generally calls us and says he's got Mrs. Jones, she needs a bone scan, she's got pain in her shoulder. Does she have any history of any injury? Does she have any history of metastatic disease, cancer or anything like that? We question them at the time that we get that phone call, we write that in the log, you know, everything that's pertinent to her case, at that time. And if somebody -- if they do not have -- well he didn't write down what he wants this for -- well then you're going to have to call me back because our doctors will not -- I mean we can't just say this lady showed up. Our radiologist will look at us like we're crazy.

MR. TELFORD: Okay.

MR. CLARK: We have to justify it to them when we take in there for them to do the interpretation.

MR. TELFORD: Okay, if I'm understanding what you're telling me then, you would probably suggest that as an alternative to a written referral, that we allow oral referrals provided they're verified by telephone and a telephone log is kept of what was actually requested from the office of the referring physician.

MR. CLARK: And we do our own scheduling, there is no receptionist involved. There are only the three technologist, we are responsible for doing our own out-patient schedule.

MR. TELFORD: So it's a direct communique from that office to the technologist that's actually going to handle the patient.

MR. CLARK: Absolutely. Or sometimes it's just the patient themselves that will call.

MR. TELFORD: Because it's sort of a standing order.

MR. CLARK: Yes.

MR. TELFORD: Okay.

MR. WHITE: What happens if the patient comes in ten months instead of one year? Do you have a way of checking that?

MR. CLARK: I'm sorry?

MR. WHITE: What happens if the patient comes back in ten months instead of 12 months?

MR. CLARK: If she's gone to the doctor and says Dr. Conners examined me and he's determined I need another bone scan, I'm having pain in my ribs or back or whatever, then we accept that also. Now if they just call and say I'm having pain, I think I need another bone scan, of course no, we don't do that. But have you seen Dr. Conner? Yes, and he told me to call you.

MR. TELFORD: Let's see, Darrel had his hand up there.

MR. WIEDEMAN: Let me describe two situations I ran into during the site visits. The cardiology clinic down in

Bradenton, Florida, they have a lot of walk-in patients. A patient shows up in the mornings. Mrs. Jones says my doctor sent me over here to get some kind of a scan. They have no phone call from the referring physician. Normally their procedures call for the technologist to get on the phone and call the referring physician's office and verify, either through the doctor or the doctor's staff -- a nurse or whatever -- that Mrs. Jones is here, what kind of a scan do you want, what are we looking for. And once they have that information, they enter it in a little slip, "contacted Dr. Smith regarding Mrs. Jones, the nurse said they want a thallium scan". Then if there was any question of what was really needed, they had their authorized users there to go right to the cardiologist and say this is what we have. And he would either approve it or disapprove it.

At Madigan Army Medical Center, the two authorized users would have a staff meeting at 7:00 with the radiopharmacist and the technologist. They'd go over the requisitions for each day and look at t he clinical indication. To give you an example, they had one where the referring physician had ordered a bone scan and on the diagnostic referral slip it said something about migraine headaches. They were trying to figure out why do we want a bone scan when the diagnosis is migraines. So in that case, the authorized user would assign that to a technologist to follow up, get ahold of

the referring physician, find out what does he really want, what are we trying to rule out. And that was just another example of how it's handled.

And when it came to out-patients that just show up, they would always contact the referring physician's office and discuss the case with them and document it. It wasn't a real big problem that I could see.

MR. LANDERS: But it wasn't written by the physician?

MR. WIEDEMAN: No.

MR. TELFORD: Okay, we had a hand over here. Tony.

LT. CMDR. PULCRANO: Well I'm beginning to believe that my situation is kind of unique because during normal working hours, okay? Between like 7:00 in the morning and 4:00 p.m. in the afternoon, we have at least one physician in nuclear medicine. He's the authorized user, he's there, that's his job. Anything that comes into the clinic, to the nuclear medicine clinic, has -- if it's routine -- has a consult from the referring physician.

MR. TELFORD: This is a written consult?

LT. CMDR. PULCRANO: A written consult. Based on the written consult, the receptionist or one of the technicians can put that person on the schedule. Before that person gets the particular scan or whatever the procedure may be, it's going to be reviewed by one of the two doctors. Okay. And they will write down somewhere on the form that the patient is required

to fill out -- and part of that form states "we're going to do a bone scan", Tech blah-blah-blah and he signs and dates it. The patient comes in, it gets done.

The only time we would run into a problem in nuclear medicine on diagnostics would be after hours. We have on call a duty tech. If the tech gets a call from a doctor and he says I've got to have this tonight.

MR. TELFORD: Lung scan.

LT. CMDR. PULCRANO: Lung scan -- tonight, got to have it. Fine. He puts in a call -- or this is what we would like to have. He puts in a call to the doctor and says "Dr. So and So just called me and says he wants to have a lung scan because this patient is having this problem. Can I go ahead and do it?"

MR. TELFORD: Who is he talking to on the phone?

LT. CMDR. PULCRANO: He's talking to the authorized user.

MR. TELFORD: Okay.

LT. CMDR. PULCRANO: And I think by the nature of the beast, you almost have to do that because number one says you're going to ensure it's indicate. Number two, you have a piece of paper from the NRC that says this is how you're going to operate, this is the authorized user, he's responsible for these eight objectives. And if you're not going to consult him, then you've taken somebody who's responsible out of the

chain.

MR. TELFORD: Okay.

MR. CLARK: Well if these orders are written, are we supposed to maintain those?

MR. TELFORD: The records of the referrals? Yes.

MR. CLARK: For that 60 day period, I had a stack of them this high (indicating).

MR. TELFORD: Okay. You do a lot of patients.

MR. CLARK: Yes, sir, we do 480 procedures a month and probably at least half of those are out-patients and in some cases more.

MR. TELFORD: Okay, we'll get to records when we get to 35.33. There's two items to come.

MR. CLARK: That's just another thing as far as you know, what do you do if you have to maintain that record, if this person shows up without one. We need to clarify that point. How can you prove a year from now that this patient had a written referral?

MR. TELFORD: Okay, let me save that question until we get to the discussion on 35.33.

Would anybody else like to -- who runs a nuclear medicine department -- Neil?

MR. CANADA: Our doctors, like I said, send referrals, half the time they don't get there with them. That's the trouble that I run into. They've already called

ahead most of the time and it's already documented in the daily log by the receptionist, and we have all that and we recheck it again with the patient before the procedure is done. You know, like we're already doing number one again, when they're sent over.

MR. TELFORD: So if I'm --

MR. CANADA: The way it's worded there, we couldn't meet that.

MR. TELFORD: Which one?

MR. CANADA: Number three, the way it's worded.

MR. TELFORD: Because of a written referral.

MR. CANADA: Written referral.

MR. TELFORD: Okay, but you said if you don't -- if you get a patient without a written referral, then you call the referring physician prior to.

MR. CANADA: Well no, usually they've already called ahead and it's written in the daily log book.

MR. TELFORD: All right.

MR. CANADA: You know, the patient's name, what they're to have, the history and so forth.

MR. TELFORD: Okay.

MR. CANADA: And what about, like in-patients? Usually the doctor will write just "bone scan" on there and sign it, you know.

MR. TELFORD: On the chart?

MR. CANADA: On the chart. And in here it says referral, you want a history and everything.

MR. TELFORD: You're skipping ahead to the Reg Guide, I think.

MR. CANADA: Well I was just defining diagnostic referral.

MR. TELFORD: Oh, you're looking at the definition of diagnostic referral.

MR. CANADA: You know, if they order a bone scan, do you want them also to put beside that why they want it?

MR. CLARK: Most of the time it's already in the chart --

MR. CANADA: I mean, it's already in the chart somewhere.

MR. CLARK: Yeah. You know, if you look on there and it says "bone scan", generally we look to see what kind of problem he's having. If the patient has a osteomyelitis, then you need to know that before you inject the patient if you're going to do a three phase, you know, or if he's got back pain, is it metastatic or is it just lumbar strain or whatever.

MR. TELFORD: Okay.

MR. CLARK: Normally you've got in that chart somewhere that will tell you what kind of problem he's got. We take that to mean that is the diagnostic clinical information as to why you're doing this thing.

MR. TELFORD: Darrel, would that satisfy our definition?

MR. WIEDEMAN: Yes, and that's what we found in probably 99 percent of the cases with in-patients, the referring physician would enter in the patient's chart "bone scan", somewhere in that chart also will give a diagnosis or indication and the diagnostic referral slip, if that's what we're going to call it, or requisition, whatever we want to call it, is just a transfer of that data to the nuclear medicine department.

MR. TELFORD: Okay.

MR. GOMEZ: Instead of using the telephone, can you send a fax?

MR. TELFORD: Fax -- that's written. I think if you send a fax of the written referral, that's the written referral, that ought to do.

LT. CMDR. PULCRANO: I think if we can just get verbal referral and at least get the scan started so that the authorized user is --

MR. TELFORD: In the loop, okay.

Lori, you have a nuclear medicine department, what do you think?

MS. HANLEY: No, we don't.

MR. TELFORD: Huh?

MS. HANLEY: We have no nuclear medicine.

MR. TELFORD: I mean you do diagnostics, right?

MS. HANLEY: No.

MR. TELFORD: You don't do diagnostics. Jean, do you do diagnostics?

MS. RHODES: Yes.

MR. TELFORD: What do you think about number three?

MS. RHODES: Well as you know, I'm the messenger, the people at the hospital didn't have any problem with it at all.

MR. TELFORD: All right.

MR. CLARK: Let me say one thing. We have never -- I've been there 16 years, we've never done the wrong study on an out-patient.

MR. TELFORD: Great.

MR. CLARK: We've not had a problem with it, even though we've not had a written order. It's kind of confusing to say she's sent for a liver scan and we do a bone scan.

MR. TELFORD: All right, that's a good testimony.

MR. CLARK: Maybe it has happened, but not for us.

MR. TELFORD: All right.

MR. DESAI: What we do is when the receptionist gets a call from the referring physician's secretary or nurse, we do not schedule the patient if there is no brief history by that physician's nurse or agent or whoever -- if there is no history, we do not schedule those patients.

MR. CLARK: That's the same thing we do.

MR. DESAI: Right. If there is any problem. I mean if somebody is ordering a bone scan, if there is no clinical history to go along with a bone scan, we do not give a bone scan for headaches, for example. If the physician says the patient is having headaches, I want a brain scan, it's not going to get done. We do not schedule that patient on the schedule unless that referring physician calls the attending physicians and discusses why does he want a brain scan for headache.

MR. TELFORD: Okay.

MR. DESAI: Otherwise, we do not schedule those patients.

MR. TELFORD: Great.

MR. CLARK: We had a person scheduled for a bone scan of her shoulder because she had rotator cuff damage. I took that to the radiologist and I said you want to look at this. He said no, we're not going to do a bone scan on that patient. You know, it's just not done.

MR. TELFORD: Okay.

MR. CLARK: At our facility. It may be other places, someone else might do it for a rotator cuff damage.

MR. TELFORD: Let me say that I'm really impressed with what you're telling me on number three. I mean, we've already done two workshops, post-trial period, and I don't think I heard as many suggestions, very good ones, on number

three to date. So you're really doing very well.

However, there's one thing before I summarize what I'm hearing -- other places we heard well for diagnostics, these referrals can't be written because if we tell the referring physicians that we deal with that by golly you must have a written referral or we're not taking your patient, their fear is the patient will go someplace else -- you know, be sent someplace else. Is that credible?

MR. CLARK: Yes.

MR. TELFORD: Okay. Let me ask you a question then. What if everybody, what if all nuclear medicine departments had to have written referrals before they could take a patient? Is it still credible?

MR. LANDERS: If they all not only had to have them, but actually enforced that.

MR. TELFORD: Okay. Now let me summarize the good suggestions I've head about referrals for diagnostic cases.

First of all, I think you're telling me that we should have some alternatives in there. We should say you should have one of the following: A written referral dated and signed by the referring physician or secondly, you could have an oral referral provided that the authorized user in essence said yes prior to administering the byproduct material.

MR. CLARK: How are you going to verify later that he said yes?

MR. TELFORD: I guess we'll have to get the guy to initial something. He'll have to sign or initial something. You bring up a good point, but we'll have to have some sort of a check off.

Thirdly, we could have oral referrals that are direct communiques to the technologist handling the patient, provided the procedure said that if you have any -- oh, -- provided that you had a telephone log on both ends such that the procedure to be done was written in the log and a history of the patient is given with this oral referral, and any questions that are generated are resolved by a call by the technologist or the person handling the patient, to the referring physician's office. So one of those three, and you've given me the last two as being acceptable ways.

That's impressive because what if you change the definition of a referral to include all three, then would any of you have any problem? But equally important, would you really think that one of the three would be sufficient to get a clear message across? And I hope you say yes to that. Most of you are shaking your head yes. Okay.

Let's move on to number four.

MR. GARRISON: I have one more question.

MR. TELFORD: Yeah.

MR. GARRISON: How about 30 microcuries on that one?

MR. TELFORD: Oh. Well now this is just a reminder,

a note that if we have 30 microcuries here, this is a reminder that this might capture some things that some folks might think are called diagnostic studies when we wrote this such that this is a reminder that if you're going to use more, you've got to go back to number two. But if we write number two to be a therapy dose, then we won't even need that note.

MR. GARRISON: Yeah, because some places routinely give I-131 diagnostic CATs for thyroid scan.

MR. TELFORD: Yeah, it might be one or two to five millicuries. Okay.

MR. CLARK: I forgot a question I wanted to ask about that a few minutes ago on that 30 microcurie thing. If we've got a standard dosage sheet --

MR. TELFORD: Clinical procedures manual.

MR. CLARK: Yes.

MR. TELFORD: For diagnostic, okay.

MR. CLARK: Yes. If that's signed by our authorized user, can we interpret that as a prescription for a specific patient?

MR. TELFORD: I don't think so because --

MR. CLARK: It's a standard, recognized quantity, and you know, in each case you would use that particular dose for that particular study.

MR. TELFORD: Right.

MR. CLARK: It don't vary from that.

MR. TELFORD: Well that's a thought, but normally, or you know, almost logically, a prescription has to be written for a patient so that the authorized user or in the case of a referral, the referring physician says this patient, Mr. Smith, should get a liver scan.

Okay. Anything else on one, two or three before we move on to objective four?

(No response.)

MR. TELFORD: Okay. Now number four is all about understanding the message, that we have some sort of procedure for training or for testing or for making sure that the technologist or anybody that's part of the actual administration of byproduct material or any steps leading up to the administration of the byproduct material or radiation therefrom, understands what they're supposed to do. Now this could be -- you could say well we only employ certified technologists, we have training programs, or we do this or we do that. But let me throw it open, would you like to delete, modify or retain this objective?

MR. LANDERS: I don't understand how we are to ensure that all of the responsible people involved in carrying out a prescription understand it.

MR. TELFORD: Oh.

MR. LANDERS: This is per patient.

MR. TELFORD: We've broken this up into an A part and

a B part. A is the referral and the manual because they work together as I've described. B is the prescription. So you could almost take this, the intent of this, as saying the person involved, every person involved, understands what they're supposed to do. They understand the directive and the steps that they're supposed to take. So what's not clear here?

MR. LANDERS: My question then is do we ask every person involved in every prescription, carrying out of every prescription, to sign a document saying I understand what I am doing in this case?

MR. TELFORD: You can if you like, but this is just one of the eight good things to do. You may not want to do that, you may want to say I have annual training programs or I have this or I have that. But would you like to delete that, would you say it's no good, throw it away?

MR. CLARK: I think that understanding the prescription would be a condition for carrying on. You would not do any procedure unless you understood what it was you were supposed to do. For me, that would be a condition of going forward. If you didn't understand it -- I mean, occasionally people might make a mistake, but not consistently.

MR. TELFORD: Yeah, you might have a procedure that says if you don't understand it, you ask questions.

MR. CLARK: Which should be common sense, or understood.

MR. TELFORD: Okay.

MR. LANDERS: If that's what you're -- if that's the intent here, then I certainly agree with it. If this does not require some positive action for each prescription, then I agree with it. If it requires a positive action, then I think we should delete this.

MR. TELFORD: Okay.

LT. CMDR. PULCRANO: I was just agreeing with him.

MR. TELFORD: Agreeing with what statement?

LT. CMDR. PULCRANO: With, you know, if we're going to have to have positive action, we've got a big problem here.

MR. TELFORD: Right.

LT. CMDR. PULCRANO: Because we could just have questions all day long.

MR. TELFORD: Okay.

LT. CMDR. PULCRANO: If we don't need a positive action, then maybe we really don't need the statement.

MR. TELFORD: Recall that we reviewed everybody's programs, recall that we went to 18 sites. Now you may have forgotten what we told you this morning.

Darrel, what would you be looking for if you got to a site for a site visit -- what are you looking for in somebody's program or what would you go ask people, a technologist or something, such that you could assure yourself that number four was being satisfied?

MR. WIEDEMAN: I'd ask to see their diagnostic procedures manual and then make sure that they understand it. I also would look at what kind of a training program, when were they given this manual, do they have annual retraining such as a review, an annual review of the procedures manual where they have in-service training to go over the manual again and discuss the different procedures and clinical indications. One thing to remember, I believe the intent was to clarify the terminology used in nuclear medicine.

I'll give you an example. In one hospital, a metastatic scan means one thing where at another hospital it may mean something else. So what we want to make sure is if like you get a diagnostic referral for osteomyelitis scan. If you open up your manual, you don't find an osteomyelitis scan, of course you'd know it would be a bone scan -- well then what would you do, it's not in your manual. You go to the authorized user and say now this is what we have, it says osteomyelitis scan. At that time, I assume your authorized user would say well we want a bone scan on this patient. And the same thing with a metastatic scan or thyroid scan, what exactly is a thyroid scan; is it with technetium, is it with iodine. And so it would be spelled out in the procedures manual.

MR. TELFORD: So what you're saying is you would question the technologist as to what they would do with this

hypothetical case and if the response was that they would seek clarification with the authorized user, that was the correct response.

MR. WIEDEMAN: That's correct.

MR. TELFORD: You're not looking for a checklist where everybody had signed off and signed their name that in fact they understood what they were doing before they did every case.

MR. WIEDEMAN: Even though there were a couple of hospitals that had that.

MR. TELFORD: Wow.

MR. LANDERS: I agree with that concept. I'm just not absolutely positive that's what that says.

MR. TELFORD: How would you like it to say that?

MR. LANDERS: All I'm doing is criticizing, I'm not offering suggestions here.

(Laughter.)

MR. LANDERS: I'm offering from a weak position here.

MR. TELFORD: Well you can do whatever you want to do. If you want to criticize, that's fine.

Yes?

MR. ARGAWAL: I would like to suggest that not every procedure, but every person working in the nuclear medicine department should be asked to sign a statement that they understand the procedure manual. Not for each procedure but

they should be trained or monitored by the chief of the staff or somebody, chief technologist. Suppose a new person comes and you give that person to do the certain case and they didn't understand it. Then there are mistakes.

MR. TELFORD: Okay, if I'm understanding what you're saying, you're saying change the focus of this -- take the focus off of diagnostic referrals and prescriptions and put the focus on the technologists, the people working in the department, to make sure that training is adequate, make sure understanding is adequate, have some sort of a positive feedback for each person. Okay, sounds good.

MR. LANDERS: Can I go ahead and phrase mine in a different way? I would modify that by making number (B) say "If the prescription is not understood by any responsible person, that person shall obtain clarification before proceeding."

MR. TELFORD: Okay, thank you. Do we have a suggestion over here of how to modify it, or any comments? Do you want to throw this away -- delete this?

Jean?

MS. RHODES: No, I think we need that.

MR. TELFORD: You need that, okay.

MS. RHODES: There's something else we haven't talked about that one, when the tech can't read the handwriting.

MR. TELFORD: Yes.

MS. RHODES: You know, it would be a terrible thing if they just held it upside down and decided that was what it meant and went on.

MR. TELFORD: Very good point.

MS. RHODES: I think you need something in policy and procedures that tells them what to do when that happens.

MR. TELFORD: All right.

MR. CAMPER: We're getting so much good input on this one, I want to give you an example of something that happened in the real world, and see what your thoughts are.

A patient came in to have a diagnostic thyroid scan, the dosage for the scan at this particular facility was on the order of 50 to 100 microcuries of I-131. The technologist went to the procedures manual and found that the procedures manual said 4.5 millicuries. The technologist ordered the dose and administered 4.3 millicuries to the patient. Again, the dosage should have been 50 to 100 microcuries. Is there anything that any of you think could be done in this particular area to offset a problem like that?

MR. GIPSON: Fire the technologist.

MR. TELFORD: Stanley said fire the technologist.

MR. CAMPER: Is there some way to get at this in better detail via training, for example?

MR. TELFORD: David.

MR. GARRISON: We require a yearly review of the

manual before you get your pay raise.

MR. TELFORD: Before you get your pay raise.

MR. GARRISON: Before your yearly review, you're required to check off -- works real well.

MR. TELFORD: Okay.

MR. GARRISON: I think there should be -- each institution is going to be different, but personally I feel -- I think every year you should review the procedure manual, you know.

MR. TELFORD: Okay. Most of your colleagues are shaking their head yes.

Yes, Tawfig.

MR. HAIDER: I know we're worried about the procedure manual, but can we just say that if you don't understand, ask somebody who knows?

MR. TELFORD: Okay, so you're following Roy's --

MR. HAIDER: Instead of looking at the book and see what it says and what it don't say and saying well let's see, does this apply, no it doesn't apply, it goes with another one -- why don't we just ask somebody who knows.

MR. TELFORD: All right, so put in a statement that says if you don't understand, you must ask somebody like the authorized user.

MR. HAIDER: Right.

MR. TELFORD: Okay.

MR. LANDERS: And in that particular instance, that's a fairly significant one because there's a discrepancy between the prescribing -- almost the prescribing physician and the authorized user's written procedure. In a case like that, I think clarification should be obtained from the authorized user.

MR. CAMPER: Yeah, I think the real problem is -- and we've seen this in a couple of other cases, I've cited one, but there are times when there seems to be a lack of appreciation, if you will, between microcurie quantity and millicurie quantity of I-131. And to what degree can licensees or the NRC as a regulator agency approach this problem. We are about to prepare an information notice that will go out and will show licensees about six cases involving I-131 recently where misadministrations or incidents occurred, and we're going to academically revisit this idea of microcuries versus millicuries and the differential exposure and what-have-you. But it is disconcerting at times when you see some of the things that take place. There doesn't seem to be a good appreciation for microcurie versus millicurie quantities of I-131 and the fact that you can get into the threshold range at very low doses, depending upon the condition of the patient. That's the point for bringing it up and seeing if anyone has any input, because we were getting such good comments.

MR. TELFORD: Tony, you had a point?

MR. TSE: This was a good example and the reason we originally decided to use the 30 microcuries as a cutoff point is essentially to try and avoid those situations, because under the proposed regulation, anybody using 30 microcuries, which currently I understand you have a question on that one, but assume that's the case -- anybody that wants to use 30 microcuries, the technologist cannot go ahead unless he gets a prescription from his authorized user and thereby avoid the questions, the problems associated with the wrong doses to the patient, iodine doses.

MR. TELFORD: Darrel.

MR. WIEDEMAN: I just want to discuss that the prescription is understood by the responsible individuals. I would think that in radiation therapy -- this is teletherapy -- that would be very, very important because there's a lot of -- not a lot but quite a few facilities that treat benign diseases. The one that comes to mind was a case quite a few years back where the referring physician sent the patient over to the hospital with a prescription slip and it says "therapy to the right shoulder". The patient walked in the front of the hospital, said "where's the therapy department", and they directed him to the radiation therapy department and they treated him with I can't remember how many rads to the right shoulder for bursitis. And after about the fourth or fifth treatment, erythema developed, the authorized user contacted

the referring physician and said I've discontinued the radiation therapy on your patient because of the erythema and at that time he was informed that that patient should be over in physiotherapy, not radiation therapy. And so that was a case where the responsible individuals didn't quite understand the prescription. However, they said that this particular physician ordered bursitis therapy with radiation in quite a few cases when the typical medical treatment did not respond. And you know, there's cases where they use it for plantar warts and acne and so I would think that you would want to really understand the prescription and have the authorized user discuss it with the referring physician.

MR. TELFORD: All right. I think you've given us some good suggestions for four because basically you're telling us that we don't have to say make sure people understand, an alternate way is to say make sure people seek clarification from the authorized user if they don't understand, is equally good. I understand the logic of that, that's good rationale.

We're doing quite well on the schedule. As a matter of fact, we have already -- where are we -- distributed the program evaluations to you. Let me suggest that we break for lunch now so that if you have questions in your program evaluations, that we have either Mr. Wiedeman or Dr. Kaplan who can answer those questions for you, or you can, you know, discuss them during lunch. But we want to give you an

opportunity to ask those questions.

Now recall that Darrel said whatever you sent in was evaluated, and if your checklist said we needed more information to evaluate that, then please don't feel bad about that because this was not exactly a licensing procedure. If it had been a licensing procedure, we would have called and said we need more information on this, please send it. We would have iterated with you until we had everything we needed and the decision was made. So don't let any of that bother you. But if it says something about what you were doing -- if you were one of the site visits and if it said that you weren't doing something when you thought you were, then it may be to your benefit to go find out why we interpreted the fact -- why we thought that you weren't and you thought that you were, because it may help you later.

On the other hand, if you want to ask questions about the program review, like you said well I thought I addressed this in my program, why do you think you need more information. Well go ask it, please.

We have a hand-out for you that's completely on a different subject. It's not quality assurance of medical use, but recently the Commission has a policy statement they have issued on what's called Below Regulatory Concern amounts of byproduct material, and we just wanted to give you a hand-out, it's on the table back there, of a booklet on Below Regulatory

Concern as well as what appeared in the Federal Register. It proved to be very interesting to the volunteers at the very first workshop, so we thought we'd make that available to everyone who came.

So let's break for lunch and come back at 1:00.

(Whereupon, a luncheon recess was taken at 11:49 a.m., the meeting to resume at 1:00 p.m., the same day.)

AFTERNOON SESSION

MR. TELFORD: Okay, let's go back to work on the eight objectives. Before lunch, we got through the first four objectives and we'll continue through the last four.

I'm going to leave the first four objectives up on this screen and then I'm going to put the last four objectives over here, so you can see everything at once in case you want to refer back.

Let's pick up objective number five. This basically says that make sure the medical use is in accordance with either the referral in the manual or the prescription in the case of therapy. And my question to you is, would you like to delete this, modify it or retain it.

MR. ARGAWAL: I would say that just as a kind of a -- we have gone through that it has to be to a prescription. Now it is somebody else that is trying to ensure that you have followed the policy. And that's only -- once it has been done according to the prescription, I don't see any -- unless -- and there is a record keeping of that -- that there is another need of somebody ensuring that it has been done right.

MR. TELFORD: Well, let's see, for a diagnostic test, you would issue a report that says what was done and you would send that back to the referring physician So your report would say -- it would really confirm that the medical use for this diagnostic test was exactly what was described in your

manual. So you would have done that that way. So, therefore, what is your suggestion that we do?

MR. ARGAWAL: I do not understand the redundancy. The second person has to come once a month to ensure that that has been done or --

MR. TELFORD: Do you mean how do you do this?

MR. ARGAWAL: Yeah, how do you do that?

MR. TELFORD: Oh, no. You don't have to do that. The report that I described, that would do that.

MR. ARGAWAL: What is the intent of that, ensuring that the medical use is in accordance?

MR. TELFORD: Oh, the intent of this is to make sure that what was supposed to have been done was, in fact, done. And you do this all the time for the -- for diagnostic studies. You send a report to the referring physician. So you know if -- you're stating in the report what was actually done to the patient; therefore, you know instantly whether or not it was what you were supposed to do.

Darrel.

MR. WIEDEMAN: Usually, or in many cases, it's one and the same. The diagnostic referral is also the same slip the report is typed up on. So you not only have the diagnostic referral slip with all of the information, but you also have the report of the findings of that particular scan.

MR. ARGAWAL: The word ensure, what are you supposed

to do to ensure that it --

MR. TELFORD: Oh, recall -- recall that this is a performance-based group. These are the eight good things to do. So you can ensure however you want to, however you think is sufficient. Now what we've suggested is that for diagnostic cases, you have the report which demonstrates that this was done.

Any comments from over here?

MR. MORRIS: But is somebody keeping a record of how many of these were done? Who knows what was done --

MR. TELFORD: Okay.

MR. MORRIS: -- unless you've got them on file somewhere?

MR. TELFORD: No, it's not on there. It's next -- it's on tomorrow's agenda, I believe. We're going to discuss records and we're going to say what needs to be kept and et cetera. So, let's save the question on records for that session. This is just the concept that do we need some sort of procedural step that demonstrates what actually happened was what was supposed to happen. That's all that is.

Roy.

MR. LANDERS: I have trouble with the word "is". You're putting the word "was" in there.

MR. ARGAWAL: That means the same thing.

MR. TELFORD: Oh, you're thinking is about to be.

MR. LANDERS: Yes.

(Laughter.)

MR. TELFORD: Okay.

MR. LANDERS: We have just gone through understanding the prescription. Are you now suggesting that we carry out the prescription properly? Not that it was carried out properly or improperly.

MR. TELFORD: Well, you could look at this, I think, either way. I mean, you could say, you'll have a procedure -- in the case of the diagnostic clinical procedures manual, that probably is your procedure for making sure that what is about to happen will be in accordance with the directive, because the authorized user is really doing the directing here in the manual. So, if you look at "is" as if it said, is about to be, then the manual would do that for you. If you're looking at therapy under the prescription, then if you had a prescription for the teletherapy or if you had a brachytherapy pre-plan or pre-implant prescription, then that would make sure that -- would ensure that the medical use is about to in accordance with what was directed.

But you could also look at this as after the fact, in the past tense. You could look back to see what was actually administered to the patient. In teletherapy, you probably do this every day. You probably have a chart on your patients and it says 200 rads is the daily fraction and you enter how many

rads you gave today or something equivalent to that. So you keep track of that for that patient over the 20 or 25 or however many fractions they get.

So, that one chart would be your procedure for both instructing the teletherapist -- the technologist, I mean, to give that patient 200 rads and it would also be your record that shows that 200 rads was given. So, I mean, that's the simple intent.

I'm opening it up. You know, is this something you want to delete or is it something you want to modify or something you want to retain?

MR. LANDERS: I just need clarification on it, I guess. It appears to me as if -- the way I interpret that is that you need to check what you're going to do before you do it.

MR. TELFORD: No. If you have -- in number four, we basically said we want to make sure -- one way to look at this, the other way around, is that the technologist, or the person doing the work, knows their job. They know how to do it and what to do over here. That's one way to emphasize this. So if this person knows what they're about to do, if it's a diagnostic case, then here's their instructions of what to do in the manual. If it's therapy, then we have a prescription that says what the patient is supposed to get. I don't think there's any intent to ensure that a patient --ensure that a

person knows that they are going to do something before they actually do it. I mean, you could look at this in the past tense and that would be sufficient. You could have a procedure that records that there was -- that what was prescribed was actually administered -- records agreement, and you can satisfy number four.

MR. GOMEZ: So you change -- you're saying the medical use was in accordance...

MR. TELFORD: We could -- you know, if you wanted to say, rewrite this and put was in the place of is, if that makes you feel better and you understand it.

MR. GOMEZ: Why? Because if you say this is after you have made the diagnostic studies.

MR. TELFORD: Uh-huh.

MR. GOMEZ: I mean the report, before you can say something like that.

MR. TELFORD: Okay.

MR. GOMEZ: That the study was made in accordance with the prescription. Is that the purpose --

MR. TELFORD: That's one way of demonstrating that the administered -- or the administration was in accordance with what was prescribed or directed.

MR. LANDERS: Again, let me ask, is it possible here, in the case of teletherapy or therapy, what you mean is that a clear set of instructions for what to do for each treatment

procedure is available, how long to leave the unit on and such things as this?

M. TELFORD: That sounds like treatment planning to me under number eight.

Darrel.

MR. WIEDEMAN: Let me give some examples of how various different participants complied with this one. In the diagnostic procedures manual, many times they would have references of the clinical indications, such as -- let's take for instance a bone scan. The procedures manual would say bone scans are given to patients with the following diagnosis and they list, oh, eight or ten various different things that you would look for in a bone scan. It also lists the typical range for adult and pediatrics. When it came to prescriptions, basically that the referring physician, what he ordered was what was given and that would be done by the authorized user. You fill out a prescription outlining exactly what type of therapy he wants. Another example I can think of is -- let's assume that you got a diagnostic referral that said I-131 scan. The first thing the technologist is going to do is look in his procedures manual; there is no listing for I-131 scan. So, we want to make sure there is a procedure in place where you can go back and find out exactly what does the referring physician want and have the authorized user and the referring physician discuss it and decide what would be the appropriate test for

the patient.

MR. CLARK: At that point, my logic tells me that if I got an order like that, I would call the physician and ask him what he wanted.

MR. WIEDEMAN: That's another way of doing it.

MR. CLARK: You know, I wouldn't -- to me, that's just a logical course of action, instead of having to go to a procedure manual. I-131 can be for several different things. To get it right, you would have to ask the doctor that ordered it, in my mind.

MR. WIEDEMAN: Exactly.

MR. TELFORD: Well, that's a procedure that ensures it.

MR. WIEDEMAN: That's how you ensure it.

MR. TELFORD: Do you guys want to make this past tense?

MR. LANDERS: Yes -- but if we do, then perhaps it's covered later on by unintended deviations.

MR. TELFORD: Maybe not. Let's stick with number five for now.

Commander, what would you like to say about this?

LT. CMDR. PULCRANO: I still get the feeling that we're still tied up with what we said over here this morning and what we're saying over here in number five this afternoon.

MR. TELFORD: Okay.

LT. CMDR. PULCRANO: It seems to me like so far we've said the same thing. If we're saying the same thing, why are we saying it again?

MR. TELFORD: Okay.

LT. CMDR. PULCRANO: In other words, why go through all of this rigmarole to ensure that we're going to do it in accordance with a procedure or a prescription and then turn around and say ensure we're going to do it that way? You know, why go through this rigmarole and then say let's do it all over again? That's what it sounds like to me.

MR. TELFORD: Okay. As this one is written, it says make sure that the prescription is understood, the person knows what to do. And over here, this says, make sure that was done. So maybe to your way of thinking, you could combine these two and say it once.

LT. CMDR. PULCRANO: I would feel comfortable with it.

MR. TELFORD: You could say the prescription is understood and --

LT. CMDR. PULCRANO: And carried out.

MR. TELFORD: -- carried out.

David.

MR. GARRISON: Yeah, I agree with that.

MR. GOMEZ: You can say confirm that the medical use -- instead of ensure, just say confirm.

MR. TELFORD: Confirm.

Roy.

MR. LANDERS: I would agree you with that if you appended it to the end of four and just say carry it out.

MR. TELFORD: All right.

Tawfig.

MR. HAIDER: Yeah, I agree with that.

MR. TELFORD: All right. Okay, group, you've got to keep up your half over here. Come on. Jean.

MS. RHODES: I was looking at the plan that we did. We talked about two different things for number four. We talked about the workers knowing how to do things and being able to read the records. And then for number five, it was identifying the patient, confirming the dose by dose calibrator and documenting the pharmaceutical dose in the record.

MR. TELFORD: Okay. But would it make it any easier to combine the two, or have no effect on you?

MS. RHODES: To us, it would have no effect.

MR. TELFORD: Okay.

MR. DESAI: I think it would be easier to combine four and five.

MR. TELFORD: Okay.

Tom, do you agree to?

MR. WHITE: Combine.

MR. TELFORD: Combine.

Lori.

MS. HANLEY: To combine.

MR. TELFORD: All right.

Jerry.

MR. MORRIS: No opinion.

MR. TELFORD: It doesn't matter. You'll do it either way, right?

MR. MORRIS: Yes.

MR. TELFORD: All right. Stanley.

MR. GIPSON: I like combining them.

MR. TELFORD: Neil. Any other comments on five?

(No response.)

MR. TELFORD: Okay, let's go to six. Six is about identifying the patient. Now what we really should -- I should confess to you that we will probably modify this to say redundantly identify the patient. We're really looking for two different ways to identify the patient. So let me confess that and then as you if you would like to delete, modify or retain.

Tom.

MR. WHITE: I agree with the modification for redundancy.

MR. TELFORD: All right. Jean.

MS. RHODES: I don't think you can ask someone too many questions.

MR. TELFORD: All right. At least twice, okay.

MS. RHODES: Well I'm a nurse, and when you give medicines, you check five times.

MR. TELFORD: All right. Lori.

MS. HANLEY: I have no problems with it.

MR. TELFORD: All right. Jerry.

MR. MORRIS: Well back to the teletherapy use you alluded to this morning, after a certain number of patients, you should know the patient, so I guess after a period of time, you don't need to keep checking, do you?

MR. TELFORD: Well that's an interesting question. What do you do on the tenth time, Roy, how do you feel about patient ID the tenth time around or the 12th time around?

MR. LANDERS: Well generally speaking, we call the patient by and if they show up and are recognized, we consider that them.

(Laughter.)

MR. MORRIS: Just one time only, not redundant.

MR. ARGAWAL: The first time two times, and then the second time it is already two times, so it is redundant.

(Laughter.)

MR. TELFORD: That's an interesting argument there.

MR. CLARK: Maybe we should add that an unknown patient is verified as the individual. If you don't know who it is, you need to find out. Then once you know that person, then you don't need to re-identify them.

MR. TELFORD: In the case of a teletherapy patient where it's --

MR. CLARK: First contact.

MR. TELFORD: Okay, upon first contact with a patient -- except what if you have a patient that -- it's a teletherapy patient and there's a span of time between treatment fractions. Maybe they went on vacation for a couple of weeks or maybe you treat a lot of teletherapy patients. A span of time has happened, and now don't you need to redundantly identify the patient when they come back?

Darrel, you had a point?

MR. HAIDER: If everybody takes a picture --

MR. TELFORD: Picture.

MR. HAIDER: Yeah, if everybody takes a Polaroid and puts it in their chart.

MR. TELFORD: So you ask them their name and then you look at the picture and that's enough.

MR. HAIDER: Well the picture has its name -- I mean you that's them.

LT. CMDR. PULCRANO: If you've got a chart with a Polaroid picture and you call that person's name, that person answers to the name in the chart and the picture matches the patient, I think we've got a match.

MR. TELFORD: Yeah, except you realize we can't tell everybody to go take a Polaroid picture because this is a

performance-based rule. We can always say it's a good thing to do to redundantly identify the patient. How you do it, we want to leave up to you. But I agree, that sounds like a match to me too.

Darrel, you had your hand up.

MR. WIEDEMAN: I was just going to say that many of the procedures that you have in teletherapy, there is a dual verification, such as photographs as you've already said. Some facilities take photographs of -- Polaroids -- of the tattoo marks, and when you're doing your patient setup, you also look at the tattoo marks and verify -- you know, if you're treating a lung and all of a sudden you've got a photograph of tattoo marks of a back, it'll make you think, well do I have the right patient. So there is a lot of dual verification that goes on in teletherapy.

MR. LANDERS: Whose responsibility might this be? Sometimes we get a patient who is not able to communicate. The physician tells us who this patient is and we have no way of verifying it other than looking on their arm band.

MR. TELFORD: This is a teletherapy patient?

MR. LANDERS: Yeah. Assuming that someone else labeled their arm band properly.

MR. TELFORD: First contact?

MR. LANDERS: Right.

MR. TELFORD: This is an in-patient with an arm band.

Whose responsibility is it? It's the authorized user's responsibility.

MR. LANDERS: Or how do we do it? The physician comes in and says this is Mary, let's treat her with the following prescription. Is he somehow supposed to again convince himself that this is indeed Mary?

MR. TELFORD: Which doctor is this, is this the authorized user?

MR. LANDERS: Yes.

MR. TELFORD: And the authorized user introduces Mary Jones to the technologist and says we're going to give Mary Jones 300 rads to the lumbar spine. Well it's the authorized user's responsibility to identify Mary Jones. And if we say redundantly, then that's still his responsibility. But there are many ways to do that, and he may know -- he may have asked Mary Jones what her name was or he may know Mary Jones, he may know her address or her date of birth or her social security number and he can ask her all those or any pair of those. It's his responsibility. He may have a picture.

Okay, any other comments on number six?

(No response.)

MR. TELFORD: All right. Pardon me?

MR. LANDERS: One more time back to prior to medical use, might that be construed to be the first of multiple treatments, or do you mean prior to each treatment?

MR. TELFORD: As written, it means prior to each medical use. There was one suggestion to say prior to first contact with the patient or upon first contact, or prior to first medical use or something like that. And that would seem to work for probably the diagnostic patients, assuming you're going to give one diagnostic test to a patient. But for a teletherapy patient, if there's this gap of time between treatment fractions, then it may not be sufficient then.

Any suggested modification, Roy?

MR. LANDERS: I don't know how to do it -- I mean I don't know how to suggest a change.

MR. TELFORD: All right.

MR. LANDERS: I have a problem with a therapy tech being sick, new tech to that machine steps in, they don't know the patient, they haven't seen the patient before.

MR. TELFORD: Okay.

MR. LANDERS: And routinely there is not a problem, but we do not in any way document that that tech checks twice to make sure that the patient is who they think it is.

MR. TELFORD: Why wouldn't it be sufficient to have a procedure that tells the tech to redundantly identify that patient? Why wouldn't that work for number six?

MR. LANDERS: That would be fine. No paperwork involved other than the procedure.

MR. TELFORD: Darrel, what would you look for at the

site?

MR. WIEDEMAN: Procedure.

MR. TELFORD: Okay. Anything else on number six?

(No response.)

MR. TELFORD: All right, number seven. Now this says identify any deviations. Now I'm sure you're going to tell me something about the word "unintended", so an alternate way to read this is to leave out that word. But basically we're after identifying deviations from what was supposed to happen. Now we're not after a record of these deviations because that comes up in the audit. We're only after a procedure that says you will make note of deviations.

Darrel.

MR. WIEDEMAN: I'll give them a couple of examples. You know that many times when your physician writes a prescription for iodine therapy, let's say for example he writes a prescription for 10 millicuries. You order it through your nuclear pharmacy, wherever you order from -- it may show up as 12 millicuries, it may show up as nine millicuries. And all we're looking for is some way of identifying that a doctor or authorized user wrote a prescription and we gave nine and it was approved by the authorized user. So you just say, "Doctor, we have nine rather than ten." If he says that's sufficient, that's more than adequate, he signs off on it, that's all there is to it.

Let's say, for instance, in a diagnostic nuclear medicine procedure, a bone scan, your procedures manual calls for 20 millicuries of technetium MDP and all of a sudden this patient is 450 pounds, your authorized user, after you've talked to him, says well maybe the 20 millicuries is not going to do the job, maybe we should give him 35. Well that's contrary to the procedures manual, but if some way it's documented that we've elected to give this patient above and beyond what our procedures manual calls for, that's basically what we'd be looking for.

MR. TELFORD: Or in the case of a teletherapy fraction --

MR. WIEDEMAN: A loose dose on the first day?

MR. TELFORD: Yeah, if you inadvertently gave 205 when you were supposed to give 200. You write in 205, you note that there's a deviation, that's it. But this is basically a procedure or mechanism to identify deviations.

MR. MORRIS: The authorized user has to note that 205 was given?

MR. TELFORD: No, just that it be identified, the technologist could identify it.

Roy.

MR. LANDERS: What's a deviation? You said nine instead of ten. How about 9.9 instead of ten? How about when I dial in 3.27 minutes and I give 3.26 minutes? What's a

deviation?

MR. WIEDEMAN: From the dose. If your authorized user has prescribed -- you're talking teletherapy -- you're supposed to give 200 centigrade per fraction --

MR. LANDERS: Yeah.

MR. WIEDEMAN: And you gave --

MR. LANDERS: 199.

MR. WIEDEMAN: 199?

MR. LANDERS: Or 199.6.

MR. WIEDEMAN: You could be three or four percent off anyway.

MR. LANDERS: So perhaps there is a little judgment involved here, but we can't quantify it. Is that the problem? A significant deviation or something, but we can't do that.

MR. TELFORD: No, the answer to your question is "all of the above". Every one of those cases that you mentioned, those are all deviations, but there's no stigma attached to a deviation.

MR. LANDERS: But there can be an enormous amount of work involved in recording something because of 1/100th of a minute off out of four minutes.

MR. TELFORD: In the case of teletherapy, don't you write in the fraction administered each time?

MR. LANDERS: We write in the dose that is to be administered and on the face sheet we have the time to be

dialed in.

MR. TELFORD: Okay.

MR. LANDERS: Technologist will dial that time in on a mechanical timer and the electrical timer will record what was done. If the two disagree with each other by 1/100th of a minute, I don't know what happened, but I know it's totally insignificant.

MR. TELFORD: That's not what I asked. Don't you record the dose given, or its equivalent?

MR. LANDERS: In that case they would record --

MR. TELFORD: That is, the time actually during which the dose was given.

MR. LANDERS: In that particular case that I just outlined, they would record 200 as having been given, if that was the dose called for.

MR. TELFORD: Okay, 200 was the prescribed dose, 200 was the delivered dose. Okay, what if you had 201, you'd write down 201 or 205. Then you've done both, you've identified the deviation.

MR. WIEDEMAN: And you've evaluated it by saying it's insignificant.

MR. TELFORD: Okay.

MR. CLARK: Let me ask one more question. For a nuclear medicine procedure, if you unintentionally deviate from the diagnostic referral, if he comes in for a liver scan and I

do a bone scan, is that not a misadministration?

MR. TELFORD: Yes.

MR. WIEDEMAN: Did your authorized user -- wait a minute, the referring physician ordered a --

MR. CLARK: Liver scan.

MR. WIEDEMAN: -- liver scan, you did a bone scan. Who decided that that patient's going to get a bone scan?

MR. CLARK: I did accidentally.

MR. TELFORD: It's a misadministration.

MR. CLARK: Right.

MR. WIEDEMAN: But if your authorized user said no, that patient needs a bone scan, not a liver scan, and initialed off and directed you to do that, then that is not a misadministration, because the authorized user is the one that can change the prescription at any time.

MR. CLARK: Is that an intentional deviation or an unintentional? That unintentional worries me a little bit.

MR. TELFORD: Let me make it easy for you, throw that word out.

MR. CLARK: Oh, we're going to get rid of that word altogether?

MR. TELFORD: Yeah, that's a deviation, the case you described, when you substitute a bone scan for a liver scan -- that's a deviation. So you would have a record of what you actually administered. You administered a liver scan. Then

you would look at it and say whoops, I was supposed to do a liver scan. You've identified it, you've evaluated it. It just so happens in this case it turns out to be something else as well, something more than a deviation.

Okay, Stanley, any comments here?

MR. GIPSON: I don't think so.

MR. TELFORD: Jerry?

MR. MORRIS: No.

MR. TELFORD: Lori?

MS. HANLEY: No.

MR. TELFORD: Ashok?

MR. DESAI: No.

MR. TELFORD: Jean?

MS. RHODES: No.

MR. TELFORD: All right. Well Neil, can I get something out of you on number seven? Have you got any suggested modifications?

MR. CANADA: Well you're not saying that if -- say the bone scan calls for 20 millicuries of MDP and we give 21, but that's still within the ten percent, then it's not --

MR. TELFORD: Well it's a deviation but there's absolutely no stigma attached to the fact you've got a deviation. You have to look at the amount of the deviation to find out whether it's reportable or not. So it's no pain to you, you know, no work involved other than the fact that you

just identify it, and you did by noting the fact that it was 21.

MR. CLARK: Same thing with therapeutic iodine, if they prescribe ten and it's not going to assay at ten exactly every time, it's insignificant so that doesn't count for a deviation.

MR. ARGAWAL: It depends how much it is.

MR. LANDERS: If it's not what was prescribed, it's a deviation.

MR. TELFORD: It is a deviation.

MR. CLARK: Well if he prescribes 10.8 or ten and you get a capsule and it's 10.8, you can't take some of it out.

MR. TELFORD: That's true.

MR. CLARK: I'm going to give it to him.

MR. TELFORD: Okay.

MR. HAIDER: I think all he's asking is that you write down that you've given 10.8, he's not asking that --

MR. CLARK: No.

MR. LANDERS: No, he is asking also that we identify that as a deviation and evaluate it.

MR. CLARK: The way we do that, we have prescribed dose in our isotope log and then the assay beside it.

MR. TELFORD: And the assay is what's administered.

MR. CLARK: Right.

MR. TELFORD: All right. And you look at ten

prescribed, 10.8, you say I'm going to give it because it's no big deal. All right, you've identified it, it's in your assay log. You're going to administer that so you know what was done. You've evaluated it.

MR. CLARK: But you're covered.

MR. TELFORD: Yeah, you're covered, you're already doing it.

LT. CMDR. PULCRANO: It's kind of one of those filled in things. You say you're going to give someone for a study but in your SOB and any instructions and the regulations, they give you a leeway of so many percent. You draw up something that's a half a percent more than what you said you were going to give -- well you've made the evaluation I'm within my guidelines, I mark down I gave that tenth of a percent more or whatever, and you go on and don't worry about it.

MR. TELFORD: Right.

MR. LANDERS: Let me suggest a change.

MR. TELFORD: All right.

MR. LANDERS: Change the words "identified and evaluated" to "identifiable and evaluatable".

MR. TELFORD: You just about lost me there, Roy. Oh, "Ensure that any deviation is identifiable and evaluatable." But you could stay home and do that, you don't have to come to work.

MR. LANDERS: Somebody has to record the fact that we

gave 9.9 and ten was prescribed. That's a deviation.

MR. TELFORD: It's in his log. Isn't it in your log?

MR. LANDERS: Exactly.

MR. TELFORD: Well you've identified it, you've recorded it.

MR. LANDERS: I haven't identified it as a deviation.

MR. CAMPER: The fact that they don't agree is a deviation.

MR. LANDERS: That's correct, but why do I have to record that it's a deviation or identify it as --

MR. TELFORD: Do you see record up there yet?

MR. LANDERS: It says "Deviation identified and deviation evaluated."

MR. TELFORD: Okay.

MR. CLARK: A regular log entry would qualify for that.

MR. TELFORD: Right. We don't get to records yet. If in our recordkeeping requirements, we said keep a record of all deviations, then you would have a concern. But check it out, see if we have that.

MR. CAMPER: Let me make a point here too, if I may. There's a couple of easy ways to solve this problem and they deal with your procedures manual. One is that your procedure manual simply define the fact that a particular procedure has a dose range associated with it. Okay? Ten to 12 millicuries,

for example. Of also the statement, which is very common in procedures manuals, that in order to reduce unnecessary exposure to technologists, ALARA if you will, that a dose, a prescribed dose or a procedure is such and such, plus or minus so and so. Because if you have something that calls for ten millicuries, it's not uncommon at all, as we all know, for it to assay at 10.4 or 10.8, but you're not going to spend a lot of time messing around with that dose and increase unnecessary exposure because of this .4 or .6 deviation.

So it's an easy thing to solve, and again, bear in mind that this is an objective. So there are a number of ways to achieve this objective.

MR. WIEDEMAN: One other thing, there's the dose calibrator. It's very common to be out of calibration by ten percent and in our evaluation we're just basically saying that we have this much leeway in the dose calibrator annual accuracy tests, depending of course on what type of dose calibrator you have.

MR. TELFORD: Well you're probably all already doing this. Any other comments on seven?

(No response.)

MR. TELFORD: All right, let's go to number eight. Now this is ensure treatment plan is in accordance with prescription. Would you like to delete, modify or retain this objective?

MR. ARGAWAL: Let me say that the treatment plan in brachytherapy and teletherapy generally is some in several steps and prior to giving the treatment there are several times that treatment planning is done.

MR. TELFORD: All right.

MR. ARGAWAL: For the physician to make his mind to prescribe, you know. And similarly in the brachytherapy, you know, it is the after-loading systems most of the time and the treatment planning is done that we'll use 40 rads but I used 50 rads, so I'm okay. And then he decides that this is the iso-dose curve at which the prescription is done. So the treatment planning is done according to the prescription. I'm just saying that the prescription is based on treatment planning, but treatment planning is not done according to the prescription, it is done for the physician sometimes to make up the mind for prescription.

MR. LANDERS: Got a cart and horse problem.

MR. ARGAWAL: Right. I agree with that, that the final treatment planning, whatever is given, will be according -- will be signed by the physician as a prescription because treatment planning can be the prescription of the physician, because the dose is decided on that iso-dose curve that this is 40 centigrade, but however, that is the dose curve at which he wants 4000 rads -- or 4000 centigrade.

MR. TELFORD: Okay.

MR. ARGAWAL: So to me, he doesn't come up before to ask me that you run a treatment plan for me to take 4000 centigrade at such and such -- that's just my --

MR. TELFORD: All right. So do you have an idea as to how you would say this?

MR. ARGAWAL: No.

MR. TELFORD: Or write what you just said?

MR. ARGAWAL: The final treatment plan is in accordance with the prescription. That I can -- with the final prescription. But the treatment planning is done, means to start with, we don't have the prescription in many cases. In many cases we have -- teletherapy, most of the time we have. But brachytherapy, generally we don't have the prescription because even if the patient is loaded -- not loaded with the -- the patient is loaded with a dummy source, and all that, then the plan is done, the radiograph is taken, the plan is completed and then the loading is made according to the physician agreeing that what he intended is what he has got.

MR. TELFORD: Okay.

MR. ARGAWAL: I don't know how to word.

MR. TELFORD: Do we have any comments from the therapy people over here?

MR. WHITE: I like the use of the words "final treatment plan".

MR. TELFORD: Add the words "final treatment plan",

okay.

MR. MORRIS: Well it seems to me that the statement is correct, when he agrees with the treatment plan, that is his prescription. So it sounds like it's saying what we want it to say. But it might could be worded better.

MR. TELFORD: Stanley.

MR. WHITE: Sometimes the physician would write in to treat 90 percent, you know, so there would be sort of a change.

MR. TELFORD: All right.

MR. WHITE: But 90 percent, for example, would mean where he wants 4500 centigrades to be delivered.

MR. TELFORD: All right.

MR. ARGAWAL: I would put "The treatment plan is approved by the physician." And that will --

MR. TELFORD: Yeah, that might be a complete alternative, just to say that the brachytherapy, teletherapy treatment plans are approved by the authorized user. Do you agree with that, Roy?

MR. LANDERS: Yes, I do. I do have a question, however, concerning some brachytherapy cases when there is no "treatment planning" done by physicist or dosimetrist or technologist.

MR. TELFORD: What do you have, do you have a prescription?

MR. LANDERS: Yes.

MR. TELFORD: Okay. So that would fall back to number five?

MR. LANDERS: This is in essence saying when there's a treatment plan, it should agree with the prescription, not that there will be and it will agree. Is that correct?

MR. TELFORD: Yeah. Darrel?

MR. WIEDEMAN: I was just going to say the brachytherapy programs that I looked at during the site visit, it was really a two-phase operation. Number one was the physician would examine the patient -- the authorized user -- and he would write a pre-treatment plan, and that usually consisted of words of "intracavitary brachytherapy, Ammon after-loader, cesium 137 sources, objective is to deliver a range of 3500 to 4500 centigrade." And then the next phase, the patient would be taken into surgery, the applicator would be inserted, the dummy sources would be inserted, then there's a combination of things. Either radiographs are taken, CT -- usually radiographs. Then comparison of nomograms and charts and a final treatment plan would then be documented, that we've decided to load 5-10-10 cesium sources in a certain type of applicator and so many milligram hours of therapy, to remain in the patient from this time to that time, and removal on this date. That's basically what I saw in most of the cases. Maybe things were done differently?

MR. ARGAWAL: That's true, that's what I'm saying

that there are several phases in which the brachytherapy is done. So -- and the treatment plan is in the beginning not associated with the prescription. It's the idea of the physician of what he wants to do rather than what the final prescription will be. It is started that way.

MR. TELFORD: Okay. Any other comments on number eight?

MR. WHITE: I would like to see the requirement that the physician sign the treatment plan, for his approval.

MR. TELFORD: Okay, you're agreeing with the two gentlemen over here.

MR. WHITE: right.

MR. TELFORD: That the authorized user should approve the treatment plan. Okay, good, I like that.

All right. Now we've looked at each of the eight objectives. There's one more part of the proposed 35.35 and that's the audit.

MR. GOMEZ: Can you say "approve and sign"?

MR. TELFORD: Yes, they have to approve it in writing, approve it by signing it or initialing it or something, that's correct -- I mean, I agree with that.

You'll have to refer to the notice, the Federal Register notice to look at the exact words for what's in there for audit, but these four items that I have on the screen here are the essence of it. There's an annual audit that says every

12 months and it suggests that -- in the Regulatory Guide anyway, it'll suggest that somebody should be doing the audit who was -- who didn't do the original work. You don't audit yourself. But actually we should delay that discussion for when we get to the Guide.

But the point I'm trying to make is that you don't have to hire an outside group necessarily to come do your audit. There should be an evaluation of that audit, we said by the licensee management, and the management should determine that the program is still effective. And fourthly, that if required, they should promptly make any modifications to prevent recurrences that they've discovered during this audit. This is a built-in feedback loop, if you will, to let the licensee self-correct. Then when the inspector gets there, the inspector could look at the audit report, the findings and what was carried out by management or directed by management, and see that they had some small problems and management determined that well, this is not a big deal, we don't need to do anything about this, or they discovered one problem area and they've already fixed it.

So I'll open it to you, what would you like to do with this? Would you like to delete it or modify it or retain it. Tawfig?

MR. HAIDER: Well we're going to have to do some major modification here, especially on two and three. First of

all, management doesn't know anything about radiation therapy or brachytherapy or nuclear medicine, and I don't feel they're qualified to evaluate it. And second of all, how can they tell whether it's effective or not? They just look at it, "oh, yeah, it looks about right, yeah, we're doing pretty good."

MR. TELFORD: Okay.

MR. HAIDER: So I think it needs to be within the department, somebody pulls out a certain amount of charts every three months or so, looks at it to see if everything is done.

MR. TELFORD: What would you like to see in place of management here? You said the department --

MR. HAIDER: The radiation therapists, could be the dosimetrist, maybe the physicist, or the physician.

MR. TELFORD: How about the department chairman?

MR. HAIDER: That would be fine.

MR. TELFORD: That does the evaluation.

MR. HAIDER: Sure, somebody who knows about x-rays and how to read charts and all that.

MR. TELFORD: All right, who do you want to make this determination?

MR. HAIDER: The same person as number two.

MR. TELFORD: Okay. Somebody else have a comment on those lines or a different line?

MR. DESAI: We have -- we already have a radiation safety committee and also the QA committee, hospital-wide.

MR. TELFORD: Okay.

MR. DESAI: That meets four times a year fortunately, and we go there and report whatever the difference is or the results of the program to the global hospital-wide peer committee. And this is going to be a duplication of what you already do.

MR. TELFORD: Let me see if I understand what you're telling me. You have a QA committee that's separate from the RSC, radiation safety committee?

MR. DESAI: The hospital-wide QA committee that is required by the Joint Commission.

MR. TELFORD: Yeah, okay. It's separate from your radiation safety committee?

MR. DESAI: That is correct, yes.

MR. TELFORD: The QA committee meets once every quarter.

MR. DESAI: That is correct, and so does radiation safety committee.

MR. TELFORD: So what do you do when you report to them? What do you -- are you saying that you do an audit every quarter and you go tell them the findings?

MR. DESAI: If we have four misadministrations, we'll go to the peer committee and tell them that we had four misadministrations in the month of February. What did we do, we say that.

MR. TELFORD: Oh, number four, what did you do to prevent recurrence?

MR. DESAI: That is correct. And we already report that to the internal QA committee of the hospital.

MR. TELFORD: Okay.

MR. DESAI: And if you want to do something else, this is a duplication of what we already do.

MR. TELFORD: Well let's be clever here, let's figure out how to make this easy. So you would substitute your QA committee for management.

MR. DESAI: That's true.

MR. TELFORD: You already do the audits.

MR. DESAI: That's correct.

MR. TELFORD: Now this would only require one of those, one out of four, you're going to do four times a year instead of one, so you're covered.

MR. DESAI: True.

MR. TELFORD: But if we said the QA committee will evaluate and the QA committee will make a determination, you don't have to do anything extra, you're covered.

MR. DESAI: That's true.

MR. TELFORD: Okay. So it seems like we need a couple of alternatives here. Do you have a QA committee?

MR. HAIDER: I have a QA committee. Every week we have a chart round and there are only five people, so everybody

is there and we discuss all the problems, and one time we did discover one problem and we found a way how we can prevent it.

MR. TELFORD: Okay.

MR. HAIDER: But it's done on a weekly basis and usually what happens is somebody types up what we have come up with and hands out to everybody else and they kind of keep that in mind. But we keep these reports every week and anybody is welcome to look at all these 52 reports a year.

MR. TELFORD: Okay, so we have a couple of alternatives so far. One would be the department chairman and one would be a hospital QA committee.

MS. RHODES: Okay, well now we go to the radiology department committee, which is a diagnostic radiologist, radiation oncologist, department head for radiology and respective heads for nuclear medicine and radiation therapy, and we discuss the results of the audits. And they make -- that committee makes recommendations which goes on to our hospital quality assurance committee.

MR. TELFORD: Okay, so you have two committees.

MS. RHODES: We have the experts to make recommendations.

MR. TELFORD: So you have the experts that do the evaluation and make the recommendations.

MS. RHODES: Yes. And then it goes on to the hospital quality assurance committee.

MR. TELFORD: All right.

MS. RHODES: Or their representatives from medicine, surgery --

MR. TELFORD: What do you call this committee that you go to the first time?

MS. RHODES: Radiology department committee.

MR. TELFORD: All right. So this would be a committee appointed by the department chairman?

MS. RHODES: Yeah, we're a small hospital, so it sort of is the department, they are the department.

MR. TELFORD: Yes?

MR. GOMEZ: They say that in order to improve discussion of the people, the workers, the radiation workers, physicians and technologists, you report what the dose should be, it should be known by then by those people. In other words, we have a meeting with the people and inform them about the results of the -- I mean the reports of the dose.

MR. TELFORD: This would be what would follow. Are you talking about what should follow the audit and this evaluation, this determination? You've made a determination that something needs to be fixed and this is a suggestion for something to do?

MR. GOMEZ: Yeah, it's a suggestion for something to do with those reports of the evaluations, with the people to be informed about those.

MR. TELFORD: Oh, they would be informed, okay.

MR. GOMEZ: They should be informed of those evaluations. In this way, they would understand many things that are happening in the department and many mistakes made in the --

MR. TELFORD: Don't we have something in the Federal Register notice that suggests that we send these to the -- the findings go to the various departments? Is that in the notice or is that in the Guide? I'm sure it's someplace. That's basically what you're saying.

Any other suggestions on the audit?

MR. LANDERS: I have a question. I question the use of the word "comprehensive".

MR. TELFORD: Okay.

MR. LANDERS: I don't know who is to make the evaluation of how comprehensive something is. And by an audit, do you mean what is normally meant by an audit; that is, that you randomly pull this number of charts and go over them?

MR. TELFORD: Yeah, randomly selected sample, that'll do for an audit, yes. What would you like to see instead of "comprehensive"?

MR. LANDERS: Just eliminate the word "comprehensive", maybe even eliminate the word "audit", I don't know.

(Laughter.)

MR. LANDERS: I mean, it sounds like --

MR. TELFORD: What do I use in place of "audit "?

MR. LANDERS: Reports brought to managements or reports brought to this committee.

MR. TELFORD: Program review -- annual program review, do you like that better?

MR. LANDERS: Yes.

MR. TELFORD: Okay. And the basis for this review could be the same sample of cases, just as you would do in an audit.

LT. CMDR. PULCRANO: A random sample of charts, procedures and calibrations, whatever.

MR. TELFORD: Okay. Well Roy, would you be willing to say "annual comprehensive review", "program review"? That way you would need to go into all aspects.

MR. LANDERS: I don't know, I guess what I object to a little bit here is the concept of the audit as opposed to if by review, you mean review records that have been kept of deviations, misadministrations, so on and so forth.

MR. TELFORD: Well we could follow the Commander's suggestion here. We could say "Perform an annual comprehensive program review based on a random sample of every patient you had during the year." So somebody would look at a sample of all those cases and see what really happened, were there mistakes made, were there any problems or potential problems

that you might detect through that review -- that's the name of the game. If you don't want to call that an audit --

MR. LANDERS: That's obviously an audit, where you go back and study a randomly chosen grouping.

MR. TELFORD: Okay.

MR. LANDERS: We're talking about instead of that, reviewing records that were maintained. I know that doesn't accomplish the same thing.

MR. TELFORD: Aren't you reviewing the same records, but you're leaving open the question of how many records or what records?

MR. LANDERS: No, I don't think I am.

MR. TELFORD: Help me out here.

MR. LANDERS: I'm suggesting that if we have -- not that we're going to, but if we have -- maintained records of deviations, misadministrations, so on and so forth, those records be reviewed by this committee, as opposed to an audit occurring.

MR. TELFORD: Well let me see if I understand what you're saying here. Let's say, for discussion purposes, that we all keep records of deviations. They're there, but you've got to go dig them out.

MR. LANDERS: right.

MR. TELFORD: Let's say that we keep records of misadministrations, whatever those are. Let's say we have

records of prescriptions in the case of therapy and we have records of the administered dose, as you probably already do.

Now if we say to a committee, review all those records. Okay, we get them into a room, here's a table, we bring this cart load of records in there and plop them down. Do you want them to go through the whole thing, all of them?

MR. LANDERS: Huh-uh.

MR. TELFORD: Okay, what do you want them to do?

MR. LANDERS: By keeping records of those, I don't really mean keeping the patients' charts, but I do fall back on -- to review a record of misadministrations, you don't have to review every chart, you only need to review the record of misadministrations. Now if you want to prove that those were the only misadministrations, then you need to do an audit or check every chart, I agree with that.

MR. TELFORD: Or check a sample.

MR. LANDERS: Yeah.

MR. TELFORD: A randomly chosen sample of those charts, or the records -- or the patient records.

MR. LANDERS: Right.

MR. TELFORD: Okay. Is that what you want to happen?

MR. LANDERS: No, I guess that's what I'm saying I don't want to happen. I don't want the audit concept of it.

MR. TELFORD: All right, this is a feedback loop, it's for the licensee.

MR. LANDERS: Right.

MR. TELFORD: To detect problems that they have or potential problems, to keep themselves out of trouble. You don't want to do that, is that what you're telling me?

Tom?

MR. CLARK: We're talking about auditing QA records here, right?

MR. TELFORD: We're talking about auditing records of the directed dose, the prescribed dose and the administered dose.

MR. CLARK: Which is kept in your QA program.

MR. TELFORD: It's kept someplace, yeah.

MR. LANDERS: No, ours is just kept in the patients' charts.

MR. TELFORD: Yeah, it could be in the patients' charts.

MR. LANDERS: We've got 1500 charts to look at, review.

MR. TELFORD: Well if we do a comprehensive review that's not based on a sample, then you've got 1500 charts to look at, yeah.

MR. LANDERS: Unless I review records of anomalies.

MR. TELFORD: Well how do you establish records of anomalies? That's a different requirement that you're adding on.

MR. LANDERS: Well it's an alternative requirement, is what I'm suggesting.

MS. RHODES: Why don't you look at ten percent.

MR. LANDERS: 150 of them.

MS. RHODES: Uh-huh.

MR. LANDERS: We're talking about a major addition of work in our case.

MS. RHODES: Well rather than do it once a year, why don't you do ten percent a month?

MR. HAIDER: Just pull out 30 charts every quarter.

MS. RHODES: Right.

MR. LANDERS: Just the manpower.

MR. GIPSON: You would have a problem with that being annual then if you did just did it so many per -- in our QA program in radiology, we're doing some things in radiology and nuclear as far as just technical evaluations to say an evaluation or whatever word we want to use here, if you said ten percent, five percent, whatever, per month, and this is reported to our radiology QA committee.

MR. TELFORD: Yes.

MR. GIPSON: Okay, at the end of the year, we might have done X amount, 100 charts, that's been reviewed.

MR. TELFORD: Right.

MR. GIPSON: Okay, we could just at some point annually make a statement reviewing our results even though

we've done it monthly or quarterly. There's not going to be a problem having an overall audit or review also at the end of the year, it would be a combined --

MR. TELFORD: Well do you find any words that say we must do this audit at one time? If you did it quarterly, couldn't you stack up these four? If you did it monthly, couldn't you stack up the 12? As a matter of fact, logically speaking, if you're doing it once a month, that's a more timely feedback loop than once a year.

MS. RHODES: If you do it every month, that's what you do.

MR. TELFORD: Yeah, as a matter of fact --

MS. RHODES: You're identifying the problems right away and finding solutions.

MR. TELFORD: Okay. Therefore, what would that -- how would that affect you?

MR. GIPSON: It would be much easier than trying to take a bulk amount of charts.

MR. TELFORD: All right, I think Jean's got a good point.

MS. RHODES: All I do is review charts and if I only worked one month out of the year reviewing everything that has to be done for the hospital, I'd be crazy. So I do it in little bits and pieces.

MR. TELFORD: Okay. David.

MR. GARRISON: I wrote up our program and when I got to this part, I wrote it up as the chief technologist, I would present my findings to our hospital QA program. That's not what you're looking for.

MR. TELFORD: Okay.

MR. GARRISON: I wasn't reviewing, I wasn't doing anything. It's quarterly, we basically do that anyway, that's the way I took it, as -- so you actually want something different.

MR. TELFORD: I think you're all right. If we changed "management" to your QA committee, they would do the evaluation of the audit.

What you're saying is you're the head technologist and you've got several technologists working in the department and you obviously don't do all the work, they do most of it. So therefore, you should be admissible to do the audit because you're not auditing your own work, you're basically auditing the work of a bunch of people. Okay, the same person is not auditing himself, that seems reasonable.

If you do it quarterly and you stack the floor up, then you've got -- you know, you at least did it every 12 months. As a matter of fact, you did it four times within that 12 months. If we change the evaluation to the QA committee here and here, then you're doing it.

MR. GARRISON: Okay, but see, I don't go through

charts. I write up something for the QA committee quarterly.

MR. TELFORD: Okay.

MR. GARRISON: I write up -- well misadministration or anything like that, or I just -- basically I don't have anything to write.

MR. TELFORD: What are you looking for?

MR. GARRISON: What I'm saying is I should be actually reviewing charts or the authorized user should be. Is that what you're leaning toward, you should review charts?

MR. TELFORD: It seems to me -- if I were you, I would be looking at the patient's chart, I would be looking at a sample of the patients to see what was administered versus what was supposed to be administered to see if I thought that the technologists that were working in my department were doing the right thing. And I would do that by looking at a sample of those cases, and then I would report the findings.

Make sense, Tom?

MR. CLARK: I'm just trying to get -- there's something I'm not understanding here. Are we -- take for instance misadministration, you're going to audit your program to see how many of those you have in a year?

MR. TELFORD: No.

MR. CLARK: Well I'm missing the point, so I'm lost.

MR. TELFORD: Well let's assume that a misadministration is something that is so gross that you would

know it instantly and you'd report it.

MR. CLARK: We keep up with that monthly on a log, number of misadministrations, zero.

MR. TELFORD: Right. But what we're really talking about here is not going back and reviewing the misadministration cases that you had during the year, but to go back and look at what was actually done for a sample of your patients versus what was supposed to have been done, to look for something that would tell you that things are going right because your program is effective or things are -- little mistakes were made and by golly, those little mistakes were only little because I was lucky, the next time they could be big mistakes, because you don't have an adequate program. It's an examination -- just as Tony says, it's really a comprehensive review of your program and your procedures. Are things working well because your program is that way or are things working well because you're just lucky this year?

MR. ARGAWAL: Checking the patients chart will satisfy that? The patients charts are reviewed every week or every month and then on the closing date the physicist closes it up and satisfies that everything has been done according to the prescription. Will that satisfy the audit?

MR. TELFORD: I don't think so.

MR. ARGAWAL: So somebody else has to come and look up at that same chart one more time?

MR. TELFORD: Uh-huh -- well not every chart.

MR. ARGAWAL: Not every chart, some charts.

MR. TELFORD: Yeah.

MR. GOMEZ: So in most places there is a radiation safety committee.

MR. TELFORD: Okay.

MR. GOMEZ: Could it be a radiation safety committee evaluation or the other?

MR. TELFORD: Yes.

MR. GOMEZ: They will understand what it's about.

MR. TELFORD: That may be an acceptable alternative. We may have department chairmen, we may have hospital QA committee or maybe the --

MR. GOMEZ: That's just representative.

MR. TELFORD: It's a little bit weak actually for the radiation safety committee because as Tawfig pointed out previously, you really need some people that are knowledgeable to do this evaluation and make the determination that the program is still effective, and to make suggestions for modification that's going to be effective.

Okay, any more comments on number eight? Darrel?

MR. WIEDEMAN: Just a suggestion on how -- it's very easy to comply with this. If I was going to do the audit, which I do a lot of audits in my particular job, what I would do is I would, number one, look at the number of cases that we

performed in the month of August. My audit report would say during the month of August, we did X number of diagnostic nuclear medicine studies and out of a random sampling of X number of charts I verified that what was ordered was actually given. My audit also consisted of a review of the utilization log. I reviewed X number of patient cases and verified that the dose that was prescribed was actually given and I also verified that the dose was in accordance with the procedures manual. And if there were any misadministrations or medical events during that period, I'd reference those and describe what kind of corrective actions we've taken if any at all.

Then I would send a copy of it to your administrator and a copy to the radiation safety committee. And you're done. The whole thing shouldn't take more than half a day per month.

MR. TELFORD: Okay.

MR. WIEDEMAN: If that.

MR. TELFORD: Would anybody object to taking about a 15-minute break?

(No response.)

MR. TELFORD: Okay, let's come back at quarter till.

(A short recess was taken.)

MR. TELFORD: We're up to the point on t he agenda for the end of proposed 35.35 where we have any additions, if you would like to add anything to the eight objectives, if you think we've missed something.

Any suggestions for additions?

(No response.)

MR. TELFORD: Oh, okay -- oh, Tawfig, okay.

MR. HAIDER: I'd like to add maybe objective number zero and that is to give everybody a chance to use your common sense a little bit, you know, so we can interpret these a little bit more relaxed, you know, you don't have to take it as a Moses commandment, that you have to do it exactly like that. I think that makes sense, yeah, that looks right, you know. I think that was the problem with the guy from Colorado, he was afraid the state was going to take it literally. I think a lot of people are worried about that too, so they want to know exactly how it's going to be implemented and all that. It needs to be a little bit relaxed, you know, there's more than one way to skin a cat. I saw my dog reading a book "A thousand and one ways to skin a cat".

MR. TELFORD: Okay. With no additions -- excuse me, no other additions, we'll go to the summary comments on 35.35.

Keep in mind what's to come is a discussion of the Guide and a discussion of the two sets of reporting requirements. So again, I'm going to give you individual air time where you can make any kind of summary comments you would like on Section 35.35. Whatever your thoughts happen to be and your conclusions on 35.35. It doesn't have to be elaborate, I just want to give you that opportunity. Last time I started

over here, this time I'll start with Stanley.

MR. GIPSON: This is about 35.35.

MR. TELFORD: 35.35, any final thoughts and conclusions.

MR. GIPSON: I don't think so.

MR. TELFORD: Okay. Jerry, nothing else. Lori?

MS. HANLEY: Nothing to add.

MR. TELFORD: All right. Tom.

MR. WHITE: Nothing to add.

MR. TELFORD: Ashok.

MR. DESAI: I think it's a good rule and we all like it. The only thing we wished out is the psychological impact on the physicians and changing the health care industry I should say. With the DRGs and managed care and those physicians are slowly becoming handicapped, they do not want any more interference in their practices. We are looking more and more into it and we get more trouble getting the physicians to agree with what we really want to do and achieve. So I think the one thing we all should have done before we got into this thing is to look into the psychological impact on the physicians and how they are going to perceive this. And we missed on that and I think we should have done some work before we got into it.

MR. TELFORD: Okay. Jean.

MS. RHODES: No additional comments.

MR. TELFORD: No additional comments.

MR. ARGAWAL: Nothing.

MR. TELFORD: No additional comments. Roy.

MR. LANDERS: Yeah, I think that overall the objectives are pretty good and I think the interpretations that we've been hearing are good and I hope that they filter down to the states. I know in therapy, I worry about them being broadly applied also to x-ray, bringing the medical accelerators under their jurisdiction, and that worries me a little bit.

A specific comment that I have that I didn't get in awhile ago concerning the audit part of it is I perceive that it's going to take quite an effort and a non-trivial sum of money to have that accomplished in our particular setting, which is a private practice, free-standing, non-hospital based setting, so we do not have a radiation safety committee or quality assurance committee in place or anything of this sort, and this will potentially have a significant impact on us.

MR. TELFORD: Okay, anything else? Tom?

MR. CLARK: A lot of the points that have come out so far I think are good ideas. I think some of the things that we've seen regarding the mistakes involving 30 microcuries versus 30 millicuries, I don't know t hat in a lot of cases the QA program is going to prevent a mistake like this. That's strictly my opinion, but I don't think you can regulate

ignorance. To me that's -- a lot of that is what that is. It comes down to a person's training what to do. I just can't personally conceive of that happening.

MR. TELFORD: Okay. Santiago, no additional comments?

MR. GOMEZ: No.

MR. TELFORD: Tawfig.

MR. HAIDER: Well -- times up.

MR. TELFORD: Okay, go for it, huh?

Sarah.

LT. KIRTLAND: Nothing.

MR. TELFORD: Tony.

LT. CMDR. PULCRANO: No.

MR. TELFORD: Okay, discretion is the better part of valor.

LT. CMDR. PULCRANO: I'll reserve comments for later.

MR. TELFORD: Okay, David.

MR. GARRISON: Nothing.

MR. TELFORD: Ken.

MR. FRYMAN: If this approach works out well, to looking into this, the ideas get a little bit more specific, I think that's part of the problem that we're having here, is that -- and there's no reason not to, I've experienced this in my facility with a cross section of individuals and how this was received, and I was surprised because I was under the

impression that the attitude was a little different. I realize that this is certainly in order, these types of ideas and progressive, possibly more specific approach to this.

MR. TELFORD: Okay.

We've now concluded the agenda for the first day. Let me give you your choice. Choice A is we can press on and we can go into however much of the Guide we can cover in the next hour and a half or so, or however much of the next day's agenda we can get through as a matter of fact. Or B, we can adjourn for the day.

MR. LANDERS: Go for it.

VOICE: Press on.

MR. TELFORD: Press on, okay.

Okay.

MR. GIPSON: One question I have. Either today or tomorrow, I don't know which would be the best time, if you have any other examples of some of these misadministrations in different areas that you can share with us as far as relating to iodine or other examples of misadministration instances.

MR. TELFORD: Sure. Right after we get through with these reporting requirements here, I'll be happy to show you those.

Okay, Dr. Tony Tse is going to go through the Guide for you, so let me take a minute to give him the microphone.

MR. TSE: Now we're going into the details of the QA

procedure we suggested, but before I go ahead, I have just a couple of points I want to make first.

One is that the Guide is a guidance document and it's supposed to match the regulation. So whatever discussion we have today, as a result of that, if we change the regulation, then that would be followed or would be reflected in the Guide, like the 30 microcuries and so on. If we modify that, the Guide will be automatically modified and match the regulation.

And second, somebody mentioned we should talk to the physicians, and we do have plan before we finalize, we will discuss with the associations like ACR, and get their views into our consideration.

And third, I will go into this Guide section-by-section. Since you already have tried 30 to 60 days and had a chance to review the Guide, I'm not going to go into detail to explain each element of the Guide, just ask you if you have any suggestions, either you want to retain that or delete that or modify that. Then you could make the suggestion at that time.

Okay, then with that, we'll go into the Guide. The first page -- you all have a copy of that, right? The first page, second page and third page are the general statements of the Guide. Anybody have any problems or questions or comments on those three pages, you may raise it now.

(No response.)

MR. TSE: Okay, there are no questions, we'll go to

page four. The first item is Responsibility, Authority and Audit. We have two elements in here and we already discussed quite a bit in the rule, when we talked about the rule.

Does anybody have any suggestions, any changes in these two sections?

(No response.)

MR. TSE: We already heard about management and so on, that's already been discussed.

LT. CMDR. PULCRANO: I have a question.

MR. TSE: Yes?

LT. CMDR. PULCRANO: When we talk here about the licensee's management, in my particular instance, I don't hold a license, the hospital doesn't hold a license, it holds a permit. Can we substitute "permit" for "licensee" here?

MR. TSE: Permittees?

LT. CMDR. PULCRANO: Yeah.

MR. TSE: Right.

LT. CMDR. PULCRANO: Okay, we can.

MR. TSE: Yes. Anything else? Yes?

MR. LANDERS: In Section 1.2, "Audits will be conducted following approved written...procedures...by people not involved with the activity being audited." Can people be involved with the activity that's being audited write the procedures for the audit?

MR. TSE: I think the audit -- yes, the answer to

your question is yes, they can write the procedures, but the person who -- according to this now, this is just a guide -- to audit the procedure, it seems it should be another person who is not doing the work.

MR. LANDERS: Right. But they can actually be following the directions of the people who do the work.

MR. TSE: Right.

MS. RHODES: I don't see why the audit can't be done by the people who do the work if you have written indicators. I mean the stuff is either there or not there, so what makes the difference? You know, they should be measurable and they should be objective, so it doesn't make -- the tech that does the work could also be the auditor.

MR. TSE: Well the idea is that --

MS. RHODES: You know, and still be objective.

MR. TSE: The idea is --

MS. RHODES: You know, unless they lie.

MR. TSE: No, no, that's not --

LT. KIRTLAND: In the Navy, we call it gun-decking.

MS. RHODES: Call it what?

LT. KIRTLAND: Gun-decking.

MR. TSE: What does that mean?

LT. KIRTLAND: When you make the results be what you want them to be.

MR. TSE: The idea is that if I make some error, if I

check on myself, I probably would not see my error, I probably would make the same error because I already have in my mind that's the way it's done. So ideally, which is what the Guide suggests, somebody else should make a check, so he or she may not have the same idea in mind that this should be done this way, therefore automatically say that's okay.

Any problem with --

MR. LANDERS: Yeah, may we suggest you go ahead and use the word "by qualified personnel who are ideally not involved with the activity", there's a difference.

MR. TSE: This is the Guide in any case, but I understand your point. Suppose somebody used this as the regulation, then they would say we must have this person.

MR. LANDERS: Right.

MR. TSE: Good suggestion.

LT. CMDR. PULCRANO: By activity, you don't mean like the hospital is the activity?

MS. RHODES: Well that's what I was thinking. I work for the hospital and I'm involved in the activity.

LT. CMDR. PULCRANO: It might be better if you would say that particular department, because you could have personnel in the hospital outside of the department that is doing this, say oncology or nuclear medicine, that you could have come in and do it. Activity sounds like if it's somebody connected with this hospital, they can't do this audit.

MR. TSE: Actually, I thought that activity in my thinking perhaps even less broad than the department, meaning the procedure I'm working on. If I'm doing the nuclear medicine procedure and I make the measurement and so on, do the calculations, that person should not audit himself on those activities.

LT. CMDR. PULCRANO: So as long as the person does not audit himself.

MR. TSE: Right, essentially that's the meaning of that. But if your interpretation is much broader like the hospital, what do you suggest, such that the intention would be clear? Do you have any?

LT. CMDR. PULCRANO: No, as long as I understand what your intent is there, I have no problem with it. Just as long as I don't audit myself, the oncologist doesn't audit himself, he can audit me and I can audit him. Okay.

MR. TSE: The problem though, many people who are not here cannot hear our discussion and may have the same misinterpretation like you had. So how can we modify it such that those people will also understand.

LT. CMDR. PULCRANO: Oh, I see.

MR. TSE: Any suggestions?

MR. LANDERS: How about just a statement that an audit will not -- an individual will not audit work that they themselves have performed.

MR. TSE: That's a good try.

MR. CLARK: I think John said maybe a department manager could do it because other people in the department have done some of the work.

MR. TELFORD: That was David's I believe, that's what he does.

MR. CLARK: I couldn't remember who said that. But even myself having done a third of it, not having done it all, I guess I could be semi-objective, I don't know.

MR. TELFORD: Probably.

MR. TSE: Okay, this is a good point we need to work on.

Any other points on these? Yes?

MR. GARRISON: The management means the licensee's management? I'm still not clear on management. We're not talking about hospital management, we're talking about say the upper -- say the radiology department management would be appropriate?

MR. TSE: Right, that's today's discussion, but originally as written, licensee's management meaning the person -- hospital, right. The hospital licensee would be the hospital management. But today's discussion, we might -- different people raised different potential persons can review, we have to think of some way to indicate or include, perhaps like licensee management or his designee, or something because

there's so many. We heard the department could do it, quality assurance committee and so on. So we will consider the discussion and probably it will be changed.

Any other points on these two sections?

(No response.)

MR. TSE: If not, let's go to item two. Item two are several general elements which are applicable to all program areas, meaning nuclear medicine, diagnostic therapy, brachytherapy and teletherapy.

Anybody have any questions or suggested deletions or modifications on these four elements?

(No response.)

MR. TSE: Some of them were already discussed. Yes?

LT. KIRTLAND: One suggestion is you might include something about how to make corrections. If you make a mistake, how do you -- if you write over numbers, some people will write over numbers and they'll say I put a 6 over the 7, so obviously it's a six, but somebody coming along later reading it, reads that it's a seven. That's not really legible. That could be corrected by a statement referring to how to correct mistakes in your own handwriting. One thing I try to do is say you strike out with a single line and then put the correction next to it.

MR. TSE: Now the element 2.1 says will be legible.

LT. KIRTLAND: Yes.

MR. TSE: And different institutions may have a different way how do they want to correct or make sure they are legible.

LT. KIRTLAND: Or in the Regulatory Guide, so that it's just a suggestion.

MR. TSE: That's right. Now how you want to add the suggestion in, meaning you want to add a new element to say that if --

LT. KIRTLAND: No, I just am throwing this out, you can take it or not, and that's just to make it -- put in a specific suggestion about how to correct mistakes that are made in one person's handwriting.

MR. TSE: Ken?

MR. FRYMAN: Along those lines too, I was thinking you could have something like "consistently documented" in there because we have different physicians who write all over the chart in different spots and while it's correct and legible and all those things she's listed it's very difficult to find and it lends itself to all sorts of different -- in the end it's kind of unclear and there's likely a misunderstanding. But that is the catalyst for that in my case. So I wondered if you could have a document, just whatever the policy or the manual, have that sort of thing documented -- I don't know if there even is one -- that there's a consistency as far as the documentation goes.

MR. TSE: So you would like to add the word "consistency".

MR. FRYMAN: "Consistently documented" I was thinking. Like when you consistently document it, legible, written clearly, whatever.

MR. TSE: Okay. Any other suggestions?

(No response.)

MR. TSE: Let me -- maybe before that, let me ask the other participants whether you think it's a good idea to add "consistently documented" and add how to correct errors, in the Guide.

MR. LANDERS: I didn't hear that.

MR. TSE: Oh, there's a suggestion to add some words consistently documented" in 2.1.

MR. MORRIS: Where is that being added? I didn't get that, at what point in 2.1?

MR. FRYMAN: I was thinking just specifying just prior to "legible", "clearly documented, legible..." and after that.

MR. TSE: Clearly is already there, written clearly is already there.

MR. FRYMAN: I'm sorry, "consistently", whichever, the adjective could be different.

MR. TSE: I think that his suggestion is that certain information should be written on certain locations.

MR. FRYMAN: Right.

MR. TSE: Of that piece of paper, whichever the paper is, consistently in that particular location so that people can easily follow it.

MR. LANDERS: No, I disagree with that.

MR. TSE: You're talking about nuclear medicine or you're talking about teletherapy?

MR. FRYMAN: Probably more teletherapy, but I could see how it would be useful in either one of those areas because right now the way it is, it could be in the progress notes, it could be in the blood work, and that would really be incorrect if I'm interpreting this correctly, and that would just seem a little bit more specificity.

MR. TSE: So that would cover the therapy as well as nuclear medicine, his comments are applicable to therapy and nuclear medicine an well.

Is there any problem with the word "consistently documented"?

MR. LANDERS: I don't understand its intention. Records relating to medical use will be consistently documented and legible, is that the suggestion?

MR. TSE: Yes. We'll take this comment and think about it. I know somebody may have some concerns of using these words, how do you interpret them.

Yes?

MR. GARRISON: I think this is all well and good just as long as it's a guide, because I think it's going to be hard to enforce that whole thing anyway. Just as long as it's a guide, I think you can put in 50 words. Writing clearly and everything, just leaves some doubt. I just think you've got to take it in the context of a guide to help people write these things.

MR. TSE: Right, the purpose of this Guide is as a guidance for people to prepare their quality assurance programs. But we have to be careful because somebody already stated very strongly some other state, agreement state, or some other people may use this Guide as the regulation and therefore -- yes?

MR. TELFORD: Tony, maybe Kenneth has the thought that he's searching for a standard format, if he had sort of a standardized record where he knew where to find this information, that may be helpful to minimize this likelihood of misunderstanding. So if he has a suggestion, you could say the use of a standard format would be helpful.

MR. TSE: Yes.

LT. KIRTLAND: Or may be helpful, make it a little more optional.

MR. TELFORD: A standard format is optional as a suggested way to --

MR. LANDERS: I wouldn't object to a standard format

as long as I got to design it.

(Laughter.)

MR. TSE: Okay, John has a good suggestion.

Any other suggestions on Section 2?

(No response.)

MR. TSE: If not, we go to Section 3.

MR. LANDERS: Wait, wait --

MR. TSE: Yes?

MR. LANDERS: Did we say anything about 2.3 yet?

MR. TSE: No.

MR. LANDERS: 2.3, keeping 2.2 in mind, if there's something that you're unclear on, it says you will stop the medical use and seek guidance if there's a discrepancy. I don't see how you get to 2.3 if you haven't done 2.2. I mean where do you start medical use if you're not clear on what you're doing to start with?

MR. TSE: Well maybe you thought you are clear to start and then halfway you find you have a problem. If you find any discrepancy, then the suggestion is don't go ahead first. Clarify, find your problems, clarify the discrepancy and then you continue. That's the idea.

Now if you truly understand from item number 2.2 then you will not have 2.3.

Okay, any other questions in Section 2 -- let's go back to Section 2.

MR. LANDERS: Yeah, 2.4. What does this mean? Does it mean that, for example, a technologist administering a therapy treatment will be reading some directions or instructions on how to do it?

MR. TSE: Well the person, for example, in nuclear medicine, before you administer the dose, you want to make sure that that's the dose and that's the patient -- that's the correct patient, that's the correct dose. And similar in teletherapy, brachytherapy, you want to make sure that these are the correct patients, correct dosages or correct sources, so on.

Any other questions, comments, suggestions, on Section 2 still?

(No response.)

MR. TSE: If no, then we can go to Section 3. Yes?

MR. GOMEZ: It says "except in emergent situations", even in therapy?

MR. TSE: No, it's just -- all 2.3 --

MR. WIEDEMAN: It says "diagnostic or therapy event (except in emergent situations)".

MR. TSE: Right, so they're all included. If it's an emergency situation, then you still go ahead.

MR. GOMEZ: If it's a therapy emergency, what?

MR. WIEDEMAN: What is a therapy emergency?

MR. GOMEZ: Yes, therapy emergency.

MR. WIEDEMAN: Compressed superior vena cava, compressed spinal cords, where they want a heavy dose immediately to relieve the pressure.

MR. LANDERS: To stop permanent paralysis.

MR. WIEDEMAN: Radiopharmaceutical therapy, I'm not sure if there is -- there's probably something that could be considered an emergency.

MR. TSE: Diagnostics possible.

MR. WIEDEMAN: Diagnostics, lung scans are many times considered an emergency, to look for pulmonary embolism.

MR. TSE: Actually this word is "emergent", which doesn't include emergency. It may not be emergency case.

We're still in Section 2. I'll just wait awhile to see if anybody else have any questions in Section 2.

(Brief pause.)

MR. TSE: Yes, David.

MR. GARRISON: If I was reading this for the first time and I was writing up a QA program, I'd look at 2.4 and read it and you made an example of the correct patient and dose with the -- I would have no idea that's what you meant. I don't know if adding regular human language would help -- I don't see how people -- I know since I've been to these, I'm kind of in tune, but if I got this Guide -- I don't know, can you add examples to help people?

MR. TSE: Yes, we could.

MR. GARRISON: I just don't see how anybody is going to decipher.

MR. TSE: Yes, we could give examples. In fact, you heard this morning Darrel's discussion, we add certain items into the review, program review criteria. We could add those items into the Guide also as alternatives. In fact, that's what I intend to do, so you have a good suggestion, to add certain, for example, elements -- for example, items into the 2.4 so that people would know what we meant.

Yes?

LT. CMDR. PULCRANO: Maybe if we took the term "medical use", took that out and said in effect that we'll verify that the radiopharmaceutical and method of administration is in accordance with the prescription or diagnostic referral.

MR. TSE: That would be part of a solution, but that would be limited to the radiopharmaceutical side. But this element we included the therapy, brachytherapy, teletherapy, that's why these words are used. However, we still understand the point that people may not be able to easily understand this element. We could expand it and add some examples. That we could do.

Yes, Darrel?

MR. WIEDEMAN: Plus medical use is defined in the regulation, intentional administration of byproduct material.

MR. TSE: Yes. Any other questions on Section 2, comments?

(No response.)

MR. TSE: I'd better wait a little bit longer.

(Brief pause.)

MR. TSE: If not, then we'll go to Section 3. Now Section 3 is additional elements for radiopharmaceutical therapy plus the iodine greater than 30 microcuries. We have quite a bit of discussion on 30 microcuries. For now, we just assume, if this is applied to therapy, that what our elements should be. As far as the 30 microcuries, per today's discussion, we will consider how we want to modify that one.

So with that, we could go into Section 3 to see if anybody have any suggestions, comments.

MR. GARRISON: I think on 3.2, it would be helpful to add at the end of the sentence "will make and date a prescription with radiopharmaceutical route of administration".

MR. TSE: The word "prescription" is already defined in the regulation.

LT. CMDR. PULCRANO: Under 3.2, can we put in some actual verbiage there that will be up front, that will allow -- or let the technologist know that he can take verbal instructions over the phone from the authorized user?

MR. TSE: Now this is therapy.

LT. CMDR. PULCRANO: No, this is for diagnostic.

MR. TSE: But this section --

LT. CMDR. PULCRANO: It says "and diagnostic".

MR. TSE: Right, but that's a procedure involving more than 30 microcuries. Now the words "30 microcuries" we had some discussion this morning, so we might consider changing it. Now even if we don't change it, the problem I think we all talked about this morning, the 30 microcurie number is essentially to alert the pharmacist and the technologist if you have iodine which is greater than whatever the amount, X -- this says 30, let's use X -- microcuries, millicuries, you must not go ahead unless you have a prescription from your authorized user. I think somebody made a statement that QA may not help to mix up with 30 millicuries, microcuries, I think that the proposal we have is to use this vehicle and if a technologist, a pharmacist sees an order for iodine 131 greater than a certain curie level, they must have a prescription from the authorized user. That way, it would avoid the technologist making some -- unknowingly making some switch, and that's the reason we put it in here.

LT. CMDR. PULCRANO: Okay.

MR. TSE: So with that in mind, would you think oral should be acceptable, or not? Except emergency, but I do not really see any emergency.

LT. CMDR. PULCRANO: Well that was the only thing I was referring to, is after normal working hours when we do not

have a physician on board. I'm not really sure how often something emergent or an emergency would crop up where you would have to get into the 30 microcurie or greater iodine range. If it's a likely possibility and if you want to wait the time for the doctor to come from home to the hospital instead of going ahead and performing the procedure, you know, then that's fine. If you can't wait the 25 or 30 minutes for the doctor to get there, then you might have a problem because you can't start without the doctor saying okay.

MR. TSE: But that's not in our framework one we're talking about. Under the definition of prescription, I think this emergency is built into that.

LT. CMDR. PULCRANO: So you're saying if it's emergent, then it's okay.

MR. TSE: Right.

MR. WIEDEMAN: I might add that the NRC normally would never question a physician on whether something was an emergency. Now I've had a lot of calls saying hey, we have an emergency case. If the authorized user said it's an emergency and the referring physician said it's an emergency, it's an emergency.

LT. CMDR. PULCRANO: Okay.

MR. WIEDEMAN: We've had cases where they want to use byproduct material in a hospital that's not even licensed to use material where they have a lung scan that they need and

they want to borrow material from another hospital.

MR. TSE: Yeah, the footnote says that if it's an emergency, you just go ahead. But then a written record shall be made within 24 hours.

Any other questions, comments?

MR. LANDERS: Are you on 3 now?

MR. TSE: Yes, still on 3.

MR. LANDERS: Oh, okay. In 3.3, I'd like to add the word "recorded" before "prescription" in the first line.

MR. TSE: Any change in the --

MR. LANDERS: "Recorded prescription".

MR. TSE: Prescription is written.

MR. WIEDEMAN: It says on the next line "will be recorded".

MR. LANDERS: Oh, you're right, a prescription is written, that's right.

MR. TSE: Okay. Then if you want to change it --

MR. LANDERS: Until it's written down, it is not a prescription. If he says give this patient two millicuries and until he goes and writes it down, it's not a prescription.

MR. TSE: But in the therapy area, I think we did not really mention oral. In the diagnostic, we had a lot of discussion, but this is therapy.

Any other questions, comments?

MR. LANDERS: Again, back in 3.2, the "authorized

user will personally make and date a prescription". Now I would assume, per our previous conversation, that anyone could write the prescription down, but the authorized user would have to sign it.

MR. TSE: We have discussed that, so I'm glad you mentioned it. We might want to consider that here.

MR. WIEDEMAN: Let's take for instance a broad scope medical program. You may have one director of the nuclear medicine department that's been approved by the radiation safety committee. But under him he may have 15 physicians that work under his supervision. Now in my interpretation, any one of those 15 physicians working under the supervision of that authorized user could sign it.

MR. LANDERS: Right. I didn't mean to exclude them, but I did mean to specify that the physician is not required to literally write the words but only has to sign and date.

MR. WIEDEMAN: Oh, okay, yeah. The technologist could write out the slip and as long as the physician signs and dates it, then we've accepted that.

MR. TSE: Correct, that's a discussion we had this morning and we will incorporate that later.

Any other questions?

MR. LANDERS: In 3.5, I remember this same conversation from before, we need to specifically state whether the dose administered agrees or does not agree with the

prescribed dose?

MR. TSE: No, I think we discussed that last time.

MR. LANDERS: And those changes will be incorporated but have not been?

MR. TSE: We will consider those, we know your comments, and if there is a prescribed dose and administered dose and it's obvious that you don't have to say they agree or not agree.

MR. LANDERS: Good.

MR. TSE: That's a discussion we had last time, but it's good you mentioned it.

Anybody else have anything on Section 3?

(No response.)

MR. TSE: No? Then let's go to Section 4. This is for brachytherapy.

MR. ARGAWAL: I have a comment on Section 4.5.

MR. TSE: Yes?

MR. ARGAWAL: "After implanting the brachytherapy sources, radiographs will be obtained", it is impossible in certain cases.

MR. TSE: Yes. We have discussed that particular item also in the pre-workshop. We have not changed it yet, but we understand this is a problem and these dummy sources or appliances would be included.

MR. ARGAWAL: After loading -- certain superficial

therapy, it's not possible. And generally after loading dummy sources, the radiographs --

MR. TSE: That's correct.

Other questions or comments on this section?

MR. ARGAWAL: In 4.9, I did not follow the sentence "The prescribing physician will make a notation of t his determination in the records of the administered dose." Like because of the patient's health he had to do this -- would that be -- if it is written that delaying treatment in order to perform the checks of those calculations will jeopardize, or he had to do the treatment, does he have to make that notation in it, that it is done and it is taken as evidence -- once the dose administered has to be entered into it, which is written, the checks will be performed and entered into the treatment chart. I do not see the relevancy of that -- saying that since the person has made the emergent treatment and that calculation has been done. Just writing that this has been done because of this, I do not understand the need of that, the recordkeeping need.

MR. TSE: Okay. The suggestion in this Guide is that before the 50 percent of the dose is delivered, you should double check on your calculation. That's a suggestion. But if it's emergency, and you don't have any person to double check and you don't have time to do a double check, you could go ahead first and do your double check later. And to be able to

do this double check later, the physician needs to say something about why I should go ahead first, which is some kind of emergent situation.

MR. ARGAWAL: What I'm saying is if it is to be done and double checked and all that, writing with this kind of a formidable schedule here does not serve any purpose, if he has to double check and calculations are to be inserted into the treatment chart. What's the need of this?

MR. TSE: Oh, for the double check afterwards?

MR. ARGAWAL: It's written that the checks of the calculations will be performed within two working days of the treatment -- they will be performed. So now why he has to write a statement, a general statement, that they were delayed because of the emergent situation? The date will be there, the delivery will be there, the person will sign that the treatment starts without the treatment (sic) but then he has to make a statement that this double check delay has been done because of the emergent situation.

MR. WIEDEMAN: It just says in there a notation. You know, if the physician put a note in the chart "this is an emergency situation, we had to reduce the size of the tumor and therefore we went on with the treatment". Two days goes by and now someone should go in and do the double check to make sure we have the right sources t here and the dose is properly distributed.

MR. ARGAWAL: I agree with that. I think the statement says that he has to say that why -- not just the emergent situation, but why he is delaying double check. Once he has written emergent situation, there should not be any need of a statement of delaying the checks.

MR. TSE: Oh, I see. You're saying that the statement here requires the physician to make two statements.

MR. ARGAWAL: Right.

MR. TSE: I thought it's only one, if he notes that this was emergency situation, then he could delay the check.

MR. ARGAWAL: Should he say delay the check or just say that this administration has been done in an emergent situation? That's all. "Emergency", and sign. Once they say emergency and the physician has signed, he has to say that now the double check can be done within two treatment days, has to put a statement in. That's what I'm trying to clarify.

MR. TSE: I don't think this statement says that he has to say that. The determination is to determine that this was an emergent situation. Once you say that, then he could just go ahead and do it without the double check.

If it confuse you, how do you think we could change it so that you would be clear on this point?

Anybody else who has this problem, therapy people?

MR. LANDERS: I don't think I see a problem. I think it allows the physician to say this is an emergency, we will

treat.

MR. TSE: That's right.

MR. ARGAWAL: Okay.

MR. WIEDEMAN: I'm not going to question the physician. That's a medical decision..

MR. TSE: Okay. Yes?

MR. LANDERS: In 4.8, the last line, I would like to suggest the word "will" be replaced by the word "should".

MR. TSE: 4.8.3?

MR. LANDERS: No, 4.8. The paragraph preceding all the sub stuff.

MR. TSE: Oh, "will check the dose calculations" to "should check".

MR. CAMPER: Let me ask you a question on that if I may. Do you have any problem with performing this type of secondary check before 50 percent of the dose is administered?

MR. LANDERS: No, unless during occasions when there's not really an emergency and the personnel to perform this double check are not available, the states comes in and asks me have I violated anything and I have to say yes, I have, because I didn't do this because the word was "will" instead of "should". I understand that I should do it. My question is on those situations when I can't do it, what kind of problems are there going to be.

MR. TELFORD: How about the word "normally".

MR. LANDERS: Yes, fine.

MR. TELFORD: Right in front of "before".

MR. LANDERS: That's fine.

MR. TELFORD: That's been suggested to us in other workshops.

MR. LANDERS: Good. I'm used to the NRC reports using the word "shall" and the word "should" differently. In one case they have teeth in it and in the other case they're trying to point out what really is good practice.

MR. TELFORD: We have to look at the verbs that we use in our whole Guide, because the whole Guide is a "should". It's not a "will", it's not a "shall". In regulation, we say "will" and "shall" but in the Guide, it's all "should" and we have to -- that's the way you should take all this.

MR. LANDERS: Right.

MR. TELFORD: But your point is well made and perhaps "normally", some qualifier like that is the way to soften that.

MR. LANDERS: Sure.

MR. TSE: Okay. Any other questions?

(No response.)

MR. TSE: No other questions on brachytherapy. Are we finished with brachytherapy?

MR. LANDERS: Finished from the point of view that back in the spring we talked a lot about this and you've just told us awhile ago that all we talked about this is still on

the record.

MR. TSE: That's correct, the notes are already here, it's still a valid consideration.

Now we'll go to teletherapy. Any suggestions?

MR. ARGAWAL: I have some comments on 5.7, I don't know whether anyone --

MR. TSE: No, please, go ahead, 5.7.

MR. ARGAWAL: In 5.7 there is an independent check. The independent check doesn't mean that the person which has been defined here also, an individual who did not perform, that means in the same institution if there are two people they can do it, one person can check the other, if the other person meets the requirements. It says that if it is different by five percent. Now suppose a person does the calculation and find five percent error. Should he first examine whether he made an error or not, or he should go ahead and call another independent?

MR. TSE: You're reading the five percent from 5.7.1?

MR. ARGAWAL: The output differs by more than five percent, at what point that difference is to be taken into account. If the person calculates 1.06, which makes it six percent, do you call an independent check or first you should go and find out did he make an error?

MR. LANDERS: That's a good point.

MR. ARGAWAL: It looks like here that as soon as he

found 1.06 he should get an independent check. I don't think I can correct it but I just wanted no

MR. TSE: Let me explai the wording is not clear but essentially it is that Part 35, there are certain requirements when you need to do an annual calibration measurement, and there's several conditions. One is annual, another is when you have a new source, another one is if your spot check is different by five percent, you need to do a full calibration measurement. If you're going to do that, the full calibration measurement, as a result of source change or as a result of your spot check is more than five percent difference, then after your full calibration measurement, you need to do an independent check.

MR. ARGAWAL: After the source change, it will always be more than five percent difference because there is no prior determination of the output, so prior data and the new source data, the output will be double or more than five percent, and this does not say -- this say that resulted from changing the source. And if the source has been changed, the output has to differ by more than five percent.

MR. TSE: That's true.

MR. HAIDER: That five percent refers to that every month you calibrate it, just the last month.

MR. ARGAWAL: Yes, I read that when it says spot check, but it says "after a full calibration measurement that

resulted from changing the source" -- don't read the "or" -- "when the output differs by more than five percent from the output obtained at the last full calibration corrected mathematically".

MR. TSE: Oh, I see what you're pointing out. Let me --

MR. ARGAWAL: This five percent rule does not apply to changing the source. If it's the spot check measurements, it's all right.

MR. TSE: Let me put it this way. The five percent only tied in to the spot check. That five percent -- the phrase "five percent" come after that doesn't apply to the source change. You either have a source change -- that's condition one -- or condition two, if you have a spot check which is more than five percent.

MR. ARGAWAL: So you want an independent check after the change of source, that means two people performing the full calibration?

MR. TSE: That's one alternative. There's another alternative stated as 5.7.2(2), is to use a TLD.

MR. HAIDER: I just have one comment about this five percent.

MR. TSE: Please go ahead, that's where we are, at the five percent.

MR. HAIDER: Suppose something is wrong with my

chamber, you know a lot of times chamber response changes and my chamber response changed and I get more than five percent. Why do I need to do a full calibration if I figure out well that was the chamber, I've got another set of chamber, or I borrow from somebody else or somebody else just came and checked the output, why do I have to do a full calibration including the wedges, blocks and all that?

MR. TSE: That's in the regulation.

MR. HAIDER: Yeah, but I'm just asking why.

MR. TSE: I think --

MR. HAIDER: I mean I know where my problem is, my chamber response changed.

MR. TSE: Suppose everything is correct, your measurement system is correct, generally you shouldn't have such a large difference from your original dose. And now you do have such a difference, obviously something is not correct there.

MR. HAIDER: Well that's true, but like I said, if I already identified that the problem is with my chamber, now why do I have to --

MR. TSE: Oh, you mean -- if you know, then that's not five percent off.

MR. WIEDEMAN: It's only when you don't know what the discrepancy is.

MR. TSE: That's not five percent off. Your chamber

has a problem, you take another traceable chamber and measure it again, measure that it's within the five percent, of course you don't have to do it.

Excuse me, did we answer your question?

MR. ARGAWAL: Yeah. The sentence reads "or".

MR. TSE: Right.

MR. ARGAWAL: I agree with that.

MR. TSE: Last time we learned you should use A or B, so I think I will do this two, and the two conditions, A, is a changed source, and B is if you have five percent. The phrase comes with that.

MR. ARGAWAL: On a spot check.

MR. TSE: Right.

MR. HAIDER: One more thing.

MR. TSE: Yes.

MR. HAIDER: When we change the sources, if I have two independent methods of determining the accuracy, does that satisfy instead of having another person take out the TLD reader and I use the TLD reader and find the output and I also have an ion chamber in there and they agree, do I still need to bet somebody else to come down and check?

MR. LANDERS: How did you calibrate the TLD?

MR. HAIDER: I buy it or I have a few chambers and I use one in water and another one in air. There are two different things, I have two meters too, and they agree. And

if they do -- it's not necessarily TLD, I have two different ion chambers, I measure one in air and I measure one in water. I have two electrometers, two independent checks.

MR. WIEDEMAN: Both of them have been calibrated?

MR. HAIDER: Both of them calibrated and inspected, yes, and they both agree.

MR. TSE: Okay.

MR. HAIDER: The only thing that's the same is just my hands.

MR. TSE: The current suggestion here under (1) is to have another independent person and another set of instruments. Now item number two is to have a TLD. But you mentioned one person, one physicist, with two independent sets of instruments. What do you think -- I just want to ask the other people, would that be independent check?

MR. HAIDER: I think it's an independent check, it's just the same person doing it.

MR. TSE: Right, the same person doing it. But if anything -- if he somehow neglects certain things by using one set of instruments, could he also neglect --

MR. HAIDER: Like I said, it's two sets of instruments.

MR. TSE: No, no, no. I'm not talking about instruments, I'm talking about procedure-wise.

MR. LANDERS: I would have a comment on that, I would

think if you're going to require the two measurements, I think either the two measurements need to be different techniques so that the same error could not be produced by the same person in the same way in both techniques, or two different people have to be involved.

MR. HAIDER: And like I said, they're in air and water, two different things. You can take the air dose or the water.

MR. LANDERS: And if your barometer is off, both of them are in error.

MR. WIEDEMAN: But you would be consistent.

MR. LANDERS: That's true.

MR. TSE: That's kind of the problem we see. But that's a good suggestion.

MR. HAIDER: But also what happens is when you buy a source, usually the manufacturer, M.D. Anderson or the University of Wisconsin, will sell you the source and tell you that okay, this source is 8000 RHM, you can convert your calibration easily to RHM and see if that matches. Mine matched within one half percent. I took mine, I took it in water, I did it in air, and I looked at when the source was delivered to me what was the RHM there and I compared all of these and they all agreed within two percent. Now the manufacturer already gives me that.

MR. WIEDEMAN: That's true, but I would take your

readings before I'd take the manufacturer.

MR. HAIDER: Oh, I took mine.

MR. TSE: That's a good point.

MR. HAIDER: Actually what I'm trying to do is save $500. I need that $500 a year to buy some equipment. And if I ask somebody -- I'm in a small town, if I have to get somebody I have to pay three hours travel time and pay the physicist to do the calibration while I know there's nothing wrong with it. If they didn't agree, then I would say okay, well there's something wrong, I think we need to have somebody down here.

MR. WIEDEMAN: Well let me ask you this, how long does it take for the TLD system through M.D. Anderson or the University of Wisconsin -- you make a formal request and they usually send it out within a week.

MR. HAIDER: Well that can be done.

MR. WIEDEMAN: That's an independent check.

MR. TSE: That's covered too.

MR. HAIDER: But is that acceptable? Like you know, you already have three different ways to do it.

MR. LANDERS: Can we take the manufacturer's calibration into account or must that be useless to us?

MR. WIEDEMAN: The manufacturer doesn't meet Part 35.

MR. LANDERS: Okay.

MR. TSE: The question is still if one physicist uses two independent sets of instruments, would that be considered a

good check. What do you think?

MR. LANDERS: If nothing is common but the human, I would think so. None of the measuring instruments, none of the temperature, pressure measuring instruments.

MR. TSE: It would be a good check?

MR. LANDERS: I would think that would be a satisfactory -- if the techniques were different, they were not both in air or both --

MR. ARGAWAL: I disagree with that. I think independent -- if it has to be checked, it has to be independent, the person should not be the same person because there are -- it's not really revealing, there are the same factors involved, it is not just the reading of the chamber. And there are factors involved. Even if it is simple, there are factors and some people make errors on simple. A check is needed because there is supposed to be an error, that's why we are -- if that error is to be found, then it has to be independent check. Otherwise, there will be no -- I don't think there will be a check -- independent check?

MR. TSE: Do you have anything?

MR. FRYMAN: I think it would be beneficial to have that too because it is totally independent, in a court of law you have to have a backup, that is what that means. I feel certain that they wouldn't recognize you doing your own work and then backing yourself up. In your case, that'd be fine if

you're good and all that, but I think that could be extremely hazardous.

MR. TSE: So your suggestion is that one person through separate instrumentation may not be --

MR. FRYMAN: Because if you ever have to be independent later on, somebody else is going to ask the same question and it's better to have it as a backup, that way you've got a verification of something that you know yourself you couldn't have made a mistake.

MR. TSE: So would you consider like a TLD would be good alternative if you didn't have another person?

MR. HAIDER: Yeah, I see no problem with that.

MR. TSE: No problem with that. Okay, thank you.

MR. HAIDER: I was just wondering, because that's what I did last time.

MR. TSE: That's okay, this is a guide.

MR. LANDERS: In Section 5.2, the second line, I would like to see "an authorized user will personally" instead of the word "make" have the word "sign".

MR. TSE: This would follow the same discussion we had, correct. Yes?

LT. CMDR. PULCRANO: The therapy physicist had some questions about some of the terminology that was used and wanted to know if his terminology was the same as what was being used here. In paragraph 5.2, they talk about treatment

volume, he told me, we don't do business on volume, we do business on treatment point. And if he uses treatment point, will that be misconstrued, or is treatment point and treatment volume okay to cross back and forth?

MR. TSE: I think --

MR. WIEDEMAN: From our previous workshop it was recommended that that be changed to "treatment site".

MR. TSE: Right, "treatment site".

LT. CMDR. PULCRANO: Go on down to 5.4, when we talk about sign the chart, sign something, they were wondering about using initials rather than signatures. We did discuss once before the possibility of saying okay, we'll start a log book and all of the doctors and physicists and technicians will print their name, sign their name and put their initials in the book and that would be updated every so often. And in this way they could go to that book and say yes, I can identify these initials as being this person and they can put the initials with the signature. Would that be sufficient rather than saying we have to sign everything?

MR. WIEDEMAN: Well of all of the therapy charts that I reviewed, there wasn't any room to sign.

LT. CMDR. PULCRANO: That's the point, there is no room.

MR. WIEDEMAN: And we found it acceptable to initial them.

LT. CMDR. PULCRANO: Okay, great.

MR. TSE: Are you -- continue if you have some more.

LT. CMDR. PULCRANO: In paragraph 5.10, they talk about calculation of dose in air, why calculate dose in air when we're really considering what's a dose to the tissue? Why shouldn't we use tissue equivalent phantoms to do these calculations or calibrations?

MR. TSE: This particular element has been discussed in many workshops and we intend to change this one.

LT. CMDR. PULCRANO: Okay.

MR. TSE: The idea is to match the measured value versus calculated value to make sure that the calculation is okay. And we're going to change it. How to change it, we're not quite sure, we're going to discuss. So that item will be changed.

Have you finished yours?

LT. CMDR. PULCRANO: Yes, I'm finished, thank you.

MR. TSE: Okay. I think Roy's first and then you.

MR. LANDERS: Just on a hit and miss basis, the same suggestion I made earlier concerning the use of the words "shall" and "should", "will" and "should", so on and so forth apply generally to the whole thing.

MR. TSE: Right, we will consider that in the whole. There's two groups of thought we used. One is called the model plan and the model plan usually works well because the licensee

can just adopt that one. But actually it should be "should" because it's a recommendation. But we'll consider this whole question together.

Okay, Tawfig.

MR. HAIDER: I have I guess two questions, in 5.10, number (2) "a field with and without the wedge of greatest angle into the water at a 45-degree angle" and then you want to compare that with in-phantom measurements. Now I don't know if that can be read to rotate my phantom 445 degrees and then rotate the entry angle 45 degrees and make a measurement and then compare.

MR. TSE: That's what I said we're going to change.

MR. HAIDER: Oh, you're going to change that one.

MR. TSE: Right, the whole section.

MR. HAIDER: Oh, the whole section.

MR. TSE: All the conditions under 5.10, we're going to change.

MR. HAIDER: And 5.9, is that really always necessary? Like for example, when I do a full calibration, I can check SST-70, 75, 80, 85, 90. I will do this and see if the inverse works or not. And say, for example, I have something at 65, do I need to make an in-phantom measurement?

MR. TSE: That's within the range or you measure outside the range?

MR. HAIDER: That's outside the range.

MR. TSE: Outside the range, you measure -- according to this, yes. Now do you think it should be measured or do you think that that's good enough?

MR. HAIDER: Well if it's off by five centimeters and English square looks pretty good, I don't see any reason

MR. TSE: But are you comfortable without measurements?

MR. LANDERS: Well you could extrapolate it to 200 centimeters?

MR. HAIDER: Well I wouldn't do that either, it's just five centimeters where I'm comfortable.

MR. WIEDEMAN: Well let me ask you a question on that. Let's assume that you don't do very -- you don't have bodies very often, maybe one or two a year. Now all of a sudden your physician says you want to do a hemi-body and I want to deliver about 400 rads on day one. That's a lot of rads for hemi-body. Now you could go back right now and take your annual full calibration or your monthly spot check and extrapolate it out --

MR. HAIDER: No, you can't.

MR. WIEDEMAN: -- and come out with some kind of a dose.

MR. HAIDER: No, I'm sorry, you can't do that because the scattering conditions are different.

MR. WIEDEMAN: Ah, last workshop a medical physicist

told us the scattering from the concrete floor had no effect at all.

MR. HAIDER: No, I disagree with that.

MR. WIEDEMAN: Well I did too, but -- but what I'm saying, it's only five or six centimeters, you know, when it's just like sometimes you want to do -- like you want to do a spine, you want to get a closer SST so you'll have a sharp fall off. In that case, scatter condition is the same between going from 65 to 60 centimeters, it's the same.

MR. WIEDEMAN: A lot of the facilities, they cannot get a field size to cover hemi-body, so they move the table out of the way and they lay the patient on the floor and now they have to extrapolate inverse square back to the source.

What we're saying here is before you do that or before 25 percent is prescribed, if it was me, I would do it before the first treatment, but you know, that's a medical physicist's decision.

MR. HAIDER: I would too.

MR. WIEDEMAN: I would feel comfortable with making a physical measurement just to verify that I'm going to get 400 rads, but you're saying that that wouldn't be necessary?

MR. HAIDER: No, I said in that case it will be. Like if it's very small, off by only five centimeters, I think I don't need to do a measurement.

MR. WIEDEMAN: Oh, I agree, five centimeters.

MR. HAIDER: So can we just say this is a little bit relaxed? Two hundred centimeters is a whole different ball game.

MR. FRYMAN: Even less than that. (Inaudible comment.)

MR. HAIDER: Well what happens with ours, it moves anyway because everybody bangs that thing. You can just use a ruler and just measure it up from the laser, 20 centimeters up, works every time. The lasers are independent, it's on the wall and the optical is in the air, I don't know what it's there for, it's moved every other day, you know, it stays wherever it wants to, but you know, somebody checks it every morning, it's okay, but I know it's not okay. I try to do it every month -- I'm sorry, every couple of weeks or so whenever I get a chance, but anyway nobody uses -- everybody uses the lasers physically. So if I have to go five centimeters up or down, where I have not calibrated it, I think I should be able to do it. But if y'all ask for it, we'll do it.

MR. WIEDEMAN: Well I would buy a five centimeter difference if you took your measurements at 80 centimeters distance and you decided to use an 84. I mean that's a very simple calculation.

MR. HAIDER: Almost everybody usually will test the English square between 70 to 90 but occasionally, you know, somebody wants -- I know a couple of weeks ago we did a spine

at 60 centimeters and the reason is he wanted sharp fall off percent of dose just because of divergence, and I didn't feel I had to measure anything. We just raised the patient up, doing an English square, it works fairly well.

MR. ARGAWAL: If it works for 60 centimeters, it would work for 150 centimeters.

MR. HAIDER: No, it won't because of scatter conditions.

MR. ARGAWAL: Scatter conditions are different at 60 centimeters too, because of the near to the beam or the fire. I'm just saying that argument, how much it differs is another question but the argument is the same, that it would differ at 60 centimeters because of the electronic contamination in beam modifying and all that.

MR. HAIDER: If you were at 20 centimeters when the beam modifies, you shouldn't have any electronic contamination.

MR. ARGAWAL: You should not have these scattering conditions like he got of 200 centimeter if it is in air measurements and inverse --

MR. HAIDER: I'm sorry, I think the scattering condition we're talking about is from the floor and the walls, we're not talking about from the blocks. If you're away 20 centimeters from the block, you shouldn't have much contamination one way or the other.

MR. ARGAWAL: You would get that difference from the

floor if you are putting it at a distance of 400 centimeters in the same line. I disagree and I think nobody can find more than half a person, which you cannot judge from the laser beam.

MR. TSE: But in any case, the idea still is correct, if 60 is the maximum you measure or minimum you measure and you want to be 59, should you do a measurement. Generally these other recommendations at that very close range, you might not need to. But if you go to 50, would you want to? You would possibly want to.

Yes.

MR. FRYMAN: To get away from this, I've done this with electrons too -- (inaudible comment).

MR. TSE: You measure the full range.

MR. FRYMAN: I measure everything I can get my hands on because I don't ever do it again.

MR. TSE: That's one way to --

MR. LANDERS: These suggested guidelines say that you will in fact do it again and again and again.

MR. HAIDER: Every year.

MR. TSE: No.

MR. WIEDEMAN: Just include the monthly spot check if you're going to start using this new source skin distance routinely.

MR. LANDERS: Right. If you don't use it, then you don't need to do it.

MR. WIEDEMAN: I think the intent of this particular requirement -- not requirement, recommended guidance, was that you check, physically measure for anything that's out of the ordinary, that's not routine. You know, your wedge factors, you know, rather than using calculations, do a physical measurement just to verify that what you calculated was acceptable.

MR. TSE: Do you want to suggest how we should modify it?

MR. HAIDER: I'm just wondering if I made a mistake two weeks ago or not.

(Laughter.)

MR. TSE: Other questions or comments? Roy, you have a question?

MR. LANDERS: Back on 5.10, there was a point I was trying to make during our first session and I'm not sure I ever got across, perhaps somebody else did. I have two different kinds of computers that I use; one is what I call a full blown treatment planning computer that puts out iso-dose curves and does regular field calculations and things of this sort. The other is a dosimetry computer, just a table look-up device for certain protocol things we have programmed into it.

In certain aspects of the treatment planning computer, the dose rate for cobalt units is recorded as 1.0. Now when I make a source change, the new dose rate in the

computer is 1.0, it doesn't change. That aspect of it, I don't think I need to recheck, but the aspects where the dose rate in rads per hour or roentgens per minute or whatever are incorporated, I do need to check. Same with my dosimetry calculating computer.

I just wanted to address that concept one more time. If I have relative rates, not absolute rates, I shouldn't have to check all of those relative conditions, just the absolute conditions.

MR. TSE: That's what this parenthetical sentence is there at the end.

MR. HAIDER: I agree with him.

MR. TSE: Okay, let me explain a little bit first. If you have a new computer code --

MR. LANDERS: That's totally different, I agree with you all the way t here.

MR. TSE: Okay, even you change for a new source, you need somehow to calculate the exposure rate at a certain point. And you need somehow to go through the percent dose calculation in associate with the hand calculation to come up with how many rads per minute because the activity is not in the computer calculation.

MR. LANDERS: Right.

MR. TSE: With that set of calculations under certain conditions, you will have certain rads per minute. Now you set

up your measurement under the same set of conditions and then measure it to see whether they're close enough. So you still need to do a calculation but --

MR. LANDERS: When I calibrate my 10 by 10, for example, on the cobalt unit, the treatment planning computer is cut out of the process now because it doesn't know the rads per minute, all it knows is the output is one.

MR. HAIDER: It just spits out the dose.

MR. LANDERS: When I convert that computer generated treatment plan to a time setting in the chart, I'm using another computer or another set of tables. Those certainly have to be checked when the source changes, but I see no reason to check the original computer code which has not changed and does not use the dose rate.

MR. TSE: Now your computer code, when you have a phantom, the dose point inside the phantom, is a computer code involved with such a calculation, what percent dose at that particular point?

MR. LANDERS: Uh-huh.

MR. TSE: Okay, so that still involves a computer calculation. Then in addition you apply your curies conversion factor, whatever, to apply to the computer result and have your total dose rate, exposure rate. So do you still need to do the calculation to be able to find out a dose exposure, a dose rate at certain quantities inside the phantom that you want to

measure?

MR. LANDERS: I don't see how anything in my computer code needs to be rechecked. If it doesn't relate to the curie content.

MR. TSE: Yes.

MR. LANDERS: Provided I have not change the geometry of my source. For example, gone from a two centimeter source to a 1.5 centimeter source. That's a whole new ball game.

MR. TSE: But when you change the source, you normally do not involve a change of geometry, do you?

MR. LANDERS: No.

MR. TSE: Well how do you suggest that we can modify this sentence?

MR. ARGAWAL: Let me ask, does that mean that in the full calibration every year, just the spot check will do the same thing?

MR. HAIDER: No, no.

MR. ARGAWAL: Then you check those numbers related to 10 by 10 field size which you have in the computer, which are the related numbers, right? Can you not record on your computer the 10 by 10 one times that, 140, so you have rads per minute, one times that 140 is 10 by 10 and then when you go into 20 by 20 that 1.0 times 140 --

MR. HAIDER: You're using the main computer, it's not for output calculation, it's just for generating isodose. He

is checking in the small computer the output and he's going to check the field size factor in the small computer that he actually calculates the time, but the main computer, it's not going to know any difference between 1.029 and 1.029 in scattering conditions.

MR. ARGAWAL: So that computer does not give you a dose calculation.

MR. LANDERS: No, it certainly takes scatter into account.

MR. ARGAWAL: But it does not give you dose calculation, it will give you related isodoses, is that right?

MR. LANDERS: No, it does not use an absolute dose rate.

MR. ARGAWAL: So you don't use that treatment plan for treating the patient?

MR. LANDERS: Yes, we do.

MR. ARGAWAL: What if it doesn't nave the treatment dose, how much dose you have given to the patient, if it doesn't have the dose?

MR. LANDERS: It tells me to do what the physician wants done, I deliver 100 rads of given dose to this port, 150 rads of given dose to that port. Now I go to my little dosimetry computer and I determine how much time to get 100 rads of given dose to this port. And it doesn't matter whether it takes ten minutes or two minutes, the big treatment plan

computer always gives me the same 100 rads of given dose.

MR. TSE: It's normalized, essentially.

MR. LANDERS: In essence.

MR. TSE: Ken has some comments.

MR. FRYMAN: I was going to say technically the behavior of different source material -- (inaudible comment) based on differential scatter and composition of the source, purity I think possibly, you'd rise to something different if you were checking possibly in a treatment planning computer even though it is energy dependent, that can affect energy in the typical output you see as far as scatter and different contributions.

MR. TSE: Right, that's -- one way to look at is that you are sure if you try this at the same condition with the measurement. So Roy, what do you suggest?

MR. LANDERS: Oh, I've got a whole paragraph written.

MR. TSE: Okay.

MR. LANDERS: You want me to read it?

MR. TSE: You can just give it to us.

MR. TELFORD: No, let him read it.

MR. TSE: Okay, read it, then it will be in the record.

MR. LANDERS: This was what I sent in for our program. "Before the first use of a new or modified computer code for human dose calculations, those calculations will be

made for typical treatment techniques and compared with phantom measurements using the same exposure conditions. If computer code uses the source strength or output rate in absolute terms, a typical reference setup will be calculated with the computer code and compared with phantom measurements using the same exposure conditions. After any source change or full calibration pursuant to 10 CFR 35.632(a)(1) and (a)(2). If the computer code does not use the source strength or output rate in absolute terms, a source change will not necessitate the above check unless the source physical dimensions or radio-isotope change, in which case the typical treatment techniques, comparison, reference in this subsection will apply."

MR. TSE: Any comments?

MR. FRYMAN: I just want to know what process he would use to verify all the things that he was saying, because we accept pieces of equipment because of individual characteristics and it's possible to have -- I've had it happen, that's the reason I'm going on about this -- the difference in what they tell you they're putting in and what you actually get, the actual location type of associated things that go with that and it's possible that it could contribute to something that would give you a different number than you're expecting.

MR. TSE: So you would still check.

MR. FRYMAN: Yeah.

MR. HAIDER: You check it anyway since you're going that far. See, if you already changed the source, even if the source remained the same, would you not check the field size?

MR. LANDERS: That has nothing to do with the computer.

MR. HAIDER: Well --

MR. LANDERS: That has only to do with the new source.

MR. HAIDER: Well the computer does have a field size factor, does it not?

MR. LANDERS: Right.

MR. HAIDER: Aren't you going to check it against what you measured?

MR. LANDERS: I'm going to check the new -- I'm going to do a full calibration on the new source. If things are different as far as field size factors, dose profiles, things of this sort, then I've got to take that into account in my treatment planning computer.

MR. HAIDER: Okay, that's what I'm saying.

MR. LANDERS: But I'm not comparing against my treatment planning computer, I'm comparing with prior results that I know are in the treatment planning computer.

MR. HAIDER: Okay.

MR. ARGAWAL: Let me put it this way. Even if you put one at one point, suppose you are treating a isodose -- and

you get on 100 and five centimeters beyond it, you are getting 125, you should check that you are getting in tne same conditions, one at that point and 1.25, the ratio has to be the same. It may not be exact numbers, but the ratio is the same. Like in a _____ treatment, there are seven points and those seven points, the doses will be different. Now you are saying that my computer program does not calculate the absolute dose, but it does do a related dose.

MR. LANDERS: Uh-huh.

MR. ARGAWAL: You could just make that related factors there and then check those related factors with your vendor, with the central access you will calculate the dose at that point and find the related factors.

MR. LANDERS: I'm saying I've already done that and if the new relative factors on the new source are the same as they have always been, why do I need to go do it again on the computer?

MR. ARGAWAL: Then it will be the same for others, those who do have the other type of computer, why should they check it. Because they have one more item there.

MR. LANDERS: Right.

MR. ARGAWAL: So what you are saying is this should be eliminated.

MR. LANDERS: For me, not for them.

MR. ARGAWAL: No, but I'm saying that for you that is

good. Instead of absolute, it should be related and for them it should be an absolute. It is the same thing for both, either you eliminate from one or another.

You see, you are saying one rad, 1.0, that number is changing, 140, but we are saying your number would change with the field size also so you have to see the related number.

MR. LANDERS: Yes.

MR. ARGAWAL: Otherwise there is no point in going with these irregular fields and other things. What you are saying they should check then, the other person should only check that the absolute number has changed from 140 to 150, that's just one number, not the treatment planning.

MR. LANDERS: No, I'm saying that if I recalibrate my teletherapy unit and I get all the same factors that I have gotten in the past with the exception of the absolute dose rate, I do not see a reason why I have to go make the checks against my treatment plan --

MR. ARGAWAL: Because somebody went into your computer and changed the rate.

MR. HAIDER: Well you know, the point is really simple, if everything remains the same, why should we check it. But essentially when you determined everything remained the same, essentially you've checked it.

MR. LANDERS: That's my point. If nothing has changed, why should I check it.

MR. HAIDER: You have essentially checked it, so why should you do it again. So that's what I was saying, you would check it and if you've checked it it doesn't matter how you check it as long as you checked it. It's the same, and if you print it out again it will be the same. Things didn't change so why do that actual work.

MR. ARGAWAL: But the same reason the other person should only check that that was 140 changed to 200, he should not check all the related values related to that 200 instead of 140. That's what I'm trying to say. Why should he be asked not to check, then the other person who has in the computer I will go tomorrow and say take that option off my computer so that I don't have to check. That's -- I don't think that's right. I think you have to make a related check to see that nothing has happened to your computer, some bug has not entered it or something -- I don't know. But that is the idea of it, and I think that both of them should check it. One related, one absolute.

MR. TSE: Okay. Ken.

MR. FRYMAN: I was going to say there's only a couple of us what we're discussing. Maybe we could discuss it tonight and tomorrow pick that back up.

MR. LANDERS: I don't think I'm going to discuss this any more.

(Laughter.)

MR. TSE: I think here is a comment.

MR. WHITE: As long as the relative measurements are the same, it should not be necessary to check the computer.

MR. TSE: Okay.

MR. WHITE: You can also generate the computer numbers to see if they are the same.

MR. TSE: Okay, we will consider these opinions when we talk to AMP and ACR and we'll check with them, but we understand the different views.

Any other item or we can finish it?

(No response.)

MR. TSE: Any other comment? I think Roy is still reading it, so --

MR. LANDERS: I've got a question on 5.8.

MR. TSE: Yes.

MR. LANDERS: Just a nitpick. If I've got a tray that has not been broken, chipped, bent, mutilated, spindled or whatever, since last year, it has just changed its color a little bit, why do I need to remeasure its transmission factor? Now with a recastable metal, I see, you have changes in composition with time as you reuse.

MR. TSE: Okay, in this one which one are you saying should not be measured?

MR. LANDERS: Well in particular here, I'm just questioning the word "trays".

MR. TSE: Unless it has changed --

MR. WIEDEMAN: Let me throw this out. The only reason that that was included is there was a therapeutic misadministration reported because there was a change in trays and it wasn't figured in the annual calibration and therefore everybody they treated throughout the year were off little. We're talking one or two percent difference, and so that was why it was included.

MR. LANDERS: Okay, it's just an example anyhow.

MR. WIEDEMAN: It's so infrequent you'd ever change trays.

MR. FRYMAN: I had a wedge 12 percent off last week when I accepted a machine just based on turned calumniators and other acceptance conditions because they don't -- apparently the companies until now haven't really done any QA on their wedge mountings. They're considered accessories, so they're not spec'd on any sheet when the machines are accepted I had an 11.6 differential on a large wedge. It seems like the larger ones are going to -- well that makes sense I guess because there's a greater change, but they're mounted optically, they're not mounted radiographically.

MR. WIEDEMAN: Are you talking about wedges or trays?

MR. FRYMAN: Wedges on trays.

MR. WIEDEMAN: Oh, okay, wedges on trays.

MR. TSE: On trays.

MR. FRYMAN: Yes.

MR. LANDERS: If the calumniator shifts, you would expect that.

MR. TSE: Other comments?

(No response.)

MR. TSE: No? Roy, you're still reading? You're finished? -- I mean your comments -- I'm sorry, take that word back. Did you complete your comments?

MR. LANDERS: Yes.

MR. TSE: Comments on the Guide.

Okay.

MR. CAMPER: Question. A concern that I've heard raised about this Guide is that there might be individuals who would look at this as all that there is for quality assurance. Like for example, using the Reg Guide, I've done everything that I need to do about QA. For that matter, we've heard the argument made about liability for misusing the Reg Guide. And my question really is this, do you think it would be worthwhile to add a bibliography at the end of the guide that would list various other publications available, those by APM, for example, and draw the reader's attention to the fact that other QA guidance exists and that by no means is this guide intended to be an end all? Is that a worthwhile thing to do, or not?

MR. LANDERS: Yes.

MR. ARGAWAL: Yes.

MR. TSE: I will ask if anybody has any suggestions or any additions we should include in the Regulatory Guide.

Larry already made one suggestion, to add some reference in the back on other QAs.

Well thank you for your help.

MR. TELFORD: Let me congratulate you for all your suggestions you've made today and your perseverance. We've gone through a lot of material today. This is probably a good breaking point. We can come back tomorrow at 8:30 and we'll start on the reporting requirements for diagnostics first, the 35.33 and then we'll do the therapy reporting requirements.

So let's adjourn.

(Whereupon, the meeting was adjourned at 4:45 p.m., to resume at 8:30 a.m. on Friday, September 7, 1990, in the same place.)

REPORTER'S CERTIFICATE

This is to certify that the attached proceedings before the United States Nuclear Regulatory Commission

in the matter of:

NAME OF PROCEEDING: Quality Assurance Workshop

DOCKET NUMBER:

PLACE OF PROCEEDING: Atlanta, Georgia

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.

William L. Warren

Official Reporter
Ann Riley & Associates, Ltd.