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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

OFFICE OF NUCLEAR REGULATORY RESEARCH

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QUALITY ASSURANCE PILOT PROGRAM

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POST-TRIAL WORKSHOP

Airport Hilton Inn

Salon C

10th and Packer Streets

Philadelphia, Pennsylvania

Thursday, August 16, 1990

The workshop convened, pursuant to notice, at 9:10 a.m., JOHN TELFORD presiding.

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PROCEEDINGS

[9:10 a.m.]

MR. TELFORD: Good morning. My name is John Telford. I am from the Nuclear Regulatory Commission, the Office of Research. I have the Rulemaking Section and the Regulations Development Branch.

I would like to welcome all of you to the post-trial period workshop. We are here, of course, to hear from you and give you your opportunity to tell us what you would like to do with both the proposed regulation and the reporting requirements, and the Regulatory Guide.

I would like to start with allowing you to introduce yourselves. As before, I would like to hear your name, the hospital you are from, or clinic, its size -- how many beds, for instance -- its location, and which department as your hospital or clinic actually participated in the 60-day trial, whether that is teletherapy, brachytherapy, radiopharmaceutical therapy, or diagnostics, or all of the above.

Dr. Kaplan has a form that he would like to pass out while you are talking, so that he can get this information for the record.

Let's start over here.

MR. BUKOVITZ: Andy Bukovitz. I am representing Armstrong County Memorial Hospital. It is a 200-bed

hospital, about 45 miles North of Pittsburgh, PA, basically participated in the Nuclear Medicine Section, both diagnostic and therapy.

MR. STRUBLER: I'm Ken Strubler, from the Greater Baltimore Medical Center just north of Baltimore. And we participated essentially in all phases, although we do not have cobalt therapy. But I participated in the teletherapy with respect to linear accelerators.

MR. GRAHAM: I'm Eugene Graham. I'm Technical Director of Imaging Services at the W.C.A. Hospital In Jamestown, New York, a 330-bed hospital.

Our participation was the teletherapy, cobalt-60, and also the nuclear medicine.

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

Brookhaven is assisting the NRC in this pilot program.

MS. PICCONE: I'm Josie Piccone. I'm with the Nuclear Regulatory Commission. And I was a licensing reviewer and inspector out of Region 1, and am now with the Headquarters Group.

MR. KLINE: My name is Ed Kline. I'm also with the NRC and a member of the Quality Assurance Team. In particular, I've met some of you in the pilot studies. I'm out of Atlanta, but will be moving into the Washington area

shortly, at our Headquarters Group, and have done licensing and inspecting with the Atlanta Region 2 Group.

MR. TSE: My name is Anthony Tse. I am with the Nuclear Regulatory Commission. I'm the Program Manager of this project.

MR. KAPLAN: I'm Ed Kaplan, from Brookhaven National Laboratory. I would like to thank you for cooperating, for sending the questionnaires back, being available in case I need to ask a question. So I'm looking forward to hearing what you say.

MR. CAMPER: I'm Larry Camper. I'm the Section Leader of the Medical and Academic Section, NRC Headquarters. And my group will be working with John's group on the QA project.

MR. KEARLY: I'm Frank Kearly. I'm at Washington Adventist Hospital in Takoma Park, Maryland. It's on the Northern corner of the District Columbia.

It is about a 300-bed community hospital. And we participated also in all three phases.

MS. FRANKLIN: Linda Franklin. I work for a private physician. And we only do nuclear medicine.

MR. HELLMAN: I'm Joe Hellman from Madigan Army Medical Center out in Tacoma, Washington.

We are about a 450-bed hospital out there. And we participated in all ph es.

MS. MOORE: Susan Moore from Nuclear Medicine Department, Samaritan Hospital. A 300-bed hospital.

MR. TELFORD: What departments did you say?

MR. DORING: Nuclear medicine.

MR. TELFORD: Okay.

MR. DORING: I'm Tom Doring from Samaritan Hospital, also. It's a 300-bed community hospital right outside of the capital district of New York State.

I am here representing the brachytherapy part of the program for my cancer treatment center.

MR. TELFORD: So both nuclear medicine therapy and diagnostics as well as brachytherapy --

MR. DORING: Yes.

MR. TELFORD: -- participated in the 60-day trial?

MR. DORING: Right.

MR. TELFORD: Okay. Thank you.

I just want to run through the agenda for the meeting very quickly to give you a feel for what is coming in the next two days.

It's a good thing you have a copy of the agenda, because I don't think you can read this one from where you are sitting. The screens are a little bit too far away.

But just as a brief recap, recall at the pre-trial period workshop, you saw the viewgraph on the left, where we told you what you could expect. And so the parts up here

about telling you the criteria that we used to do the program evaluation on paper and then the criteria that were used to come to your site, if we did come to your site to do a site review, we're going to tell you about those two sets of criteria this morning.

Dr. Piccone and Mr. Kline will do that, and they will also tell you the results that they found, both from the program reviews and the site reviews. In addition, Brookhaven evaluated everybody else's programs. That's the total of 70-odd minus the 18 site visits. And we will hand those out. We will hand out what is called a checklist, where you can see what kind of impression we had just from looking at your paper program.

We'll do that for you this morning because we promised it to you at the pretrial workshop, and the rest of the agenda we would devote to you. We're going to go through, this afternoon, the proposed 35.35 rule. We're going to go through it piece at a time. We're going to pick it up and examine it and decide what to do with each piece of it. That is, we want to hear from -- from all of you who want to talk about any piece of it. So, we'll go through it a step at a time.

Then if you can see the viewgraph on the right, that's tomorrow's agenda. The first thing we're going to do in the morning is Dr. Tse is going to lead you through the

Regulatory Guide. We will follow a similar format there, in that we will look at each section a piece at a time, and we will be asking basically the same questions about it that we will be asking about 35.35.

And then in the afternoon tomorrow, we will go through the proposed reporting requirements. Now, since you folks devoted 60 days of time and effort, I feel that you've got some -- a basis now to -- more than having just thought about this -- you've actually subjected yourselves to this, so that we would like to know what you would do with the reporting requirements. And we will go through that piece at a time. So this meeting is for you.

Now, at some of the workshops, we will have more than a few observers. And the number three item here on your 9:00 a.m. item is groundrules. The groundrules are simple. We're hear to listen to you -- the volunteers. So, the observers, if they want to ask any questions or make any comments, they get to do so at the end of the second day, that you'll find at 5:30 on Friday.

Now, that's so that we can devote the time to the people that have invested the work and time into the trial program, and allowing time for the observers to ask questions or make comments at the end of the proceedings.

So, I'd like to turn it over to Dr. Piccone, who's going to talk about the program and site review criteria.

[Slide.]

MS. PICCONE: As John said, we promised you at the pre-pilot workshops that we would talk to you about the evaluation criteria that we used in looking at the programs and on doing the site evaluations as well.

There was a QA team that was developed as part of this pilot program. The team consisted of four individuals from NRC; three of those individuals had a good number of years in medical practice, in nuclear medicine and in oncology, and also as NRC license reviewers and inspectors. So it was based on that background, that the criteria were developed for reviewing the programs.

So what I'd like to do for the start of this morning's session really is just to give you a little bit of background -- bring you up to speed to where we were and then talk about this program evaluation criteria. We'll step through the eight objectives and tell you the things that we were looking for when we reviewed a program; also highlight how we fleshed out those items when we did the site reviews, and then present to you some of the results of the programs that we went out to visit.

I will point out that although we didn't visit all of you, that we did -- your programs were reviewed. The 18 that were visited were reviewed by the QA team, and the remainder of the programs were reviewed by the contractor,

Brookhaven, using the same evaluation criteria and checklist.

So that the first thing the team did was to develop the review criteria. The program evaluation criteria was developed so that it could be used as a basis for guidance for license reviewers. And our thinking here was if this rule were to become final, we had a little jump start on it; that we started developing the guidance that would be needed for our license reviewers and inspectors.

And we developed site evaluation criteria, which really just expanded a bit on the program evaluation criteria and this would be used as a basis for inspecting the quality assurance program.

Now, in doing this, we did choose 18 facilities. These facilities were randomly selected from the regions. And they consisted of 11 NRC licensees, seven agreement state licensees. The 18 altogether included 15 diagnostic nuclear medicine programs, 12 therapeutic radiopharmaceutical. And whenever we talk about therapeutic radiopharmaceutical, we're going to include that greater than 30 microcuries of I-131 and I-125. So that's how we're going to be making the distinction -- radiopharmaceutical therapy and the greater than 30 microcuries of iodine, five brachytherapy departments and 8 teletherapy.

[Slide.]

MS. PICCONE: Just to give you an idea of how these facilities were spread out throughout the country, I think the people, certainly at the sites we visited, they were well aware of our travel schedules and our late arrivals and etcetera for this.

You can see that they 18 -- there certainly are a larger number in Regions 1 and 3; that's because those two regions have most of our NRC medical licensees, and in fact about 70 percent of the medical licensees. And there were sites from the agreement states that have the majority of medical licensees as well: California, Texas, Florida, New York, Illinois. So that the 18 were pretty spread out throughout the country.

[Slide.]

MS. PICCONE: When I talk about the evaluation criteria, and when we get into the results section, we will be referring to medical use programs. And we've divided your practice, so to speak, into four medical use programs: The first being diagnostic nuclear medicine and any iodine work less than 30 microcuries; the second, as I mentioned before, radiopharmaceutical therapy and the greater than 30 brachytherapy and teletherapy.

[Slide.]

MS. PICCONE: Just to give you an indication of how these medical use programs were represented in the 18

sites that the team evaluated, can see that there certainly was an attempt to get the biggest spread that we could, even in this 18. So that -- you see that there were -- there was hospital representation, both in NRC licensees and agreement state licensees and private practice facilities, private practice nuclear medicine, brachytherapy and teletherapy.

[Slide.]

MS. PICCONE: Now, I'm going to start talking about the evaluation criteria. And when we talk about that, I will be handing out to you your program evaluations, and you'll be able to step through some of this, if you like, by going through your program evaluations.

For those three of four sites that we also visited, you, in addition, will be getting a copy of your site evaluation. These checklists are what we used in evaluating the programs. So when I step through the objectives, we're going to be talking about both the program evaluation and what we found would be the things primarily lacking and also, in site evaluation, what additional items we looked at and what were the most common things that were lacking there.

Let me give you these so that you can follow along, so that you're all getting the same program evaluation -- okay -- checklist. The only thing the people who were site visited are getting additionally, is the site

visit. The site visit was a little bit bigger than the program evaluations. We had all programs participating. that's why yours is thick.

[Evaluations distributed.]

MS. PICCONE: The first program that I'd like to go through is the -- the diagnostic nuclear medicine and procedures less than 30 microcuries.

[Slide.]

MS. PICCONE: What I've put up on this viewbox are the first four objectives that are listed in that draft quality assurance program. And I'll keep the objectives on this side, just to keep us on the right track and online when we go through the objectives. Because when I discuss them, you'll see that I've used shorthand certainly, in stating the objectives.

[Slide.]

MS. PICCONE: I will point out to you that the team considers these evaluation criteria and certainly the checklist that we use, to be living documents, okay. They were our opinion -- our, you know, first go around at what -- what we would use to evaluate the programs, how we would evaluate your programs. And we've made many changes already to them, in the course of the pilot, and as a result of some of site visits on some of the items that we looked at.

And let me point out one other thing to you. If

this were actually being performed in the licensing arena, and this would hold true for the agreement state licensees as well, when we receive your program and look at it, if we have a question, you know, what happens? We don't hesitate to get back to you and ask you for additional information. So there was that step that -- that was really missing in this process.

So when you look at your program evaluations, you may see some no's, where you'll say to yourself, that -- I have that -- that's not a no. It may be, on what you submitted to us we had a question, and normally we would have followed up with you on that question, we would have asked you to confirm something or to give us some additional information.

And that is why, when we actually went out on the site visits to some of the facilities as well, we found that they were actually -- the procedures that they actually had and their implementation, in many cases, far exceeded what they sent into us on their paper program.

[Slide.]

MS. PICCONE: Okay. The first objective is that medical use is indicated and on the checklist that you have and what I'm showing up there as well; by every objective there is the proposed regulatory reference and also the Reg Guide references, if we felt there was a Reg Guide reference

that was applicable to that objective.

So, what did we look for on your program -- on the paper -- piece of paper you submitted to us? In -- for this objective we were looking for something that said that either an authorized user reviews the request for studies, or the physician under his supervision, or for diagnostic nuclear medicine, that the procedure was ordered by a physician.

And, in fact, we were able to pick that out of all of the programs that were submitted to us.

[Slide.]

MS. PICCONE: Two and 3 I put together on this slide for diagnostic nuclear medicine because the regulation as it is now -- and let me make another aside; that this criteria, certainly, and the site visits, were based on the proposed regulation, okay -- not on what changes we think we're going to make or what's going to evolve as a result of these meetings.

We were looking at the rule as it is proposed now. That rule for diagnostic nuclear medicine offers the option of either having a prescription for the study or a diagnostic referral made. In most of the cases, it is a diagnostic referral.

We had a couple of nuclear medicine facilities who said that they have prescriptions for all of their studies,

but on a site evaluation, since the prescription didn't meet the definition that is currently in the proposed rule, we took them all to be diagnostic referrals, okay? They were ordered by a physician.

On the site visits, okay, so these would be the kinds of things for everybody. If the rule were to become final, this is the kind of material or the items that an inspector may look at in trying to see the process. What we did was; we actually asked for cases studies -- a number of case studies -- and followed the process from start to end; you know, the phone call that came in to order the study or whatever, the paperwork that came in. That's how we actually reviewed what information was presented for a particular patient study.

[Slide.]

MS. PICCONE: Okay, the fourth objective that instructions be understood by the responsible individuals; okay, again, there are the regulatory guide references. Now, on the paper quality assurance program, really we looked for almost anything that addressed this at all.

If you said instructions are understood, if you confirmed that objective, that was adequate in what you submitted. If you committed to the Reg Guide, that was adequate. In general, our or's are some additional item that the QA team members felt would satisfy this objective.

If you told us that in the training of your personnel, they're instructed that records -- that they must understand all records and requests and that they must clarify this, then we accepted that. So, we accepted most anything, as long as it addressed this objective in the submittal.

The problem was, most of the programs, okay, that you sent to us, didn't even address this objective which is why it appears that many of the programs -- there will be no's by many of your evaluations of this item. You know, if we had any question at all, we consider it a no.

Just to refresh your memory, since I've made regulatory guide references as well, Regulatory Guide 2.1, that section deals with records being legible. It says, you know, that you will ensure that records are legible, and 2.2 states that individuals will request clarification if they're not sure about something.

Now, what did we find on site? Frequently, we couldn't find anything in writing on this. When we asked the question after the initial shock reaction, so to speak, on the licensee's part, like, are you kidding -- of course, we ask clarification, that this is -- we found to be for the most part, a professional understanding by licensees.

We talked to individuals about that so that we would get a nice warm feeling that what they were saying is

actually what they do in practice. So, when I talk about the next one, I'm going to elaborate a little bit more.

We actually talked to the technologists, the physicists, the physicians. We asked them what happens. We gave scenarios. You know, if a physician ordered such and such a study and he gave as an indication of use, you know, something that was way out, and so that we got these appropriate responses on how they would react.

So, on site, we accepted this general understanding, this professional understanding, this common sense kind of thing. We accepted that as meeting the element, especially with my introductory comments to you that if you're paper program didn't address it, we would have gotten back to you and said, well, what about this?

You would have said to us, most likely, either confirm that you will do that or that this is a professional understanding, you know, or this is covered in training or whatever. We didn't fault on the site evaluations for what we weren't able to follow through on the front end.

[Slide.]

MS. PICCONE: The fifth objective is medical use in accordance with instructions. Again, we accepted most anything in your paper submittal that dealt with this. If you confirmed this objective, that was adequate for us. We weren't looking for procedures in most of the cases on your

program submittals, because of the performance based aspect of the rule.

If you said you were going to meet the objective, that was enough in your program to us. Again, if you committed to the Regulatory Guide -- and this item in the Regulatory Guide just says that the medical use will be in accordance with a prescription or with a diagnostic referral and the procedures manual. So, this assumes that if you get a diagnostic referral, that it is somehow checked against your procedure manual.

Okay, now we have one of our or's. Again, if you indicated that personnel were instructed in this area that they must make sure that they have the right dose and the right radiopharmaceutical, et cetera, that we accepted that in this area as well. Now, this again, on site, was one of those -- we found primarily unwritten understandings and common sense things as well.

[Slide.]

MS. PICCONE: On site, we elaborated in this area a little bit. As I mentioned before, in talking to individuals and trying to asses their understanding of their quality assurance program in the key procedures for that quality assurance program, we assessed their knowledge in this area.

[Slide.]

MS. PICCONE: Objective 6 is patient identify, clarifying patient identify.

Here, we went a step beyond what is written in the draft rule and Reg. Guide for that matter, in that the member of the team, we felt strongly that your patient identification procedures should include some redundancy, so that you should do more than say, you know, John Smith, and have someone respond to that.

On the program evaluations that were submitted, and this holds for all of them, because we found the same kinds of things for all of your patients, whether the team reviewed them or the contractor reviewed them. Most of the time this was a "no" or a "needs more information," because you didn't address patient identification at all in your submittal. You didn't say what you did about it. So this wasn't an objective that you really elaborated on.

And on site, we found the opposite, that, you know, there are established patient identification procedures at most of the facilities, and they do include redundancy, except, in many cases, for outpatients.

So if there was a, I guess a common problem on site, it was in redundant procedures for outpatient studies.

[Slide.]

MS. PICCONE: The seventh objective is that you identify, have some procedures to identify deviations, any

deviations, throughout the process, not just misadministrations. Any errors that, or deviations that could lead to misadministration, as such, that you have some procedures to identify these and that you evaluate them.

Again, if you confirmed that you did this, that was enough for us. If you committed to the Regulatory Guide in this area, that was sufficient as well. If you instructed personnel that if there is a problem, if they see a problem, they are not going to continue, they are going to clarify the problem or whatever first, we accepted that as well.

The "b" item on that slide, the record of prescribed and measured dose, and we assume the measured dose is the administered dose, that is currently required by the Part 35 regulations.

This is one way of identifying deviations. And the agreement state facilities that we visited as well have similar requirements from the agreement state, that they have to record the dose that they have administered.

And so we looked to see if people were doing this and if they reconciled the two, the administered dose with the, either the dose in their procedures manual, or that the, or prescribed by an authorized user, whether they were reconciled.

On site, we elaborated in this area a little bit,

because any of the things that you do through the process, okay, will meet this objective, or help to meet this objective.

For example, if, in reviewing the process on site, if the technologist is describing what she does when she gets this referral or when she is talking on the phone to make the initial order, and if the indication of use doesn't seem right to her, she will resolve it at that point or take it to the authorized user or to the referring physician if necessary.

So it is these kinds of activities that all come into this Objective 7.

[Slide.]

MS. PICCONE: The last objective in the proposed rule is not applicable to this program of the next one that I'm going to be covering. Just for completeness, we'll put it here. You will see that when we get into the therapies.

Okay. The next medical use program, radiopharmaceutical therapy, and remember this also includes the greater than 30 microcuries of I-125 and I-131.

[Slide.]

MS. PICCONE: Now, the program review and the site evaluation, of course, is very similar, and in many cases, exactly the same as diagnostic nuclear medicine. And we certainly looked at the two of them together, because they

are in the same department. Okay. And so you consider the two together. You don't generally separate these medical use programs.

[Slide.]

MS. PICCONE: Again, the first objective is that medical use indicated. In this case, we were looking for the authorized user to review these cases, okay, not just an order by a physician in this case, that the authorized user is in the loop for these radiopharmaceutical therapy studies and these iodine studies.

And when we talk about authorized user, I won't be repeating myself, and this way maybe Ed won't have to repeat this, either. We mean the authorized user or a physician under the supervision of the authorized user.

So when we refer to that title, authorized user, that is what we mean.

[Slide.]

MS. PICCONE: Okay. In the case of these therapy procedures, the proposed regulation requires a prescription. And the prescription is defined in the proposed regulation.

On the programs that were submitted to us, we had questions on almost all of the programs submitted to us, because most people didn't elaborate on the prescription. They may have said we will, you know, there will be a prescription, or whatever. But we had no idea if it

included the elements as are currently required in the proposed rule.

If we had a problem, it was primarily because you didn't send us a sample prescription of you didn't confirm that your prescription would contain all of these items, or prescription changes weren't address at all.

We had questions on what happened if the prescription was changed -- the physician decided he wanted another dose, was that written by the prescribing physician?

On site, as I mentioned, we actually reviewed cases. We looked at these prescriptions and we did find for therapy that there were prescriptions, they just didn't have all the elements that are described in the proposed rule. And the common ones that were missing were: Chemical form, route of administration and physician form.

And we got indications from a number of -- now if these items were listed in the procedure manual, okay, we accepted that as being part of the prescription in this case. If, for example, the procedure manual on iodine therapy said, we only use capsules at this facility and its sodium iodide, we accepted that as part of the requirement for this prescription.

But those three things were the most common elements missing. And I think most of you can understand why. Because certainly, at many of the facilities that we

visited, what radiopharmaceutical therapy has done is I-131 therapy for a hyperthyroidism or carcinoma, so they don't have any other therapies that are going on and their response to us was "we only use iodine, you know, of course it's sodium iodide -- and we always get capsules, so why write every time we get a capsule, or it's taken orally." So that's an item certainly, we'll be looking at.

But that is for -- the biggest reason why you will see no's on that items, both in the site evaluation and in the program evaluation. Either we couldn't determine if you had all of those elements, or one or two of the elements were missing on the site evaluation.

[Slide.]

MS. PICCONE: Okay, the third objective, diagnostic referral made, is not applicable to this medical use program, because the proposed regulation requires that a prescription be made.

[Slide.]

MS. PICCONE: Okay, I'm not going to spend too much time on the remainder of the objectives for this medical use program because they are very similar, if not exactly the same, to the same objectives or discussion we had when we talked about diagnostic nuclear medicine.

So, again, that instructions be understood by responsible individuals, we accepted anything that you gave

us on site. We determined this by questioning individuals. We asked physicians how many times the technologists go to them with questions on administration or on what to do with the patient, of if the technologists went to them at all. So we confirmed that there was this interaction on site.

[Slide.]

MS. PICCONE: Okay, objective 5, that medical use is in accordance with instructions. In this case, if you committed to Reg Guide 3.4, we accepted that in this case as well. And the 3.4 just says that you will confirm the identify of the patient, the radioisotope and the dose before administration. So it's confirming some -- what we were routinely told in the field were comments and understanding kinds of activities.

[Slide.]

MS. PICCONE: Again, we questioned people for radiopharmaceutical therapy on their understanding of the quality assurance program; not so much the Reg Guide proposal, but what was submitted to us as the facilities quality assurance program to meet these objectives. So we questioned them on some of those items and their understanding of those items.

You can see to this list for therapy, we added the requirement for in content of prescription -- item two under there.

Okay, again we looked for patient identification procedures for this medical use program. We were looking for redundant procedures. Let me elaborate a little bit on that, because -- since I mentioned to you most of the problems we found were with outpatients.

For inpatients, there were -- you know, at some institutions, two, three, four kinds of verification procedures that went on: There was the patient ID bracelet; they asked the patient's name; frequently the patient signed a consent form; the chart came down with the patient, so they verified the order in the chart as well.

With outpatients most of the facilities that we looked at didn't have an ID bracelet, although we do have some, and I think the - some of the hospitals have a photo ID system for all of their patients, whether they're in or out. But for the community hospitals and the private practice facilities, this isn't the case. And often times a referral may be made over the phone.

In diagnostic nuclear medicine, that was one of the big items we found, that, although there is a real push towards trying to get some paper follow-up from the physician for outpatients, that if a patient presented and the patient was on the schedule, but didn't have the written request, that that study would be done anyway. And so identification is really asking someone's name and the

person responding to that.

[Slide.]

MS. PICCONE: Again, Objective 7, unintended deviations.

Again, we looked at the whole process. In the paper program, if you said anything in this regard, we accepted it. In the process, whatever was done to identify errors, or deviations, we considered to be part of your procedures in this area.

[Slide.]

MS. PICCONE: The last objective, Objective 8, again has to do with treatment planning, and is not applicable to this medical use program.

So that one will be covered primarily in brachytherapy and teletherapy.

Now, since we have a few minutes, are there any questions on the criteria we discussed for those two medical use programs only, for the diagnostics nuclear medicine, or the radiopharmaceutical therapy?

[No response.]

MS. PICCONE: So, in summary, we accepted, we had quite a latitude of acceptance in your paper program. If you identified the objective in your program at all, we accepted that as your program, you know, addressing that objective.

Okay. Well, we have two choices. We can take a little break now, which I think may be the good thing, or to go on. And this is a natural break now, so why don't we do that? Because then when we come back from our break, let's say 15 minutes, we'll start into the therapy, the two therapy medical use programs, where we'll spend a little bit more time in elaborating some of the criteria that we came up with, and what we looked at in the site evaluations as well. And then we will give you some idea of the results that we found for the 18.

In the break time, certainly, if you have a question on your individual scoring or evaluation, we're available to you, if you want to discuss. We have copies of what we gave you. We also have the programs that you submitted to us. And we can discuss some of the items, if you would like.

Okay. Thanks.

[Brief recess.]

MR. KLINE: My name is Ed Kline and I was one of the individuals on the pilot team, part of the QA team that was given the opportunity to come out and visit your sites. I've met some of you and some I haven't. We had a total of 18 site visits of which we divided up the pilot team into two groups.

With our limited schedule, we tried to

geographically visit these sites most effectively and efficiently as we could. I do appreciate your cooperation in allowing us the time to come by and intervene in your daily activities, especially in a clinical atmosphere where sometimes it can be very hectic.

[Slide.]

MR. KLINE: What I would like to talk about are the two programs addressing brachytherapy and teletherapy and also touch on some of the results from all four programs, of which the first two, Dr. Piccone addressed. Again, as was talked about earlier, these are what we call living documents.

They're documents which will or could have changed during the course of the onsite pilot study. We often found that what is clinically practiced is sometimes a little bit different from what we had originally designed as an objective and these forms which we have been using, did have to be somewhat modified in definition as we evaluated the various programs.

I might be a little bit redundant while I'm going through some of these objectives, but I want to try to tie them into our onsite evaluation form so that everybody understands that we're talking the same language here.

The first objective, Number One, ensuring that medical use is indicated for the patient's medical

condition; our onsite evaluation form which was pretty much identical to that of the diagnostic and nuclear medicine therapeutic nuclear medicine, addresses this with the verbiage, medical use indicated.

Again, the reference under 35.35A.1. This the first objective, so we give a reference beside that. Also, we reference the Regulatory Guide 4.1, if you chose to follow that, or if you use that as a basis for maybe generating your license condition or your proposed QA objective.

Now in this first objective, the criteria that we used was authorized user reviews each case or as was stated earlier, the physician under the supervision of the authorized user reviews each case. We found that most -- as a matter of fact all -- of the programs which were submitted, the programs that were written and sent to us to review, did meet this criteria a hundred percent of the time. All 18 facilities addressed that objective.

[Slide.]

MR. KLINE: On site, we also found that all 18 facilities met that objective. In brachytherapy, since it's a more of a one-on-one relationship, you have a smaller department and this is more focused in nuclear medicine. The physicians had the opportunity to sit in chart rounds or weekly meetings or daily meetings for constant dialogue with

the patient, referring physician, oncologist, pathology; these were the people with the patient who allowed that sort of feedback loop.

There consequently was a number of opportunities for the authorized user to sit down and discuss with staff and individuals, the case history, the chart, the modality of treatment and these sorts of things. How are we going to approach it? What are we going to do? Who is responsible?

We thought that was nicely met in practically -- in all the cases that we addressed.

[Slide.]

MR. KLINE: The second objective, Objective Number Two, ensure prior to medical use that any prescriptions made for an teletherapy procedure, any brachytherapy procedure -- and we won't address radiopharmaceutical therapy since that was addresed by Dr. Piccone earlier -- this objective, again, is referenced -- let me see -- under 35.A.2, and also Regulatory Guide 4.2 and 4.4.

If you look at 35.2, that's put into this objective because it is addressed as part of the definitions. The definitions are necessary to be known in order that you can meet the criteria of what this objective is. A prescription is a written order or directive dated and signed by authorized user or supervising physician, containing radioisotope, treatment site, total dose or

treatment time, number sources and combined activity.

This objective also included an evaluation of any prescription changes which are required to be written or dated or signed. We felt that that was necessary. Often in brachytherapy, you have to revise or update your prescription based on the actual number of sources which are intercavitarily implanted or interstitialy implanted which is common practice which has been, I believe, always the way pretty much the medical community has addressed brachytherapy.

This was an element that becomes very important, because we felt that people have to know what sort of changes are ongoing. It's absolutely necessary that the authorized user document and date that change in that particular prescription so that all the associated actors -- the technologist, the dosimetrist and other physicians in the program understand what has happened and you have a history of what has happened for the patient.

In this prescription, we look for the radioisotope, the type of source that was used, the treatment site. The treatment site often would be either notated, written, or it would be a diagram which would indicate the anatomy of the individual. There were also various references that the patient chart could be used which would describe certain areas that would be treated in

the patient.

We even saw where certain clinics would have separate documentation that addressed the same items here that would be in your hot lab or your room where you have your sources, the cesium vault area. The total dose was always the case.

Everybody would write down the dose that was necessary for that particular treatment, or you could have the treatment time, number sources and combined activity. We saw various derivations of these elements, these particular elements in this objective.

Another area that we looked at was the actual source loading. Was this recorded? Often, changes in source loading can occur, and it's necessary that you document which source were use and which were not used; which were returned, for example, to the safe. This revision in source loading is a revision in the prescription, because consequently your dose changes and your time changes.

Again, this is similar to the prescription change where you have a source loading change which is reflected on your prescription. In the programs that were submitted, approximately 40 percent of the people addressed all of these issues.

On site, it appeared that we had about 80 percent

that met that objective. It appeared that some people didn't address key, point-on-point, these particular elements of this objective. On site, they were performing these particular parts of the objective.

[Slide.]

MR. KLINE: Number three, in regards to brachytherapy, addresses less than 30 microcuries. No, I'm sorry. More than 30. Well, Objective 3, (a)(3) addresses diagnostics referral made. In brachytherapy, we didn't address any sort of diagnostic referral. It's not diagnostic; it's a therapeutic procedure, and it applies, since only the brachytherapy is therapeutic.

[Slide.]

MR. KLINE: Objective Number 4: Ensure prior to medical use that either the diagnostic referral and the diagnostic clinical procedures manual or the prescription is understood by the responsible individuals.

We, on our evaluation form, addressed this in the form of instructions are understood by responsible individuals. And there is Regulatory Guide 2.1 and 2.2 that specifically address those key aspects.

In your program, you could have submitted that you can confirm all of the above. You can use similar language or identical, which would be Regulatory Guide 2.1 or 2.2. Or personnel were instructed on the importance of accurate

and clear records or requests, and personnel were instructed to cl ~ify and clear records or requests.

Getting back to the Regulatory Guide 2.1, that addresses records that would be legible and written clearly and precisely to minimize misunderstandings. We felt that one avenue of possible errors, and what was designed for the treatment program, is misunderstandings. What somebody misunderstood but didn't bring to the attention of the authorized user, what one of the technologists might have thought was a numerical 6 instead of a numerical 8, handwriting, these sort of things we were looking at, with 2.1.

In 2.2 of the Regula~ory Guide it talks about authorized users request clarification regarding any of the elements of the prescription, whether they appear ambiguous or erroneous, these sort of things. Anything that just does not look quite right.

We wanted to see if there was some sort of mechanism by which individuals in the oncology department and brachytherapy program could feed back to the authorized user or to the physicist, or to the supervisor, that would feed back to the authorized user, hey, we have a question here, I'm not sure if I should proceed, I'm not familiar with this particular protocol, because we've never done this before; let's assure this be done right; or this particular

treatment regime appears quite different; the treatment time doesn't look quite right.

Because it is such a small department and you have individual actors that spend a lot of time there, after a while you get a feel for therapy, you get a feel for what is an appropriate time to leave in sources. You get a feel for source loadings. Any of these sort of questions should be brought up. And there shouldn't be any sort of hesitation on behalf of the technologist or physicist to bring it to the attention of the authorized user.

So we addressed what sort of feedback mechanism they had, in particular looking at those Regulatory Guide 2.1 and 2.2 areas.

[Slide.]

MR. KLINE: I'm going to proceed on to Objective Number 5.

Okay. Number 5 addresses medical use, insurance that it is in accordance with either the referral and the diagnostic clinical procedures manual, or the prescription.

Our objective addresses medical use in accordance with the instructions. It also references Regulatory Guide 2.4 and 4.3. Instructions in this case would be your prescription. It's another way of saying prescription.

We look for procedures to verify the radionuclide and source strength with the prescription. And this would

be prior to implantation.

Verification can be performed by a number of different mechanisms. We are quite broad in the interpretation of this. We know that there are some logistics, and looking at sources or handling them, that makes it difficult sometimes to spend much time around those sources. And it's not to the benefit of the individual to receive any unnecessary exposure.

But a number of methods, for example, checking serial numbers behind the shield, color coding. Often a lot of manufacturers use color coding. And eventually there will be a standardized system of color coding amongst manufacturers. So all the colors mean the same, milligrams of radium equivalent, or the same activity of the particular isotope you are using regarding larger sources of intercavitary implant.

Clearly-marked storage spaces, areas in your safe that are clearly marked or designed so that you can put your sources in there and you know exactly what sources should go where. Areas where you have a checkout mechanism where you can see on a board that you took so many sources out and there are so many remaining, and it is clearly seen that there is a certain area where sources should be put and should be there at all times. We look for that sort of mechanism.

Also, some facilities look at using radiation detectors, where they would take the sources out and do the activity. With some sort of detecting device, you could tell whether or not there were 10, 15, 20-milligram tubes of whatever isotope you might be using.

For remote after-loading devices, we didn't have any facilities which we reviewed that had remote after-loading devices, but we would have looked for procedures to ensure proper input of data. Mechanisms by which you could do that, which we were looking to, if we did run into that situation, would be verifying computer input or verifying that the data put in was correct, verifying that the output from let's say the treatment plant for input into the afterloading device was correct, looking at transit times and making sure that any of the data input regarding transit times of the sources was correct.

Maybe, in some cases, some people could do some rough calculations to verify that there was a proper procedure to ensure the input of the data.

The third category: actual loading or implantation of sealed sources or prescription changes promptly recorded. We wanted to see if individuals -- authorized users, had documented that after the implant or after the sources were used for whatever means, that there was some sort of documentation of any changes along the way.

It appeared that most people ran into problems, whether they be in the operating room, or once they come down with the dummy sources, or there were some anatomical reasons, morphology, or there could be just the configuration -- what's seen on the radiograph -- did not fit what you were looking for. So, there could be changes, once the actual sources went in and these would need to be modified on your original prescription form.

MR. KLINE: In this objective, number five, it appeared that 60 percent of the people did not -- did address this objective; whereas, in the field, on site when we went to evaluate the programs, 100 percent of the people were doing this. So it might not have been brought out in your program, but, in reality you were doing it and we found that that was nicely met.

[Slide.]

MR. KLINE: Also in this objective, we looked towards the understanding of the individual players of the -- of this facet of the QA program and we did, I guess some of a -- tried to be as objective as possible, a quick evaluation of what the understanding of that objective was and whether or not people understood what's trying to be conveyed by that objective. That's where we have the excellent, good and fair.

And we also looked at examples and key procedures

-- the understanding of these key procedures, the requirement for and content of a prescription, exceptions due to patient's emergency condition, patient identification and clarification of unclear records. These were certain things that we looked for, not any one in whole, just -- they could be as a conglomerate, a number of issues addressed, in one, as a whole, or they could be in part.

[Slide.]

MR. KLINE: Objective number six, ensure prior to medical use that the patient's identity is verified as the individual named on the diagnostic referral or the prescription, again, we're dealing with the prescription or therapy.

We focused on a redundant patient identification system, which might not have been clearly understood in the objectives that were requested, or the objectives that were submitted by all the facilities for review. We found that none of them addressed this one aspect. But, on site, it appeared that 100 percent of the people were doing this.

The redundant patient identification could be: an individual's name, compared with their ID; comparison with the picture, a signature, invoice on billing; some mechanism where the person comes through a central receiving office and there's a redundancy in the person checking in and when they come down to your department; signing in on a log.

On a number of the treatment plans, the treatment charts or sheets, however your facility addresses it, there would be diagrams with the individual's name and hospital number, treatment site. There would be a number of places where there would be a consent form that had the person's signature on it, Social Security number, address. Any of these mechanisms can be used for a redundancy. By asking the patient, by seeing some documentation.

We know that it sometimes may be a sensitive issue, when you have people in oncology coming in for some sort of a therapeutic procedure -- and so we are quite liberal in what would be interpreted as some sort of double check. I know the last thing you want to do is cause some sort of turmoil with the person not having an ID or bracelet, that's an outpatient. These sort of things can just add to problems with your patient.

So any sort of mechanism that -- that appeared to be a second check was what we're looking for. And it appeared that all people were doing that.

[Slide.]

MR. KLINE: Objective number seven ensures that any unintended deviation from either the diagnostic referral and the Diagnostic Clinical Procedures Manual or, in this case, the prescription, as identified and evaluated.

Objective number seven on site, we defined as

unintended deviations identified and evaluated. We referenced again, the objective and regulatory guide 2.3 or 4.7. If your program that you submitted to us confirmed the above in similar language, or equivalent language, that was fine or if you committed to Reg Guide 2.3 or 4.7 that was fine; or if your people were instructed to terminate medical use, if discrepancies were identified and discrepancies are identified in evaluating corrected.

It appears that a majority of programs already had some sort of quality assurance that was in place, often due to other organizations that require you to have this, or highly recommend it, or certain individuals just had a good quality assurance program of their own which is now meeting a lot of these initiatives for quality assurance in the medical industry.

On paper, in the programs that were submitted to us, about 60 percent of them addressed this issue. On site 100 percent of them addressed the issue. Again, everybody seemed to be doing it. It seemed to be somewhat of a current practice industry -- whatever you might describe it, that people were instructed or had gone through professional training programs or were registered technologists or were certified through different organizations.

We were quite lenient, I guess, or we had a lot of latitude or range for interpretation of whether or not that

(a)(3) criteria, how it was to be met. But a lot of facilities would address it in the sense that, well, this is the sort of thing that people are instructed professionally to do before they even come to work, by taking examinations or through professional classes or didactic tra ning.

And the second part of (a)(3) that addresses discrepancies -- often the quality assurance programs that were in place addressed the discrepancies, documented the, tabulated, collated, submitted for quarterly reports through your quality assurance committees, which went to your administrator, and sometimes there were even protocol systems set up which were reviewed by other agencies -- almost in a pilot program in themselves, through different societies.

So the in-house quality control seemed to be addressing this -- this one objective.

On the b aspect of (a)(3), record of administered dose and agreement with prescription. If -- if you had document on a treatment plan or prescription what the prescribed dose was, then you had entered, at the end of the prescription plan, what the total dose was for the number of hours. This was adequate for record of agreement. We didn't need to see that somebody wrote yes, these two agree -- that's pretty obvious, if you have one number and it matches another number, that those two are in agreement.

But we did look for was this agreement on one sheet of paper. We feel that if you have a prescription here and you have the patient's chart way out here, and you're not comparing the two, that that could be an avenue for mistake. You have to know what you were supposed to give, versus what you did.

So we want it in the same document or area of reference for those two prescribed and administered are located.

In this program, I think I mentioned 60 percent addressed it, or this objective, and 100 percent met it in the field.

[Slide.]

MR. KLINE: Objective No. 8 ensured that brachytherapy and teletherapy treatment planning is in accordance with the prescription.

Objective No. 8, treatment planning in accordance with prescription, also referenced as Regulatory Guide 4.5, 4.8, 4.9.

The criteria for evaluation of this particular objective centered around the method used by the facility for the basis of calculating delivered dose. There were a number of different ways that can be done. We addressed that as current industry practices. This could be inclusive, not in whole -- well, in whole or in part or a

combination of methods. It could include radiographs, comparable imaging modalities, CT for example -- Computerized Tomography, nomograms, dose tables or other equivalent methods.

If the facility had any of these methods or equivalent nature, that met the objective.

Under B there's the objective procedure for confirming dose calculations are accurate prior to completion of treatment. That would address whether you have an independent checking mechanism, a double check mechanism.

There are a number of ways that can be met.

If you had independent calculations and you only had one person on site, if that person that was doing the calculations could use a different method of determining the dose, meaning doing a different calculation that was adequate, doing a check of your calculations by different calculation method, that sort of thing is what we're looking for.

If you had an independent check where you had the option of having two people on site, a dosimetrist or even a technologist that could check your calculations or you check theirs, if you had a computer treatment planning system that gave you a particular dose to a point or an isodose curve you could verify, rough approximation, what that dose should

be using a hand calculation and usually it would involve just about four variables.

We are not asking for complete verification of, let's say a complex treatment regime. For example, if you had a irregular field and you were treating an area which was anatomically complex, we're not asking that you go in after your computer has generated that plan and you generate the same plan by hand. We realize it would take a lot of time. You have to draw from a number of sources, a number of tables and it would take quite an effort develop that same plan but you can do a quick check to a specific point or you can do a rough estimate by using tabular data, comparing it to that computer plan.

Getting back to the first part, A, method used as a basis to calculate delivered dose, radiographs appear to be the majority of the cases. Most people using radiograph, an AP view orthogonal film, a diagnostic machine or simulator, portal films used on the cobalt-60 machine itself, these sort of things were used with appliances, dummy sources or active sources after installation or after installing the appliance.

It also appears that more and more and more people are using CT systems, which they're digitizing electronically the information directly into their treatment planning system, which is more accurate in placement of the

patient in proximity to the machine and it also gives you a little more morphology for the oncologist to deal with.

Any of these methods were fine.

You could use just dose tables, if you didn't have a computer, if you didn't do many cases, some people might just want to use dose calculations based on their experience in the field to determine the dose distribution, though not many people do that. I think the majority of people are going to use treatment planning systems. I think it is the thing of the future and it's the way everybody is going for more accurate and more efficient treatment planning.

In this objective 80 percent of the facilities, the submitted plans addressed this issue in regards to A and B, 100 percent on site based on our evaluations were actually doing A and B, so it appears that most people are in line with these objectives or these elements of this objective.

[Slide.]

MR. KLINE: Okay, a continuation of this objective, we looked at procedures for confirming dose calculations are accurate prior to completion of treatment.

We looked at who performs this and when, dosimetrists, physicists, technologists.

Number 2 up there, the manual dose calculation, can be used as a method for confirming dose calculations

Number 3, computer generated calculations and number 4, computer and manual calculations.

Number 2, the manual dose calculations, the team was looking in this one aspect for arithmetic errors, correct transfer of data from prescriptions, graphs or tables, correct use of nomograms, correct use of all pertinent input or all pertinent data use for input in your calculations.

Computer-generated calculations, we examined the computer printout or we requested or we asked the participant if they examined the computer printout to ensure correct input of data from your computer system and you could also address it in the form of calculating dose to a key point, manually and comparing with that of the computer, which I talked about a minute ago. There are a number of ways that that could be looked at and checked.

On the fourth item, computer and manual calculations, on the computer end you might address how it was done in item No. 3, where you examine the printout to ensure correct -- examine the output to ensure correct input data or calculate a key point manually and then look at the second part of that, the manual calculation, or you look at the computer and then the manual and you could do checks of either method and make sure though that whatever method you are using in complement with the others that that

information is correct because then your total dose is going to be affected and one side of the equation could be proper but the other side could not.

Whatever the problem might be, you want to make sure that if you're combining manual and computer plans that the data is correct as best you can tell.

[Slide.]

MR. KLINE: Remote after-loading devices; we didn't run into any -- oh, I'm sorry; let me take that back. We did run into one, one facility which did have a remote, after-loading device, but during the pilot study, no patients had been treated so therefore we did not evaluate that program because we felt that it would be unfair to address these objectives in this program if they didn't treat a patient or had not used any treatments using that device.

Again, we addressed the method of dose calculation, the verification of treatment time, the verification of dose calculation or verification of patient setup. These are different ways that that objective could be met.

With high dose after-loading, your dose calculations would have to be checked or double-checked prior to treatment. Obviously, you would not want to treat and then check your calculation afterwards. Again, we did

have the opportunity to review that particular modality of treatment in the field.

[Slide.]

MR. KLINE: I'd like to go on with teletherapy and again, we have to go back through these 8 objectives. Some of these will be redundant and the same. Objective Number One; again, ensure that the medical use is indicated for the patient's condition.

In this particular case, we looked at the medical use indications; whether or not they authorized user had reviewed each case. All the programs submitted a statement to the effect, or else a procedure by which this can be done. In the field and onsite, we found that everybody had reviewed or was reviewing the cases, case-by-case, or a physician under the direction of an authorized user was addressing each patient that was coming through and examining each case.

Similar to brachytherapy since there used in the same department, you would discuss these in chart rounds or at least one a week status updates, and of course, initial consultations with various participants in the treatment program.

[Slide.]

MR. KLINE: Objective Number Two, the prescription; again, as in brachytherapy, a prescription is

a written direction and order dated and signed by authorized users or supervised physician, containing -- and now we have some different elements in that objective -- the total dose, the number fractions and the treatment site.

Prescription changes are written, dated and signed. First of all, the authorized user in all of these site visits was writing a treatment plan to begin with, and that would address the treatment modality that he was going to be using, the treatment volume. Also in that definition, we found that the portal and field arrangement were also addressed.

The total dose and the number of fractions that were to be delivered, whether it be over time or just per fraction or per total dose and the treatment site, they were all addressed in that prescription. Almost 90 percent of the programs looked at this element and talked about all these parts of that objective or the elements within that objective.

About 90 percent of the time onsite, we found that everybody was doing this. Everybody was addressing total dose, number of fractions and treatment site. Prescription changes were also recorded, documented, dated and signed by the authorized user or physician under the supervision of the authorized user in one hundred percent of the cases.

As you changed your treatment regime or your

treatment chart, the physician was either initialing it or signing it or making sort of notation that that change had been reviewed and approved and was part of the treatment plan. Any changes that were abrupt, due to the patient having side effects or problems, I guess, with receiving the particular dose and they had to start another treatment regime; that was also documented, the prescription was updated and reflected that new course of treatment.

[Slide.]

MR. KLINE: Diagnostic referral; again, is not applicable because we're talking about therapeutic use which is through authorized users.

[Slide.]

MR. KLINE: Objective Number Four; ensure, prior to medical use, that the prescription is understood by the responsible individuals; we -- there appeared to be, again, -- I wouldn't say there was a problem in this area, but the programs did not address that particular objective, though, a hundred percent of the time, we felt it was being met in the field during the site evaluations.

Again, this was, as in brachytherapy, a professional understanding that was amongst the individuals that, of course, if there were any problems, that immediately the treatment would be stopped and there would be in inquiry into why this was different, why there

appeared to be an error. There was discussion for clarification.

We would often ask the physician, do you have an open rapport with your technologists or physicists? Will they come to you and ask you questions regarding that treatment that has to be performed? All the physicians said, yes, we have a very good dialogue and the physicists and technologists and myself are in a constant feedback loop. Everybody is informed of any changes in the patient, the treatment regime or how to calculate something that is different than originally was planned.

Reg Guide 2.1, again, addresses records will be legible and written clearly and precisely. So, this was considered a professional understanding and most people, if there were any questions, would go to the physician or the physicist and say, hey, what is this you have here? I don't understand what this number means or why are we doing it differently?

In Reg Guide 2.2, all workers request clarification from the authorized user; again, that appeared to be an ongoing thing in the field. We seemed to get a pretty firm feedback from everybody and the technologists that we talked with all seemed to have a pretty good rapport and understood that if there were any questions, we definitely would go to the oncologist and ask for further

direction.

[Slide.]

MR. KLINE: Objective Number 5: Ensure that medical use is in accordance with either the diagnostic referral, which doesn't apply in this case, or the prescription.

Medical use in accordance with instructions is, again, what we were looking for, the same as in brachytherapy. And instructions, we consider that to mean prescription.

We evaluated mechanisms by which the facility incorporated procedures to detect errors in the daily cumulative dose or any prescription changes.

We felt that currently most medical practices have a weekly chart check that is used for detecting errors in the daily cumulative dose summations.

And we also found that during this weekly chart check that any prescription changes were either noted or made in the treatment chart regarding the fractionation or total dose to be received by that patient.

So it appeared that all the programs that we looked at addressed this in the formal QA program that you submitted to the NRC, and 100 percent of the people in field were doing weekly chart checks, or some sort of review mechanism similar, if not the same, as a chart check.

A lot of the programs that we had an opportunity to visit had a nice mechanism by which they would tabulate the detected errors or the unintended deviations or mistakes that have been made during the treatment process, and they would document this, and they would collate and collect this information. And some people had developed some software programs by which they could spit this information out and present it to their quality assurance people, which, again, would submit it to the committee which would address that with the hospital administrator.

So it appeared that the collection of information regarding any errors noted on the treatment charts was brought to the attention of the authorized user and was often collected and used as part of the quality assurance program, which was meeting other standards of the industry. And it appears that more and more quality assurance is ing this way, where the errors are documented, and follow-up is incorporated. And we found that follow-up was incorporated in all of the errors that people showed us as example cases, or case histories.

[Slide.]

[Pause.]

MR. KLINE: Objective Number 6: Ensure prior to medical use that the patient's identity is verified as the individual named on the prescription.

The procedures on this other graph are identical to that of the brachytherapy. So I feel it is redundant to go back to those procedures that we were looking for in the earlier objective.

Again, we look for a redundant patient identification procedure, except in emergencies, where in the professional opinion of the oncologist or the authorized user, the safety of the patient could be jeopardized due to a delay with a redundant verification system. If that sort of emergent thing were to happen, then of course the patient redundant identification system need not be performed until, I guess, after the treatment had been performed.

We felt in a majority of the cases, there weren't that many emergencies.

[Pause.]

MR. KLINE: Okay. Objective Number 6, where we left off, patient's identity verified.

This was addressed only about 13 percent of the time in the programs that were submitted for review. On site we found 100 percent of the people were doing a redundant patient identification.

The treatment chart, for example, would have a picture of the patient, the patient's face. It often would have a picture of the treatment site. You might have different views of the treatment site. You might even have

a picture of the treatment setup or associated, oh, I don't know, compensators, boluses that were used, and fitted with the patient.

That met what we felt was the intent. You had a mechanism by which you had a second check besides the person's name, besides the chart, you also had pictures, you could have had an appointment book where you signed in at the front desk. The technologist, in the majority of cases, would come out and ask for Mr. Jones and would go look at the appointment chart or else the patient would bring a billing card or invoice receipt or a number of different ways.

Some facilities, the therapist, authorized user would come in and actually see the setup. He would verify in that mechanism that that person was who was supposed to be treated.

We are just looking to see if in particular there were any circumstances where you might have a person with the same name, same gender, same race, that comes in at the same time, that could possibly be mistaken for another person. And it appeared that most of the physicists, oncologists, or authorized users, technologists, if they were aware that a patient with the same sort of name or same sort of treatment site was coming in at approximately the same time of the day, that they would make sure that they

had the proper patient for that particular treatment and they were aware or were on alert to that fact, to that, in effect, that they could identify that person properly.

[Slide.]

MR. KLINE: Objective Number 7: Ensure that any unintended deviation from either the procedures manual for diagnostic, but in our case, the prescription is identified and evaluated. On site we address that as unintended deviations identified and evaluated. That could be confirmed by the above statement, or committed to the Regulatory Guide, 2.3 or 5.4, or was instructed. People in the field were again requested to terminate medical use if discrepancy identified. And once the discrepancies were identified, they were evaluated and corrected.

As in brachytherapy, the quality assurance programs that we were able to review had already instituted these sort of documentation and evaluation and correction of errors were noted during the treatment process, and were often submitted and nicely presented in these particular meetings that addressed quality assurance in the hospital.

Regulatory Guide 5.4 under (a)(2), after the Regulatory Guide looks at that in the context, after addressing, or after administering a dose fraction, that a qualified person will make, date, and sign a written record in the patient's chart or equivalent describing that dose

administered.

It appeared that all the charts that we looked at, which were case histories that the facility presented to describe how they documented administrations of doses, met that criteria. There was a written record. The patient's chart often reflected written records. But the department nicely satisfied, as a matter of fact, in 100 percent of the cases, all the different aspects of the treatment regime, including the dose fraction that was administered.

In the programs that were submitted, 63 percent of the people did not address or did address the unintended deviations identified and evaluated, though 100 percent in the field were doing this.

Under (b) again, in 7, record of administered dose and agreement with prescription. Well, the treatment charts would have the administered dose and the prescribed dose, and they were on the same sheet. So when these daily checks of the weekly chart, or the weekly chart checks were done, then these discrepancies might be picked out and identified, and the adjustment made accordingly.

[Slide.]

MR. KLINE: Objective number 8 ensure that brachytherapy and teletherapy treatment planning is in accordance with the prescription.

On site, we addressed it on our forms as treatment

planning in accordance with prescription. And then we have a number of Regulatory Guide references. We looked at a procedure to confirm dose calculations are accurate prior to completion of the treatment.

If possible, a person under the supervision of an individual qualified can check these dose calculations. If this is not possible, if you did not have another person, a dosimetrist or a technologist -- if it was available, then an alternative method for calculating dose could be performed by the physicist or authorized user, somebody that is qualified to do that calculation -- again qualified.

We looked at if the licensee or the facility felt that -- that the calculation could be performed by that individual and we -- we wanted to see if, in actuality, that -- that was being done. And it appeared that -- that the people which we talked with seemed to be well versed in how they could do a double-check.

You may also address the manual dose calculation for arithmetic errors on some brachytherapy, collect data transfer, proper information that was being used. And, when you're using a computer, as we talked about in brachytherapy, you could check the input. And you can check the input on the output sheet. When the program is spit out, input variables are listed again; and you can go through and make sure that the proper field size, the proper

total dose, the proper dose per fraction was being used.

If you're using a wedge, a filter of some sort, a compensator, these sort of things, if they're in your treatment plan, you could verify that was properly entered.

On item number b, independent check of full calibration measurements required by 35.632, and that's (a)(2)(i) and (ii). This independent check can be performed by, or could have been performed by an independent individual, so you could have another physicist checking the full calibration and, hopefully, with a different dosimetry system, to eliminate any programs with the same dosimetry systems, or you could use possibly a TLD service.

We saw that some individuals were actively involved in a protocol with particular institutions like M.D. Anderson, or the RPC, that actively submit TLD's to their program for verification. This would have nicely satisfied that independent check.

The 35.632 addresses changes of sources, so you would want to do a full calibration whenever you change your source or when spot checks differ by greater than five percent, so you could be plus or minus five percent. If it exceeded that, you'd want to do a full calibration; and this -- it just addresses an independent check of that calibration. That could be a method by which that could be performed.

Under item c, we looked at the calibration process itself. And full calibration includes check of the beam-modifying devices. What we mean by beam modifying devices can be just about everything you interject in front of that beam, which could be: trays, wedges, compensator material, block material, recastable block material, like cerebend. Any of these -- these sort of devices that are used to change the profile of the beam. We look to see whether or not the full calibration incorporated a measure to check that.

Now, the method by which to measure these devices -- again, there's a number of different ways. Some people use actual direct transmission measurements on the same blocks. Some people use films and use the densitometer and would measure the dose, or the transmission gradient through the block on the film. There's just a number of different ways that are acceptable and there's not any one exact way that is the correct way.

So the latitude to develop a system is there and a lot of people are using different various mechanisms.

Under number d, we look for a procedure to measure output, when nonroutine treatment parameters are used. This mainly addressed different parameters that were not addressed in your full calibration. If you were doing a different treatment from that that is ordinarily done in

your facility, you'd want to check, for example, of field size -- it's beyond the scope of your full calibration.

Treatment distances. If you change your treatment to a greater SSD, you'll want to do a measurement verification to see what sort of output, how that's effecting the output and consequently the dose to the patient.

B-modifying devices. If you have a different material, constantly they're developing new immobilization sorts of casting material of different density. When you have that, you have to measure that. You have to pretty much know what your transmission is so that your patient is receiving what the calculated dose is.

In asking the facilities if they were doing this sort of thing, I believe all the facilities we looked at said yes, we are. If we have any nonroutine parameter, we will measure it, and that's just good sound physics. And it appeared that everybody was doing that.

Under e, before first check, or after source change, computer program dose calculation checked against physical measurements. This is the same thing as saying, do you do acceptance testing?

The -- when people would receive a new software program from the individuals that we reviewed and looked at, they went through some sort of acceptance testing. The

testing would be in the form of running a set configuration for a particular field size in output and distance in tissue in the program, then they would do actual physical measurement with the water tank, or with some sort of tissue equivalent material and then compare the two.

They would sometimes even do a very elaborate way of looking at all sorts of profiles, and then getting at a water tank and measuring those profiles and collecting this data.

And some facilities would use tabular data, BJR data, and compare it with -- measure tank water data, and some facilities would use the actual input data from the calibration process that was digitized into the computer and then they would run a particular patient set-up in the computer and just compare the data on the doses to certain depths in tissue.

Whatever you might want to check, there are a number of different ways to do it. And we felt that -- that based on our review, that everybody seemed to incorporate some mechanism by which they were checking dose and verifying that the treatment plan from the computer was actually what was being delivered.

[Slide.]

MR. KLINE: I'm going to talk quickly about some of the results. And what I would like to do is look at what

we call the facility statistics from the site visits, before we get into the actual results.

This is more or less a summary of all the facilities we looked at, and some of the things that we found.

We found that five private practice facilities included two diagnostic, three teletherapy, and one brachytherapy program. These statistics encompass the diagnostic nuclear medicine and therapeutic nuclear medicine. So this will also complement the earlier talk in nuclear medicine.

Thirteen of the hospitals ranged in bed size from 150 to 1,000 beds. So we had some small facilities and quite large facilities.

Fifteen diagnostics nuclear medicine facilities, they averaged a workload of 180 to 7,500 procedures per year.

Twelve radiopharmaceutical therapy facilities averaged 3 to 52 procedures per year.

Five brachytherapy facilities averaged a workload of 40 patients per year.

And eight teletherapy facilities averaged a workload of 30 patients per month, which was approximately 400 to 500 treatments per month. That would be a treatment, not a fraction, but a treatment for that particular patient.

MR. BUKOVITZ: Clarification: When you say "[illegible]nt," do you mean a complete course of treatment, like more than one fraction, 10 fractions, 20, 30 fractions?

MR. KLINE: It would be actually the treatment that day for that patient. It could be a fraction or it could be a number of fractions encompassing that particular treatment. So if you had a patient come in and they were treated, oh, whole brain, midline, okay, that would be a treatment, even though it had two fractions associated with it, for that particular day.

So you have a treatment on that particular day that occurred.

MR. BUKOVITZ: I'm confused. But we'll discuss that later.

MR. KLINE: Okay.

[Pause.]

MR. KLINE: An evaluation of the eight objectives in nuclear medicine for the 15 facilities was tabulated in this histogram, where we're looking at each objective. And you have Objective Number 1 through 8. And then we have from zero to 20, the facilities meeting that objective.

Now, the legend shows that the program reviewed refers to the QA program that you submitted to the NRC for review addressing each of the eight objectives.

That is the striped line at the top. Then the

solid line is the site audit, or the evaluation by the QA team, and how each facility fared in regards to meeting that objective.

Now, nuclear medicine, for diagnostic nuclear medicine, which we defined as less than 30 microcuries of iodine-131 of iodine-125, or non-use of any therapeutic procedure in nuclear medicine, it appeared that 100 percent of the facilities submitted a program of which 100 percent on site were meeting the objectives as described in that program.

Under Objective Number 2, it appeared that two out of the 15, or 13 percent of the facilities had submitted or had met the 10 of the criteria by submitting to the objective their method for meeting that, the elements of that objective. But it appeared that we had a problem with having that objective implemented on site.

[Slide.]

MR. KLINE: And the best thing to do, so you can see what objectives are what, as I put it up here, the first objective was to ensure that medical use is indicated; that was met 100 percent of the time in both cases, the program and the on-site evaluation.

Number 2 objective was to ensure prior to medical use that prescriptions made for any therapy, that since we are dealing with nuclear medicine and non-therapeutic, it

would be any radiopharmaceutical procedure involving more than 30 microcuries of iodine-125 and iodine-131.

Again, 13 percent submitted to this. On site it appeared that there were problems in parts of that objective, in part, not so much in whole. The areas that problems were to be found were that written changes were not addressed or items were missing in the definition of administration. Samples, the 13 percent only, some people sent samples of what was addressing that Objective Number 2. But in the field we did not seem to have, I guess those samples, which are meeting all of the elements as described.

Objective Number 3: Ensure prior to medical use that a diagnostic referral is made for any diagnostic radiopharmaceutical procedure. Note that these procedures involve more than 30 microcuries of iodine-125, and iodine 131.

Objective Number 3, it appeared that 80 percent addressed this program area and 67 percent in the field actually met that program area.

Now, again, we looked at the definitions. And you had to satisfy all the parts of the definition in order that that satisfied the objective.

Objective Number 4: Ensure prior to medical use that either the diagnostic referral of the diagnostic clinical procedures manual and the prescription is

understood by the responsible individuals.

It appeared that the programs were about 50 percent that addressed that and 50 percent which did not address that. But on site, it appeared that 100 percent of the people were actually meeting that objective.

Objective Number 5 addresses medical use in accordance with the diagnostic referral and the clinical procedures manual, or the prescription.

Eighty percent or I believe 12 people addressed that in their program. A hundred percent in the field were actually doing it. That is Objective Number 5.

Number 6, the patient's identity is verified as the individual named on the referral or the prescription.

Forty percent of the people submitted to this in their program; 40 percent of the facilities addressed that. Seventh-three percent of the facilities in the field met that definition, and were actually meeting the objective as set forth.

Number 7: Ensure that any unintended deviation is evaluated and identified.

Again, 40 percent in the field, or 40 percent of the people submitted information that met that objective in their program that we reviewed. But 100 percent of the people in the field were actually meeting that objective.

So it appears that in these last four objectives,

that people were doing more than what they thought they were doing, or else failed to note that in respect to their program that was submitted to us, or possibly interpreted the objective differently from what we felt the interpretation or what our team had designed the objective to meet.

So it could have been a number or combination of those reasons why those objectives were not met.

The Number 8 Objective addresses the quality assurance program and it addresses, in this particular case, brachytherapy and teletherapy and since we're talking about nuclear medicine, that would be on a subsequent graph and we'll look at that.

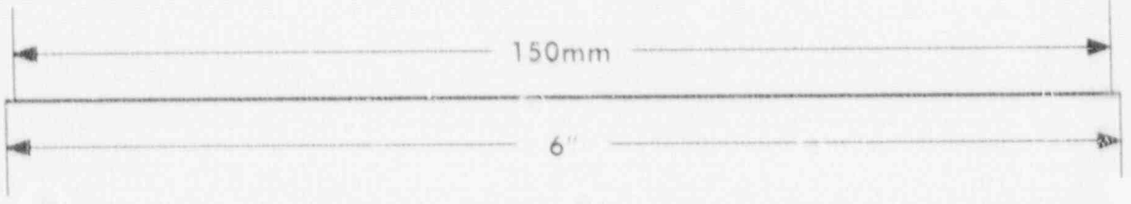
[Slide.]

MR. KLINE: Looking at the Eight Objectives for pharmaceutical therapy, the medical use indication, 100 percent of the people submitted a procedure which addressed that and it appeared that a hundred percent of the people onsite were meeting that objective.

Objective Number Two; assure prior to medical use that a prescription is made -- and we're talking about pharmaceutical therapy -- it appeared that 3 of the 18 facilities addressed that -- of the 12 facilities, excuse me -- and only one was actually performing the objective in the field, so there was 25 percent versus 8 percent.

1

IMAGE EVALUATION TEST TARGET (MT-3)



Now, on Objective Number Two, it appeared that that prescription seemed to be the problem where people were not addressing each element of the prescription. In other words, if you didn't talk about all the necessary aspects as defined in the definitions in 35.2, then that particular element in that objective was not met.

Also, if written changes were not addressed, if any change in a prescription was not addressed, then it did not meet the objective. Also, there were cases where items were missing from the definition of prescription in the program.

Onsite, it appeared again that this definition of a prescription was the problem area where you could have possibly not listed the chemical form or the physical form or the route of adminstration for that pharmaceutical. Those, as were talked about earlier, were somewhat redundant in the minds of individuals which had the programs in tact. If you only use, let's say, sodium iodide in pill form, why would you have to say, ah, I'm using sodium iodide in pill form when that's all you have in the department.

So, again, that definition of prescription seemed to be the problem that we ran into with regards to meeting that objective, though the other aspects of the objective could have been met in full.

Objective Number Three; that's the diagnostic

referral and we're talking about therapeutic, so that does not apply in this case. Objective Number Four; ensure, prior to medical use, that the prescription is understood by the responsible parties; it appeared that 50 percent of the applicants and their programs addressed this element, this objective. A hundred percent were actually performing this objective in the field.

This was the item in the program that was either not addressed or thought to be professional understood by all participants in the program. On the site evaluation itself, it apparently was the case where most people were knowledgeable of; well, hey, if I've got a problem, I know to identify it and I know who to contact and I understand the procedures manual and we have a signoff in our training booklet that says we've read the procedures manual and this sort of thing was addressed in field.

Objective Number Five; to ensure that medical use is in accordance with the prescription; 83 percent, 10 of the 12 facilities, addressed that as an objective in their submitted program. Onsite, a hundred percent of the people were meeting that objective.

On Objective Number Six; ensure prior to medical use that the patient's identify is verified as the individual named on the prescription, a little less than 50 percent were meeting that in their program submitted,

whereas 83 percent in the field met that in its entirety, or we felt, met the intent of the definition.

Often, the procedure was just not addressed in the program that was submitted to us. There was no notation or documentation submitted addressing that objective or that particular part of the objective.

The other area that we found maybe some problems with was in the area of outpatients in nuclear medicine where there was not some sort of redundant procedure for outpatient verification. The inpatient verification redundancy was met with the armband, usually, and a chart that went with the associated patient.

The outpatient was a little more involved with people coming outside of the facility in as to some sort of redundant mechanism to check. Objective Number Seven; ensure that any unintended deviation is identified and evaluated from the prescription; 25 percent of the programs submitted met that, whereas a hundred percent in field actually met it.

Apparently it was just not noted in the program or it was not addressed, but people were identifying problem areas in their QA program, had actively and were actively doing this at the time of the site visits, so I believe it was a little bit more of a documentation problem and more interpretation of that objective that might have led to why

that was not addressed.

Number Eight; this brachytherapy and teletherapy applies only to those two programs.

[Slide.]

MR. KLINE: The evaluation of eight objectives in brachytherapy for the five facilities that we went by and visited, it appeared that Objective Number One was submitted in your program and also met on site in all five facilities, so it was a hundred percent of the time.

Objective Number Two was addressed 40 percent of the time, only two facilities. Again, we're talking about small numbers here, so when I talk about percentages, the difference is not to statistics; it's just a percentage based on these small numbers that we looked at.

Forty percent addressed it in their program, whereas 80 percent met the objective on site. Again, the definition possibly had a problem here in meeting certain of those elements in the definition.

Objective Number Three, again, is not applicable because this is for diagnostic referrals of less than 30 microcuries in nuclear medicine.

Objective Number Four; the prescription is understood by the responsible parties; 40 percent addressed it in their programs, whereas a hundred percent of the people actually were confirming that there was an

understanding of what the prescription meant and what it entailed with the responsible parties. The majority of the problems with the programs that were submitted, we believe, just did not address the issue, not so much as not performing the intent of the objective.

Objective Number Five; ensure the medical use is in accordance with the prescription; 60 percent of the programs -- 3 of the programs -- seemed to meet that on paper, whereas a hundred percent met it in field.

Number Six; ensure prior to medical use that the patient's identity is verified as the individual named on the prescription; number six we have blank. It doesn't mean that nothing was done. It appeared that in this case, it was interesting that none of the procedures addressed that objective, though everybody met that objective -- that's Objective Number Six.

There appears to be a redundant identification process and as to why that was not addressed, I'm not sure, but it appears all facilities were looking at photographs, names, ID numbers, sign-in logs, billing. There was a redundancy. The authorized user looked at the patient, the technologist confirming the picture with that of the person in person or the individual that they were treating so that redundancy was there.

Objective Number Seven, unintended deviations are

evaluated in the prescription and they are the acted on. It appeared that 60 percent, three of the five facilities, addressed that, whereas a hundred percent actually performed that objective.

Again, the QA program identifying the problem areas in their existing program seemed to meet the intent of what our objective was in this case.

Objective Number Eight; 80 percent of the programs submitted addressed that objective and met it. A hundred percent of them were actually performing that objective.

Objective Number Eight addresses the brachytherapy treatment planning is in accordance with the prescription and that addressed the independent check, the computer checks, the non-routine parameters and things of that nature, seem to be done in clinical practice.

[Slide.]

MR. KLINE: The last histogram addresses the teletherapy facilities. And just in case -- I'm sure everybody has these memorized by now, but just in case you want to reference those objectives again.

The patient's medical uses indicated for the condition. It appeared that all eight facilities addressed that in their program submitted to us for review and also on site.

Objective number two, 88 percent -- seven out of

the eight addressed it on paper, 100 percent met in field. And objective number two is the prescription that's made for any teletherapy procedure. And the prescription elements again, might have been the problem with one facility, where meeting all of the elements by definition.

Objective number three is not addressed in teletherapy, it's a diagnostic referral.

Objective number four. We had three out of the eight facilities, 38 percent, meeting the objective on paper, versus 100 in field.

The, again, the professional understanding in the community in medical physics, the prior training, certification programs seem to take care of this. And people felt it was some what of a redundancy to have to state this on paper, that, oh yes, I do understand the prescription, if I don't, then I go to the physicist. It was almost an ironical question to ask somebody. One comment, I believe, was, "well, we're all professionals, do we have to be this double-keyed redundant in order to meet that objective?"

So it appears that everybody was meeting that objective in field.

Objective number five. We had 100 percent, on paper, meeting it, 100 percent in field or on site meeting it. This is your -- ensure that medical use is in

accordance with the prescription.

Number six. We only had 13 percent of the people, on paper, meeting this; but 100 percent of the people in the field were meeting it.

It appears that that identify process or that identify verification of patients -- the procedures were just not submitted addressing that, though it wasn't being performed. The same thing with brachytherapy.

Number seven. Ensure that any unintended deviations are identified in the prescription and evaluated. Sixty-three percent of them, on paper, met it; 100 percent, in field, met it.

Objective number eight. Ensure that the teletherapy treatment planning is in accordance with the prescription. Twenty-five percent of the individuals met that and that was those four elements that we talked about: The independent check, computer program check, measurements, nonroutine parameters. But 100 percent of the people in field were addressing that and were performing it. So there was a nice verification of any new treatment plan or new treatment planning system and the associated full calibration necessary under the requirements of that objective.

In summary, just looking at all these histograms, it appears that a lot of the programs did not address each

of the objectives in whole, maybe in part. But it appeared that, on site, the majority of programs were meeting the objectives, which was more important, I think, of the two. It just shows that people either misunderstood our objectives or did not address them with a roadmap or follow them quite as closely as we thought they would have done -- necessary to evaluate the program accordingly.

But, on site, it appeared -- everybody seemed to be meeting each of objectives a little more closely than on paper.

Okay. All right. I'll hand this to Mr. Telford.

MR. TELFORD: Okay. We've come to the point on the agenda where we have a period for questions and answers. Well, I'll give you a couple of minutes. If you want to ask any questions about this. If not, we'll break for lunch and come back and get into the individual objectives for the proposed 35.35.

Anybody object to breaking for lunch now?

[No response.]

Okay, no objections.

It's about -- well let's say it's 10 till and let's come back at 10 till -- I have almost 10 till 12:00, let's come back at 10 till 1:00.

MR. KAPLAN: Will you fill this form out and just drop it off with me, please?

MR. STRUBLER: Can you elaborate on that?

MR. KAPLAN: Yes.

MR. STRUBLER: In other words, authorize the activity to participate.

MR. KAPLAN: Right. Authorized column pertains to your license; active, whether or not you have an active program going on in that area, despite the fact that your licensed; and participating means whether or not that particular program participated in our pilot project.

MR. TELFORD: Any other announcements.

MR. KAPLAN: Oh. Just to remind you of something close and dear to your hearts, on the reimbursements. Please, this time -- I really need original receipts -- no copies, please. And if you need any more worksheets for your expenses, I have them here. Feel free to take them. Thanks.

MR. TELFORD: Okay. Let's break for lunch.

[Whereupon, at 11:50 o'clock a.m. the workshop recessed for lunch, to reconvene at 12:50 o'clock p.m. that same day.]"

AFTERNOON SESSION

[1:20 p.m.]

MR. TELFORD: This afternoon let me call your attention to the agenda. What we want to do is go through the proposed Section 35-35 regulation. We want to examine each piece of it and get your suggestions for what to do with it and how to treat it, et cetera.

Now this viewgraph I have on the left here, part of that is relevant here. In particular No. 5 and No. 6 at the pre-trial period workshops we told you that we were going to carefully listen to you and this afternoon we are going to begin doing that.

[Slide.]

MR. TELFORD: I'd like to start -- you see from the agenda the Item No. 1, the purpose. You can visualize this as the purpose paragraph that is in the Federal Register notice under 35-35. This basically says that each licensee shall have a QA program which will prevent, detect and correct the cause of errors in medical use. It further says that the purpose of the regulation is to prevent errors in medical use, so that is what the viewgraph on the left is cryptically trying to say is that we'd like to declare those purposes and that objective of prevention.

Now does anybody want to make a suggestion?

[No response.]

MR. TELFORD: Okay, the theme here is out in -- after Item No. 2 there I have the cryptic message "delete, modify or retain." For each piece of this that we pick up, look at, like this purpose paragraph here, what we would like to hear is would you retain this as is? Would you modify it? If so, how? Would you delete it? If so, why?

Does anybody have anything to say on the purpose paragraph? Go ahead.

MR. STRUBLER: There's a lot to say, I think, and also seeing what is going to happen tomorrow where we are going into individual guidelines which some of us have some critical comments to make regarding that.

I'll just open things up and offer a few things that come to mind.

The broad question has been addressed a couple of times and discussed in the first workshop regarding the purpose of the program. We I think are all in agreement in this room that we need to have an established basic quality assurance program, which we all have. Whether they are sufficient to meet the purpose of the whole program is something that all of this is being discussed.

The first comment I think to make again is that the purpose is to reduce and minimize the number of errors that are being made that are primarily perhaps human errors and to have a quality assurance program to ensure that these

are in fact going to be reduced or minimized.

The concern that I have initially and I will raise it again is that the impetus of this, as I understand, is that there were misadministrations and errors that are being made over the last ten years of record-keeping and documentation which still amounts to some fractional percent and whether that is something like .04 percent and are we trying to put our resources and investment of time and money into reducing a .04 percent to .03 or .02. That is kind of the broader question in terms of implementing a program.

I think that in terms of requiring it from a legislative point of view in regulatory agencies that if there's not a QA program requirement that does not exist now I am in favor of adopting some kind of a program for the Nuclear Regulatory Commission. The question is that it seems to be that this is going to be done and how it is going to be done is something that we in these workshops can comment on.

I still raise the broader question again in terms of is the time and effort and investment of our resources really going to achieve an improvement and lessening of errors that are being made.

MR. TELFORD: The question I put before you is if these -- if this is our declared purpose, to prevent, detect, and correct the cause, or if this is our declared

objective, prevention not minimization, but it says prevention, would you propose to change that to minimization?

MR. STRUBLER: Well, I don't think you can prevent 100 percent of all errors. I think we all would agree to that.

MR. TELFORD: Okay, to provide high confidence then.

MR. STRUBLER: To provide high confidence that errors will be prevented, I think that statement is a reasonable statement.

MR. TELFORD: Okay, see, I want to give you a carte blanche to tell me whatever you would do to this, so if you would prefer to see "minimization" I would like to hear it and I would like to hear why.

I think you are telling me that you are comfortable with saying provide high confidence that errors will be prevented --

MR. STRUBLER: I'm comfortable with the language. I am uncomfortable with is it in fact going to achieve, because when we looked -- and we saw that there was perhaps discrepancies between what was in the program but in what was actually being done -- and we'll get to those later in some of the specific comments -- but you found out that there was still 100 percent reliability and what was

actually being done in these programs in achieving the objectives 100 percent of the time for many of the objectives being cited, so that there is already in existence programs that are meeting the objectives that you are hoping to achieve.

My question is then is the purpose -- are we spending the time and effort appropriately in regulating and establishing guidelines to achieve something that is already being achieved and met and that there are other guidelines in existence from other organizations and maybe reference to those should be made.

It's not so much that I object to the purpose of this because we'd all ascribe to that, it's just what extent are we going to go to achieve these values.

MR. TELFORD: Okay. Somebody else?

CAPTAIN HELLMAN: Well, I think the purpose is -- I don't have any real heartburn about what the intent is. Again, I have to agree that I'm not so sure I see a total need for it, but your intention is good. It makes sense.

MR. TELFORD: Okay. Frank?

MR. KEARLY: Well, I agree a lot with what Ken says. We have talked a lot about this.

I think that you have to recognize, NRC has to recognize that the professions, especially in therapy, for the last fifteen years have done a lot of work to get

everybody doing the righ things and we all acknowledge that professional and it is a very basic thing in training programs for everybody now, so what you find when you go into a therapy facility is people who are trained to think that quality assurance is what you have to do.

Perhaps it doesn't need regulation to the extent that you're thinking.

MR. TELFORD: Okay. Is there another way? We will be meeting with the AAPM and ASTRO, and meet again with ACR to try to use anything that they have developed. And we will also meet with JCAHO. And we can work on ways to incorporate what they have already started with and tried to certainly minimize any overlap or maximize the use of their stuff. We can certainly do that. But see, for, like the sample of 18 that you heard about, most of those were NRC licensees, because, of course, the NRC is going to license and inspect those folks.

If we have a final rule, it would be a matter of compatibility for all agreement state licensees. And there are approximately 4,000 of those.

Currently, as of April 1st of this year, agreement state licensees are now required to report misadministrations using the definition in 35.2. Prior to that, they were not required to even report.

So if you took on our problem for a minute and

said how do we prove we're doing our job, how do we prove we are guaranteeing adequate safety to members of the public, if we did just have reporting requirements, you would look at the misadministrations that have occurred and you would say how are we showing that we are doing our job.

If, on the other hand, we have some sort of regulation, even though it is performance-based, and would give a lot of latitude to licensees, it demonstrates that we are trying to do our job to guarantee safety.

Now, this is all assuming that we are in concert with the professional organizations that exist. So if you have a suggestion for how we could try to do our job but do it, you know, try somewhat differently, that would be interesting to hear.

MR. KEARLY: I think, as Ken said, we all agree that we do need a QA program. I'm in agreement with what you have as the, what we're talking about here, the first paragraph.

MR. TELFORD: Okay.

MR. KEARLY: What I would say is, I would hope that you would work very hard to minimize the redundant burden on the facilities. The redundancy is in documentation as well as program format, which we have several agencies who tell us to do different things and want to see it in different formats.

If you are going to be another one of those, without any promise whatsoever of improving clinical practice in any way, other than to add a documentation and reporting burden to us, I think you are doing the wrong thing.

I don't think it is wrong to require a quality assurance program, but I think that part of it, and that is what we will go through I hope in detail, later, that part of it is very bad.

So minimize the irrelevancies.

MR. TELFORD: I sense that you are focusing on the reporting requirements that cause you some concern.

MR. KEARLY: Some of the quality assurance part of it as well.

MR. TELFORD: Okay.

MR. KEARLY: But I am, I do believe strongly that the reporting requirements fall into that.

MR. TELFORD: Good. We'll go through those in detail tomorrow.

Anybody else on the purpose paragraph?

MR. BUKOVITZ: A question for clarification.

MR. TELFORD: Yes.

MR. BUKOVITZ: What really was the impetus of this?

MR. TELFORD: Impetus of?

MR. BUKOVITZ: Impetus of establishment of this basic QA program.

Was there something that said that people out there were not doing an adequate job or somebody in the NRC said I think we should do something about this? Somebody within the NRC says maybe we better show people that we are doing our job? But just the rationale behind it. Maybe that would help us understand it.

MR. TELFORD: I tell you what I can do for you, is, it takes a while to do it. But I have several viewgraphs on recent misadministrations. And after we get done with 35.35, if you like, I can go through those. And it sort of builds a story for what the problems are we are trying to fix, and kind of establishes not only the need but the proposed solution, and the kinds of generic solutions that we are trying for here.

So if the volunteers would like that, I can certainly do that at the end of this. Unfortunately, it's not a short answer. And to understand it, I think you have to look at the details. So I'm certainly willing to do that, for as many of you as want to sit in for that.

Okay. Anybody else on the purpose paragraph?

[No response.]

[Slide.]

MR. TELFORD: We're going to step through this

outline here for 35.35, sort of in order. We looked at the purpose paragraph and then we're going to look at each of the objectives, and then we're going to look at the audit requirement.

So let's take Objective Number 1 right now.

What you have to keep in mind here of course is that this is a performance-based regulation.

We're listing here eight good things to do. If the QA programs address these eight objectives in some fashion, that would either meet the guidance that we will have in the regulatory guide, or would be something equivalent, then you should be allowed to do it.

So please don't take these as prescriptive statements. If you can meet these objectives in some way, then that ought to be sufficient.

So who wants to talk about Number 1, Objective Number 1? Should we retain that; should we modify it; or should be delete it?

MR. KEARLY: I'd like to make a comment.

I think Objective Number 1 is, when compared especially to what appears later in the Reg. Guide, you are being entirely simplistic. The ACR has come out with clinical recommendations for physicians on this item. This is a very complicated question. The appropriateness of treatment. I mean, when you say is the patient, is it

indicated for the patient's medical condition. We're talking about therapy, now. It's a different question than diagnostics altogether.

But "to be indicated" can also mean is it the right, is the treatment given the right way, for instance. Not only should there be some treatment, but is this the right treatment as well. And that is a massively complicated question that the physicians consider very important and they cover it by a range of activities, including requirements on diagnostic information that is available, comparison to certain schemes of staging and so forth, conferences prior to treatment, conferences after the beginning of treatment. It's an extremely complicated question in total that you are covering by the statement in the Reg. Guide that says, has a physician looked at this patient and said it's okay.

MR. TELFORD: Examined the patient or the patient's records.

MR. KEARLY: Right. This one bothers me because it is, to do it right, you have to be a clinician. For you to evaluate if it is being done right, you have to be a clinician.

MR. TELFORD: Okay. Therefore you would delete this or modify it?

MR. KEARLY: Well, I'm not sure what I would

recommend. But it makes me nervous. Your interpretation, if you want to say that the physician has to see the patient prior to treatment and pass judgment on it, that's fine.

But to say that the, to ensure that the medical use, that the use is indicated, I think implies an awful lot more than just that.

MR. STRUBLER: I'll embellish on that, too. I have similar thoughts and comments. Effectiveness in preventing mistakes, I gave that and F. And for similar reasons: (1) I think it's both simplistic and complex. Complex in the way that Frank is describing it, in the sense that, if you ask a physician, well was this medication or surgery or therapy indicated for this patient, you know, obviously, yes. They're going to say no, it wasn't indicated, but I did it anyway.

There are obviously situations and diagnosis where it's done for legal reasons, obviously, and that's a separate question and not appropriate to this discussion. But, in terms of the simplicity or simplisticness of it, it's axiomatic. It's an obvious statement, and to have to make that, again, it comes under the comments that were made several times, regarding professional understanding and that -- we'll come back to that, I'm sure.

But it's I think axiomatic to -- to, in medicine, to say, well, this therapy was appropriate and it doesn't

have to be regulated or should not be regulated. And the complexity enters into the comments that Frank made appropriately, regarding -- there are some gray areas -- lots of gray areas in medicine, it's more of an art than a science and so -- the cost of meeting the objective I don't think is a problem here. But I would not rate it very highly in preventing mistakes -- I would probably.

MR. KEARLY: But how do you even meet the objective? If you meet it at the simple level, it's a low cost. If you truly meet it, there's a lot of work that goes into it. If you do it --

MR. STRUBLER: If you meet it at the complex level, it could well be --

MR. TELFORD: Okay, therefore, for your QA program, you wouldn't have it?

MR. STRUBLER: I would not have it.

MR. TELFORD: Okay. You wold delete it for the reasons you stated. Okay good. That's all right.

MR. KEARLY: I guess I don't agree with not having it. I think the physicians have this as a requirement.

MR. TELFORD: Okay.

MR. KEARLY: But they make them go through an awful lot.

MR. TELFORD: Okay.

MR. KEARLY: The ACR recommendations for

appropriateness of treatment --

MR. TELFORD: Yes. There's about 16 things they want to see in their prescriptions.

MR. KEARLY: There's a lot.

MR. TELFORD: Right.

MR. KEARLY: And in the process, documentation, and then procedures you go through for making sure -- peer review and that sort of thing -- which is JCAH-required.

MR. TELFORD: Okay. You would have it, but you would --

MR. KEARLY: But, I think --

MR. TELFORD: -- give better guidance?

MR. KEARLY: I don't think you guys are capable of evaluating it.

MR. TELFORD: Okay. What should we take as evidence that it was done then? Maybe a prescription, or a written directive?

MR. KEARLY: Well, this particular one, I'm not sure that if it's your business, to tell you the truth.

MR. BUKOVITZ: We would tend to agree.

MR. TELFORD: Okay.

MR. BUKOVITZ: One reason -- may I make a point? Are you -- I'm sorry, I didn't mean to interrupt. But the ACR has a commission on -- it's called Technology Assessment and Efficacy. And in May they looked at something very

similar, but they picked 20 different disease entities. And there are -- just within members on this commission, there was vast disagreement whether or not a certain diagnostic procedure should be or should not be done to look at the same disease entity. And this is what they're looking at.

Now, if these physicians were going to do this in conjunction with pathologists, surgeons, neurologists, etcetera, cannot decide among themselves whether or not it's efficacious, I seriously don't think the NRC really has any justification in number one.

MR. TELFORD: Oh, well, I mean, our intentions here were just to say that we want -- we think this is a necessary step. You know, the cognitive process that someone has looked at this patient, has looked at the patient's records, they've decided. The authorized user has decided that this patient should get this dose, or some dose of radioactivity.

MR. BUKOVITZ: But the physicians themselves aren't even sure. You may have two physicians within the same hospital with the same degree of expertise, who will say, I think this patient should get this procedure done; where another physician would not even dream of having the procedure done. It really depends on how they look at their processes of diagnosis.

MR. TELFORD: Well, in this case, either

authorized user could meet our intent, by saying, I'm the authorized user, I looked at the patient and the patient's record, I decided. We have to say yes to that. So, it's not a disagreement. I mean, we would not second guess an authorized user. But, rather, if that authorized user said yes, this patient needs this test, needs this treatment, that's fine.

MR. STRUBLER: I think Frank and Andy are pointing out the complexity of interpretation -- one way of interpreting this is very complex. And they're quite right in their statements.

The other thing I'm pointing out is that from a simplistic level, it's like you have to have a regulation if you're taking your car to work you say, well did you start your car before you took it work, as a simple analogy.

MR. TELFORD: Right.

MR. STRUBLER: Again, I'm saying, from that point of view, you're stating the obvious. Did the physician spend a little time in making a decision that this was appropriate medical use for this patient. And again, an obvious statement like that should not have to be regulated.

MR. TELFORD: You would take it out of your QA program?

MR. STRUBLER: I'm not saying it's not important. I'm just saying it's a very critical point.

MR. TELFORD: Frank, what if we had a written directive from an authorized user that said for a diagnostic case or a therapy case. Could you live without number one if we had that written directive?

MR. KEARLY: I'm not sure I understand what you're saying.

MR. TELFORD: Oh. In a diagnostic situation, you have an authorized user that has some way endorsed the test, has agreed -- you've got a referral -- a patient that's been referred. The authorized user, in some way, has agreed that this patient should get this test; or in the case of therapy, the authorized user has said, this patients needs this therapy. If that acknowledgement is committed to in writing; in the case of therapy, that's obvious, that's a prescription; in the case of a referral, maybe that's just some sort of an initial agreement that the authorized user has checked over that referral and has agreed to it by putting their initials on it or something. If that were the practice, would we need number one?

MR. KEARLY: You mean without a regulation then?

MR. TELFORD: No. Just delete -- what I'm saying is that what if we had that, could we delete number one?

MR. KEARLY: For NRC's competence, yes. NRC is not competent to judge efficacy or appropriateness of treatment. That's what that says in real terms, and you

aren't competent to judge that. But, so, if the only thing you're trying to accomplish is to make sure that any patient that makes it to therapy goes through a therapy physician -- if that's your intent, that is what's done 100 percent of the time. There is no such thing as a patient going to therapy without a therapy physician saying go there. That just doesn't happen period, anyway.

And if that's the only thing that NRC is trying to accomplish, then this is not necessary, because it is done for therapy.

MR. TELFORD: Okay, so under the conditions that are outlined, you would be able to delete number one?

MR. KEARLY: Correct.

MR. TELFORD: Okay, Joe, you had something to say?

CAPTAIN HELLMAN: I think that number one simply is one of those statements that's inflammatory enough that it gets the physicians' hackles up. And I think it's worth dropping because number two and number three will result in the same thing.

MR. TELFORD: Okay.

CAPTAIN HELLMAN: And I think it's just easier to drop it and you'll still get -- you'll still get what you want, be it, number 2 or number 3.

MR. TELFORD: Okay. Does anybody else have anything to say about objective number one? Gene?

MR. GRAHAM: No.

MR. TELFORD: Linda?

MS. FRANKLIN: No.

MR. TELFORD: Tom?

MR. DORING: No.

MR. TELFORD: Okay. Let's move to number two then.

Now, number two, what we're trying to do is get the directive committed to in writing. I mean, we've said here, we'd like to see a prescription, and we'd like to see it, certainly in the case of teletherapy, brachytherapy, or radiopharmaceutical therapy.

If it's therapy, you know, that probably happens, you probably have the prescription. Maybe you -- we've thrown in a little wiggle here. We've got greater than 30 microcuries of I-131. So, would you retain this? Would you modify it, or would you delete it?

Joe?

CAPTAIN HELLMAN: Just a definition, the description I don't remember now. Is that now being written by an authorized user?

MR. TELFORD: It's signed by an authorized user. Dated and signed by an authorized user.

CAPTAIN HELLMAN: Or a physician under the direction of an authorized user?

MR. TELFORD: Yes. Under the supervision.

CAPTAIN HELLMAN: Yes.

MR. TELFORD: We have a definition of supervision in 35.2 currently, in the regulations.

CAPTAIN HELLMAN: You redefined it, and I wasn't quite sure.

MR. TELFORD: Well, what we did when we defined prescription was we said it is dated and signed by an authorized user. And we specified a certain content, certain minimum content.

Like for radiopharmaceutical therapy, we said the isotope, the chemical form, the physical form, the route, the dose. So it is those things that you would expect to be there, just added to our definition.

As a matter of fact, does everybody have, everybody's got this, right? This handout?

Let's look. This is Page 1447. Definition of prescription.

Yes. Prescription means a written direction or order for medical use for a specific patient dated and signed by an authorized user.

Then what follows the A, B, C, D specifies the content that we are looking for depending upon whether or not it is radiopharmaceutical therapy, teletherapy, or brachytherapy. Because it obviously makes a difference.

CAPTAIN HELLMAN: Anyway, I have been working with A, B, or C, and my nuclear medicine physician says he understands the intent about D, and is satisfied with it.

MR. TELFORD: What would he like to do with D?

CAPTAIN HELLMAN: Well, he said he's satisfied with it, but he knows other members of the community who would feel uncomfortable about what would still be considered diagnostic levels of I-131.

MR. TELFORD: Okay.

CAPTAIN HELLMAN: But he has no objection.

MR. TELFORD: All right. Gene? What would you do with Number 2?

MR. GRAHAM: I think I would hold on to it.

MR. TELFORD: Okay.

MR. STRUBLER: Yes. I think this is appropriate. It may be very obvious, particularly in most therapeutic procedures. There is the greyer zone for those hovering around the 30 mics of iodine.

MR. TELFORD: Okay.

MR. STRUBLER: That again is perhaps also axiomatic that people are not going to give therapeutic doses without authorization by a physician. Written -- well, with exceptions, verbal. Verbal authorization at times.

MR. TELFORD: Okay. Does anybody else want to say

anything about number 2?

[No response.]

MR. TELFORD: No? Do I take it that most people are comfortable with number 2?

MR. KEARLY: Let me just raise what may or may not be a minor issue with respect to this. The same question will come up each time.

Ensuring that a prescription is written down and signed by the physician prior to treatment, if it doesn't happen, what are you making us do? What kind of records do we need to keep, for instance, in this case?

CAPTAIN HELLMAN: I.e., telephonic prescription.

MR. KEARLY: Well, no, even the physician who has just gone through simulation, the charts are all filled out, he just forgot to put the daily dose in and he walks by the dosimetrist and says I want 180 rads a day, but I've got to go over to see Patient B over here. The dosimetrist may do a calculation for a treatment that's to take place that day but that won't get filled in 'till later in the day. Now, that's a technical violation of the terms of this.

MR. TELFORD: What did he specify in writing, the authorized user? What did he sign his name to? Nothing?

MR. STRUBLER: That's what he said. He forgot to sign.

MR. KEARLY: Right. And he had to go see another

patient while this one is going to start. Sometimes things get very busy. Now, what are we obligated to do? You're not talking about any clinical --

MR. TELFORD: This is teletherapy you're talking about. And --

MR. KEARLY: You're not talking about any improvement in the clinical environment by requiring that this guy not go to that other patient, he has to sit down and spend five minutes filling out his prescription.

MR. STRUBLER: Let me interject also, this prescription here, you should probably clarify that. I guess that you do have some definitions. But it might be proper to write "written prescription" if that is exactly what you mean.

And there are many cases, particularly so, maybe brachytherapy, where there will not be a written prescription, because it's a fluid kind of thing in the sense of the dose is not going to be determined until a lot more information has come in terms of critical tissues. And the written part may even be unnecessary for that matter, may be quite verbal, because it is a very interactive kind of thing with the physician and whoever is doing the treatment planning, with brachytherapy.

MR. TELFORD: Yes. We recognize that brachytherapy is a very interesting case.

MR. STRUBLER: So that, now that I'm reflecting more on this, that I would probably raise some concern about.

MR. TELFORD: I think in our Regulatory Guide we will talk about a written pre-plan for brachytherapy. Because I think the situation you are thinking of is prior to implant.

But after implant, then you could have a prescription. Because what is left over, the only thing left to define is the time that the sources stay in. And we do mean a written, we say written direction or order.

MR. STRUBLER: Oftentimes the time is determined by the physicists in conjunction with the physician, for example.

MR. TELFORD: Okay.

MR. STRUBLER: And the physicist will make a recommendation, or the dosimetrist, and then there is some discussion. And then the physician says yes. Because oftentimes the physicist has some more insight because of experience in the physical foundations of what is going on and will be making lots of recommendations to the physician who makes the final decision.

And so, you know, the physician says well, tell me when it comes up, this is what I want, and through collaboration a decision will be made.

So there still may not be something initialled when you are also in a small facility, I think there may not be something initialled until the physician dictates what the details of the procedure have been and what doses have been delivered. And it could even be at the completion of therapy.

MR. TELFORD: Well, --

MR. STRUBLER: I can see some problems with it. Not serious problems. But --

MR. TELFORD: With brachytherapy.

MR. STRUBLER: Correct.

MR. TELFORD: Because it requires a written pre-plan which has to be altered after the implant is done, most probably, and then the parameters specified after the implant.

MR. STRUBLER: It would be more a formality, because it wouldn't be such that it would prevent mistakes, because there has to be that interaction and there has to be that discussion of what time the sources are going to be coming out and even what strength they may be. And so that it is something that would be very soft in terms of preventing mistakes, but it would be --

MR. TELFORD: The strength of the sources, those have already been implanted.

MR. STRUBLER: Right.

MR. TELFORD: They are there.

MR. STRUBLER: They couldn't even be modified after, because of the timing of when it is going in and when it's coming out, they'll say let's do this, and then we'll study it and we may modify it. We don't want it to come out at 3:00 O'clock in the morning, so we'll take it out. You know, lots of variables that are going on here.

MR. TELFORD: Okay. Well, the intent that we are trying to accomplish here is that let's take the case of brachytherapy. We would like what is about to happen to be written down. That could be in the pre-plan. You make an implant, and now you are going to specify the time that they stay. So that the ideal case is to have that directive in writing so that people know exactly what to do and can follow it and they don't forget.

In the case of teletherapy, in teletherapy, they usually go to a lot of trouble to fit the patient for maybe a beam-shaping device or immobilization, and they go through a trial run where they just use the laser instead of the beam.

It seems that --

MR. KEARLY: Well, there's no question it can be done. I don't, I think it's a good requirement. I'm not arguing with that.

I'm just saying what if it fails; are you

requiring us to keep records of such things?

For instance, what do we have to do if it does fail?

MR. TELFORD: Let's suppose that this is the performance-based rule, number two, and we have an allowance for emergency situations.

MR. KEARLY: But it's not an emergency for this patient.

MR. TELFORD: Okay. So then perhaps, the program should specify under what conditions that you would not ask the authorized user to sign off.

I mean, the case you've described is the authorized user is busy. Now, is that a good enough excuse not to initial something?

MR. STRUBLER: It's not an excuse; it's a reason. I mean, that's why it happens.

MR. TELFORD: Is that a good enough reason?

MR. STRUBLER: Yes, it is.

MR. TELFORD: Okay. That's what I'm asking.

Okay. So you would specify that under certain conditions --

MR. KEARLY: This makes it seem that we're doing something illegal when that happens, and it does happen. So what are we obligated to do?

MR. TELFORD: In this case, it would be against

your license condition if you had committed in writing to always have the written directive signed and dated by the authorized user, prior to. Now, most likely, that's what we're looking for. So you are saying that an adequate reason is that he is busy.

MR. GRAHAM: Our common goal there I think is to try to stop the misadministrations. And I don't think this is conducive to, for a potential problem, if just hollering that I want to go to, whatever terms he was using, across the way to a dosimetrist, and then go ahead and treat the patient with that thought.

MR. TELFORD: Yes.

MR. GRAHAM: I think we have to sit down and discuss these things and try to get it appropriately done prior to the treatment.

Consequently, misadministrations will be minimized.

MR. TELFORD: Yes, that's the goal. Right.

MR. GRAHAM: But being in a hurry I am not sure is conducive to minimizing misadministrations.

MR. TELFORD: Okay.

MR. STRUBLER: I don't think we're commenting that it's a problem of being in a hurry. It's a problem of oversight in not -- he writes everything else down but he forgets to sign.

MR. GRAHAM: We didn't say that I don' think.

MR. STRUBLER: Well, I'm saying there are lots of scenarios, there are many scenarios that are very common and some of them oftentimes are going to be verbal dose changes, a verbal one. A physician wants to make a change and is in another part of the hospital or another hospital for that matter and instead it becomes much more difficult in brachytherapy but I think the intent of this is fine. I agree with it. It's just that it has to be softened enough for those situations that are not uncommon where these circumstances occur they are not going to result in a misadministration or problem with the delivery of care, it's just a technical oversight if in fact the regulation says "it must be signed before treatment" and there will be many situations where it will not be.

MR. TELFORD: The situation that Frank presented us with was I think I recall it's teletherapy and somehow through all of the prior planning here and the alignment and all the device fitting and all of that, the dose has not yet been specified for this daily fraction and the physician says I want this patient to get 180 rads today. He has got everything else -- he or she has got everything else written in the prescription. They even dated and signed it but the 180 is missing for today, so how would you have this softened? What are we supposed to leave out?

MR. STRUBLER: You just change to say "usually or customarily" so that when those occasions arise and the physician signs it the next day it will give you a mechanism so that someone doesn't come in and say, aha, this was not done beforehand because I spoke with your technologist and she said she did it over the phone, so that you aren't going to get into the detail of a regulation and therefore a citation and all the other repercussions.

MR. TELFORD: Okay, but we're listing objectives here as to what we ideally would like to see happen.

MR. KEARLY: I'm not really even arguing with the objective -- by law you have to have it before any treatment. Everything has to be in writing. I suppose we could live with that. I was just wondering what we'd do when it doesn't happen.

MR. STRUBLER: It would even be hard to live with if a physician is at Hospital B and you are at Hospital A and the patient comes in from 30 miles out and you say, well, you know, we can set you up but we can't treat you because he didn't initial it. I know what is to be done, I know how much to give. I know where to give it. Everything is fine but the regulation says it must be initialled.

MR. TELFORD: I see. As an objective you would say it ought to be in writing and things ought to be specified.

MR. STRUBLER: Well, if we're sticking to the rule as specified rigorously, all I am just saying is we have to back off to allow the flexibility of the system, which has many factors and complexities involved with it. Less so with the teletherapy but there are these occasions that we're pointing out that are just small oversights and not intentional and they have nothing to do with I think the outcome or potential for serious outcome even.

I mean we are being focused here I think on this very small matter that we need to go on to these other objectives I think but from my point of view I'm saying we have to have -- to soften it to say that it does not have to be 100 percent rigidity because it will not happen that way.

MR. TELFORD: To allow for some cases that are brought about by extenuating circumstances?

I mean you are agreeing that --

MR. STRUBLER: Yes, very minor circumstantials.

MR. TELFORD: You are agreeing that you wouldn't want that to happen as a standard practice of somebody giving an oral directive --

MR. STRUBLER: Ordinarily you will have a written prescription. You shouldn't even have to document what the other non-ordinary things are because there are so many of them.

MR. TELFORD: Just to somehow allow for --

MR. STRUBLER: You say "ordinarily" and if you see someplace -- that becomes hard from a regulator's point of view to come in and say, you've got something very clear, and say yes or no, but we are pointing out in medicine there's lots of these gray areas and we are all trying to meet the same objective here in terms of preventing serious outcomes.

MR. KEARLY: May I make -- here's a suggestion. Just think about this.

The footnote at the bottom of page 1449, footnote No. 3 I think it is, to that paragraph, if you just take out the first four lines and start with "an oral instruction may be acceptable but a written record shall be made in the patient's record within 24 hours." Forget the rest of it up above.

MR. TELFORD: Is that the emergent situation?

MR. KEARLY: Yes. Forget the emergent.

MR. TELFORD: Forget the emergent situation but "An oral instruction may be acceptable but a written record shall be made within 24 hours."

Okay, why is an oral directive acceptable?

MR. STRUBLER: Why not?

MR. KEARLY: Why not?

MR. TELFORD: Miscommunication.

MR. KEARLY: Well, you can miscommunicate in writing as easily as you can orally. It's the same person giving an instruction.

MR. STRUBLER: We've all seen 7s and 2s misinterpreted, 5s -- very, very common and of course those are caught by some of these other objectives. That again is I think axiomatic in our patient care.

I can hear as well as I can see and I think an oral prescription is perfectly satisfactory.

MR. KEARLY: It's not a one shot thing. There's very few treatments that take place in one day.

CAPTAIN HELLMAN: Some of these are though. Some of them are listed in paragraph R, one shot deals.

MR. KEARLY: Oh, that's true. I'm sorry. That is true, that is true. I'm sorry, yes, that's true -- but teletherapy is not a one shot thing.

MR. TELFORD: Okay. You made a suggestion. You have given us the reason, okay.

MR. STRUBLER: But even for the one shot thing --

CAPTAIN HELLMAN: I would say that it's not, an oral instruction is not acceptable.

MR. STRUBLER: You don't think it's acceptable?

CAPTAIN HELLMAN: In my facility we do not allow oral or any type. If it is not signed we do not treat. I just prefer keeping my technologists covered that say. If

the physician did not sign it, that's it.

MR. STRUBLER: The one shut must be written, yes.

MR. BUKOVITZ: If a patient has 30 fractions, an oral for one day is going to be more than adequate.

CAPTAIN HELLMAN: For teletherapy, you're right. For anything else I think it is unacceptable.

MR. TELFORD: This is like half-way through or something or some time during the course of the 30 fractions?

MR. BUKOVITZ: Oh, no, Joe -- within, after the first treatment.

MR. STRUBLER: As soon as possible, yes.

MR. TELFORD: Okay, the first treatment has been given and the authorized user says I need to make a change and so they give that change orally.

MR. BUKOVITZ: Then they can put it in writing.

MR. TELFORD: It should be in writing?

MR. BUKOVITZ: Yes.

MR. TELFORD: Okay. Any other comments about Objective 2?

MR. STRUBLER: Yes. I will make one final comment.

Even in the single -- just to show that there's a lot of complexities involved in the circumstances, even in a one shot situation Physician A says, oh, I want to have the

dose from 800 antibody to 600 and he's out at another place and so he calls Physician B, who doesn't know the patient -- this is what I want to do. Physician B will give the written prescription. We all say, well, that's acceptable and I think that is appropriate to do, but I am saying here we are Physician A calling Physician B and Physician B making the final written.

Technically everything is fine but from a point of view of authorized user and the physician, the one physician doesn't know the patient.

MR. TELFORD: Is A the authorized user?

MR. STRUBLER: A is -- it could be both authorized users. A knows the patient, seen the patient; B has never, he or she has never seen the patient. They are partners, you know, and professionally that is an appropriate thing to do. From our point of view, the technologist would never make that kind of prescription because it's a physician responsibility.

I am just showing the nuances here in the sense it would be fine but from another sense it doesn't make any sense at all because Physician B is just following a regulation to sign it and permit usage based on an oral conversation and we are saying oral conversations are not good.

CAPTAIN HELLMAN: Then you go back to number 1.

The physician has n[illegible]iolated No. 1. B has now violated No. 1 if he doesn't ensure that it is appropriate.

MR. STRUBLER: Well, he hasn't violated it because he has confidence of infallity.

MR. TELFORD: You're saying B is really taking the risk.

MR. STRUBLER: I am just picking out little things here and I am saying these frequently come up, these kinds of things that cannot really be effectively regulated. They are medical.

MR. TELFORD: And you are pointing out that Physician B is taking the risk here.

MR. STRUBLER: Yes.

MR. TELFORD: Okay. shall we move on to Objective No. 3?

This is diagnostic referrals.

Now during the pre-trial period workshops we heard a lot of volunteers say we don't do that, we don't have written referrals so what we said was you put into your QA program what you do. If you use written referrals some of the time, say under what circumstances you would use oral referrals or if you operate that way all the time, say so in your plan.

MR. STRUBLER: Could you remind us again what you mean by diagnostic referral compared to a prescription?

MR. TELFORD: Well, number 3 is all about diagnostic tests.

MR. STRUBLER: But is a diagnostic referral written?

MR. TELFORD: Oh, yes, page 14.

MR. STRUBLER: And a prescription is written?

MR. TELFORD: Well, let me clarify. We're saying here we're recognizing that the way most hospitals or clinics operate is that a patient comes in with a referral. And what we wanted to happen was that what's requested in the referral matches what's in the procedures manual and have the authorized user approve of the clinical procedures manual, and at the same time, we recognize that some people would use prescriptions, some hospitals would use prescriptions even for referrals.

So by putting this in parentheses, we say that's okay, but in answer to your question of what's a referral, the difference is page 1447, I believe, where we say a referral is a written directive signed by a physician, not necessarily an authorized user. So this could be the general practitioner across town that has sent a patient to your department and the referral says liver scan, but it's signed by the general practitioner or the internal medicine specialist, a non-nuclear physician. So we were trying to allow those patients to come into the hospital by easy

mechanism.

Now, we said written and said that was the ideal case, is the patient should appear with their written referral and whatever's requested in the referral matches what's in the clinical procedures manual, and the clinical procedures manual then would interject the authorized into the picture by virtue of the fact that the authorized user had approved of that manual and those procedures so the technologist receives the patient, says liver scan, goes to the manual and knows exactly what to do.

MR. STRUBLER: I understand that. So let me ask you a question then. What has been your response on reflections from the early workshops knowing that many facilities do not have written referrals?

MR. TELFORD: Well, we certainly didn't twist anybody's arm during the 60-day trial period to make them do otherwise, but we're going to look at all the results of what the written evaluations say for all the volunteers. And there's also a section in the evaluation form for did you detect any intermediate step kind of problems, like patient I.D. or something, and we would like to find out if an oral referral in any way a source of problem. So we're going to look at that, but what we'd like to hear is what would you do with number 3? And the ideal case, we're talking about a written referral. So maybe when we talk

about number 3 we also have to talk about this definition, how would you modify this or would you retain it or would you delete it?

MR. STRUBLER: Well, that's kind of the question I asked you in the sense that knowing that many facilities, and I don't have a flavor for how many, what the percentages, but it could be a very large percentage, 40-50 percent, who take verbal diagnostic referrals. They may have some other confirmation process following that, but that would affect many of the small clinics and outpatient clinics. Maybe some of these others can comment.

MR. TELFORD: Yes. Maybe you're really asking me if you advised to use oral referrals, are we going to accept that? And I think the answer to the question is, if you can recommend that we should allow oral referrals and have a reasonable rationale for why that should be, yes, I think we would propose that.

MR. STRUBLER: Okay.

MR. TELFORD: Linda?

MS. FRANKLIN: I would retain that, I think that's very effective. And I don't think it's a problem. I think we do take referrals over the phone, obviously, to schedule appointments, but the secretaries were simply instructed to have either the patient, if they called, but it was usually the doctor's office, have them write a script and give it to

the patient. If the patient wasn't there, then they could send it to us so we had it. That wasn't a problem.

MR. TELFORD: Okay, so you would essentially get the written referral?

MS. FRANKLIN: Yes.

MR. TELFORD: Okay. I sense that you would allow patients to come in that forgot their piece of paper.

MS. FRANKLIN: Okay, but if they came in without their piece of paper, the secretary told me, and I simply called the referring physician's office.

MR. TELFORD: A follow-up phone call?

MS. FRANKLIN: Yes.

MR. STRUBLER: Then you don't have the referral and then you do it anyway.

MS. FRANKLIN: No, but I'm the technologist, so once I talk to the referring physician and he said to do it, then I asked please send us the written script, but I would go ahead and do the scan.

MR. STRUBLER: But that's my point. You're saying in those occasions, which may still be rare, but in other facilities would not be rare in my feeling, that you have follow-up confirmation that satisfies you and I'm sure satisfies the intent of all of this, but it's still not a written prescription, and therefore you are violating it, and I'm saying we've got to make allowances for those kinds

of situations.

CAPTAIN HELLMAN: In our facility, again, that other case of her's, where someone shows up without a referral, we insist on a written referral, but what we then do is we have our nuclear physician talk to the referring physician. We do not do anything without either the diagnostic referral or the nuclear physician coming up with something himself. But again, we're a larger facility, we're not the smaller facility.

MR. STRUBLER: In looking at the small facility, my feeling that I'm getting, and again, mostly in the oncology area, is that for the smaller facility, this kind of situation arises much more frequently. And you may be following confirmation that's fine and adequate, but it does not follow the intent of this.

MS. FRANKLIN: It says that a diagnostic referral or prescription is made for diagnostic radiopharmaceutical procedure. I'm getting the diagnostic referral.

MR. STRUBLER: No, that's written, both are written.

MR. BUKOVITZ: You're getting it orally.

MR. STRUBLER: That's why I asked the question. I wanted to clarify it in my own mind, are both of these written? And the answer is, yes, and it's just whether one is an authorized user or not.

MR. GRAHAM: But I think we're talking just in the initial program, though. If you have a long standing where you insisted on script on every patient you performed, after a 3-6 month period you would have all your referring physicians acclimated, but that's the only way you'll do that.

MR. STRUBLER: No, I don't think so, because they may given them to the patient and the patient says, oh, yes, I had it, it's here in my purse. Oh, I had the wrong purse.

MS. FRANKLIN: Yes, I guess it's up to the NRC as to how strict they are.

MR. STRUBLER: Well, I don't think that's appropriate.

MR. BUKOVITZ: If a patient drives 30 miles for the study --

MR. GRAHAM: Especially from a rural area. And that's essentially what we're doing. We're not doing it now.

MR. STRUBLER: But you're doing it because you think it's unsafe to do it?

MR. GRAHAM: I think that if we can see in the past where there have been scenarios where a secretary will call our secretary and ordered the wrong examination.

MR. STRUBLER: Yes, but if your physician calls the referring physician and says, yes, this is what I've

done, you're going to turn them away because it has to be written?

MR. GRAHAM: What we are doing now and our radiologists are, quite frankly, backing us on it, we insist upon a written document, period. And that's the way it is.

MR. TELFORD: If I could rephrase a proposed modification, I think based on what Linda is really saying is that rather than insisting on written referrals, to say written referrals are the best, but if you don't have a written referral, then you have a direct communication between the referring physician and the authorized user or the referring physician and the technologist.

MR. STRUBLER: Confirmation must be done and I think we're in agreement. Just exactly how it's done is open. But I would disagree a little bit in the sense that on every case you must have a written document.

As long as there's confirmation, I think we're all in agreement there. There has to be some specialized confirmation of it.

MR. TELFORD: Susan? Tom?

MR. DORING: I'm in agreement with that. And as a matter of fact, in our institution, we changed during the pilot program. In the past we accepted verbal orders. During the pilot program, we demanded that scripts be sent to us. It was met with a little -- it was not well

received. But by the time the 60th day rolled around, we were -- we were getting it on a regular basis. It didn't take six months.

MR. GRAHAM: It's a communication and orientation process.

MR. DORING: The point that I wanted to try to make is this says you need a written script of some type. How do you retrospectively evaluate whether those scripts -- whether you have those scripts or not?

The reason why I ask this question is our institution -- we're in the process of becoming computerized, throughout the whole hospital, and more specifically, in our department as well. An issue came up in regards to the amount of paperwork that we have. And it would have been a real bear to deal -- to keep the requisitions on hand until the reports came around and then take the requisitions and put them together with the reports and then finally give it back on the patient's file. It's a real clerical bear.

I called the state and I don't know about other states, but New York State specifically told me you needed certain indications; you needed the history, you needed essentially what we're talking about here; but it doesn't necessarily have to be a written form. You just have to have verification of the reason why -- the study that was

ordered, who ordered it and why it was ordered. And as long as you have some verification. It can be electronic. And, in essence, that's what we're going to use.

We're not going to have a piece of paper, after everything is said and done. So, we're not going to be able to retrospectively look, you know, a month later, to see if I have a piece of paper there, because it's going to be on mag tape. What are we going to do?

MR. TELFORD: You save the mag -- a record of the mag tape?

MR. DORING: Yes, that's going to be saved.

MR. TELFORD: Oh. So you could print that any time you like.

MR. DORING: Is that what you'd require for many of these?

MR. TELFORD: Well, what the referral here says is that it's dated and signed. All right, so the date is -- in answer to your first question, the date is supposed to prove that it was done prior to, because then there's a record of the actual administration, so you can compare the dates, in retrospect. But, if you have a mag tape, rather than a piece of paper and it comes up on a screen, then that's certainly a directive.

Larry, you want to say something?

MR. CAMPER: Is your concern driven by a need to

verify at a later time, say for inspection purposes, for example? Because again, the objective is to ensure prior to medical use. If you ensure that, then you've met the objective. It seems like your concern is --

MR. DORING: Yes, but how are you going to retrospectively take a look at that? I mean, most of us in our facilities already do this. But the intent of regulations is to make sure it's done and also, you have to verify that is done sometime down the road.

MR. CAMPER: As an inspection?

MR. DORING: As an inspection. And how are you going to do that without that little written piece of paper?

MR. KEARLY: Is a policy statement enough? Can we put a policy statement in our policy manual that says, we shall have this prior to treatment? Will that satisfy an inspector on this point?

MR. TELFORD: I would think in your quality assurance manual, that you would have more than a policy statement, you would have a directive to all concerned that you -- you have this referral.

But I think Tom's question is -- he doesn't have a piece of paper, he's got a mag tape. So, here comes an inspection a year later, and the inspector could then say, let me see your mag tapes? Look at them and say, get a print-out of one if he wants that, or if he or she wants

that for verification. You can look at the date of the referral and compare it to the date of the administration. Why wouldn't that be sufficient? I've got two of the best inspectors here?

MR. KEARLY: There's no difference between a telephone referral and a written one, in that case, if it's all going to be put down on paper by somebody else, is there?

MR. TELFORD: No. He's saying the tape -- no. It's -- he doesn't -- what if you didn't have a paper system? What if you had an electronic system, so your department gets -- the technologist gets the directive, not through a piece of paper, but a manual.

MR. STRUBLER: But how does that differ from electronic communication, or the phone, or some other mechanism?

MR. KEARLY: By proof?

MR. STRUBLER: I mean, you can't prove that?

MR. TELFORD: Well, you look at one and you hear the other.

MR. STRUBLER: But that's what we're saying. Your directive says written.

MR. TELFORD: Wait, wait. Linda had a proposed modification to three.

MR. STRUBLER: Yes. I agree with that.

MR. TELFORD: Okay, but, so take that.

MR. STRUBLER: But we're looking at this now, and focusing -- if you change it and say, all right, it's modified, based on confirmation, and maybe based on modification that Tom was bringing up that are interesting too, because, therefore, there is no confirmation necessary, nor is it written, but it's electronic.

MR. TELFORD: Well he's saying -- he's talking about the department of the future, that doesn't have paper, it's all electronic.

MR. DORING: It's right now. It's happening all around us.

MR. TELFORD: Okay.

MR. DORING: My second thought on this is we're spending a lot of time talking about this and, I, like all of us, in relation to rules and regulations and law; what we're talking about now, maybe really misconstrued in some way, shape or form, five years from now, and the intent that we're talking about now -- really -- it depends on -- on the person coming in evaluating you, as to whether or not you're fulfilling these obligations, whether you pass or fail, so to speak -- make the grade so to speak.

I'm really concerned about the way you're wording these things. It can really be misconstrued, no matter how you word them, five years from now.

MR. TELFORD: What words did we use?

MR. DORING: I'm not sure. I don't have the answer to that. But I wanted to throw that out to everybody. And I think -- I've talked to a few people and it's on other peoples' minds.

MR. KEARLY: I agree. And I think that was the comment I was making with number two, and we spent a lot of time on that. If a problem does happen, what -- what do we do and what are we liable for, especially if it has absolutely no clinical consequences, as far as patients are concerned?

MR. TELFORD: Okay. Part of what you're asking is in the reporting requirements, so we'll get to that.

MR. KEARLY: But, I'm not sure how we'll --

MR. TELFORD: That's the trigger level.

MR. KEARLY: I'm not sure that these are covered by the reporting requirements as they're written earlier. Something like, not having a diagnostic referral; was that covered in the reporting requirements?

MR. STRUBLER: If you know that you don't a signed consent, what you do is say, well, we're not going to harm the patient, but I'm going to turn them away, or maybe they'll come back.

MR. TELFORD: In the case of number three, if we considered Linda's proposed modification; if we had a direct

confirmation?

MR. STRUBLER: This still fails, in terms of the electronic communication. It still fails with the modification?

MR. TELFORD: Why does it fail?

MR. STRUBLER: Because it is not written.

MR. DORING: A year from now I'll have it on mag tape, but you don't necessarily know if I had a written request a year before. I'm just -- I've got some information --

MR. TELFORD: You're going to cheat the system. I get it.

MR. GRAHAM: You're going to convert the medical records?

MR. DORING: Everything is going to be electronic.

MR. GRAHAM: Outpatients still should come with a slip of paper, and then which could be archived.

MR. DORING: Why does it have to come with a slip? It doesn't have to come with a slip. A patient comes through an admissions process as an out patient. It's all on the computer. They stop at point one, information is obtained. They stop at point two, the information from point A is related to point two. You just go on from there.

MR. TELFORD: That's a different department though. That's not even nuclear medicine. The admissions

department, right? That's separate.

MR. DORING: They're just doing patient demographics, and they're collecting that in nuclear medicine?

MR. GRAHAM: But when a patient walks in, he still could hand you a script, which could be put on your hard copy?

MR. DORING: Yes. But theoretically, it's not necessary.

MR. GRAHAM: Well, it depends on how you --

MR. DORING: You wouldn't know --

MR. GRAHAM: We're I know I'm splitting hairs, but yes.

MR. DORING: Theoretically you wouldn't know a year from now, if you had that piece of paper or not, because it's on magnetic tape.

MR. GRAHAM: So, you're only going to keep your hare copy for --

MR. DORING: I'm not keeping any hard copy.

MR. GRAHAM: No hard copy at all?

MR. KLINE: What you are saying, Tom, is true, and I think everybody realizes that electronic transferred data; phone lines, microwave, is going to be a thing that will happen, it's just a matter of time before people can afford it and it becomes reasonable, and evolution of the

technology.

It appears that that in context, by having somebody send that medium, with the information, in theory, is -- it sounds logical. The only question then about this -- this argument is the person sending it. How do you verify that the person who sent that diagnostic referral is the physician?

It can't be the technologist or a nurse or the receptionist calling up and saying, Dr. so-and-so's receptionist, he wants a bone scan for this patient, we're sending him over.

Now, a mechanism for identifying that the physician ordered that particular study via transmission, a code, something of this nature, where it has to be verified that the physician has that in coding and he enters it or these sort of things. I think the question is who sent the message. Is it somebody that is a physician, that is qualified to send that diagnostic referral or is it some guy that is in the office that maybe thought it would be a good scan to have, that this person should have the diagnostic study performed on them.

MR. STRUBLER: See, that's the kind of thing that could always happen. Somebody could say, all right, I've got a slip of paper, because as I went out I grabbed a pad and I'm writing my own prescription. And you're never going to

stop that entirely.

But these things are very interesting questions here, I think, in the sense that a physician generally says to his or her nurse or receptionist, would you call Dr. X and schedule a nuclear scan for Mrs. Jones, and this is what I need. She does all of that.

And she may even write all of it down on the prescription, which he then signs. So there are various levels of communication which may be oral, at some point, certainly.

MR. KLINE: So then it comes back to the oral --

MR. STRUBLER: And then you get back into electronic communication --

MR. KLINE: -- orally what is considered acceptable, oral versus written.

MR. STRUBLER: Yes.

MR. KLINE: I guess the, what the Commission has looked at has been mistakes in oral interpretation of orders. Orally, did the person understand what was requested of them to send or to write or to give to the hospital, to the patient, to be given for the treatment.

That is why a written document ties a person down to I want this and that.

MR. STRUBLER: I can understand and even support that. It's just that all these things are being raised.

MR. TELFORD: Yes.

MR. STRUBLER: It makes a lot more complex, I think.

MR. DORING: The original intent of my question is, when you come in a year from now and see whether I'm doing this appropriately, I'm not going to have a written piece of paper; I'm going to have information on a tape. And if that is sufficient to meet the needs of Number 3, then that's fine. And I hope it remains that way from time immemorial.

MR. TELFORD: Okay. So your question is really a suggestion to us that we consider that the electronic referral should be equivalent to a written referral.

MR. DORING: Yes.

MR. TELFORD: Because you are keeping a record, a mag. tape record of that referral.

MR. DORING: It's not the original. It's the original put into an electronic medium.

MR. TELFORD: Well, we can certainly take that suggestion, certainly.

Anybody else on Number 3?

[No response.]

MR. TELFORD: Okay. Let's go to Number 4.

On Number 4, the intent of Number 4 is just to say that the people involved, the people doing the work

understand what they are supposed to do.

Now, in the case of a diagnostic case, you've got a technologist that you have to make sure either understands or will follow the clinical procedures manual, or the, in the case of therapy, they will follow the treatment plan.

Now, this kind of comes under the umbrella of appropriate supervision of the personnel.

Would you retain this, would you modify it, or would you delete it?

MR. KEARLY: I think it's one of the vaguest things you've written. How can you verify to anybody's understanding

MR. STRUBLER: You're stating the obvious.

MR. KEARLY: Also, how can you verify anybody's understanding, technically?

MR. TELFORD: Do you want to change the word "understand"?

MR. KEARLY: I'm not sure what I want to do.

MR. TELFORD: Come on, this is your chance. Again, would you delete this?

MR. STRUBLER: I would delete it, or maybe one of the other aspects of these objectives in the quality assurance program that people understand, and if there is misunderstanding, they ask questions to verify, confirm, just like some of the written things, where if not coming

in, they call the referring physician.

MR. TELFORD: I've put up Number 5 here. And number 5 says to make sure that it is in accordance with what's directed.

If that happens, do you need Number 4?

MR. BUKOVITZ: I think what you need to do is establish that the responsible individuals have met certain criteria.

MR. TELFORD: For?

MR. BUKOVITZ: Well, as far as their knowledge and capabilities and training for doing that type of work.

MR. TELFORD: Training, minimum training.

MR. BUKOVITZ: Minimum training.

MR. TELFORD: They pass some test.

MR. BUKOVITZ: They pass some test, whether it is a registered nuclear medicine tech. or whatever. And that way, or even if it's not a registered tech., if it's a nurse, like a lot of private offices have nurses. At least that nurse has met a certain minimum amount of training and it is verified and documented by that nurse's supervisor, i.e., the physician, that they are competent.

MR. TELFORD: This is training in some sort of accredited training program, rather than just being given by the authorized user?

MR. BUKOVITZ: Well, training in an accredited

program or training by the authorized user. Because they may only do one or two studies. If you go to a cardiologist's office, all they may do is MUGGAs. MUGGAs and thalliums.

MR. TELFORD: Okay. So as long as the authorized user is willing to say that they have given a minimum amount of training to this person, that would be good enough?

MR. BUKOVITZ: Well, I'm not sure you can say that.

MR. STRUBLER: Yes. I wouldn't even, it may be inappropriate to put it in the regulation, because we have certain criteria for credentialing of physicians and physicists, for that matter, and technologists. And then each state is addressing the situation with technology now as well.

But you are asking them to say do you understand what I'm telling you. How do you ensure that? And the only way you really do it is by credentialing and education.

So again, I think it is stating an obvious situation that you can't really regulate or put into a regulatory --

MR. TELFORD: What if Number 5 happens? Is that good enough evidence that the person understands? Joe?

MR. STRUBLER: Yes. I would say so.

CAPTAIN HELLMAN: I was thinking of changing

Number 4 to something like: Ensure that if the written referral, whatever is inconsistent with the diagnostic manual or inconsistent with traditional prescription, seek clarification from the authorized user.

MR. STRUBLER: That kind of gets into Number 5 as well, I think.

MR. TELFORD: I think Joe's suggestion is this is a feedback that is supposed to happen if anything looks wrong before you get to Number 5.

I mean, it is in the spirit of making sure Number 5 happens that the administration is in accordance with the directive. But it is a way to show evidence of understanding, that is, the technologists, they are obligated to ask questions if any thing looks fishy.

So then, therefore, they would have to understand what they are supposed to do in order to ask questions about anything that looks in variance to that.

Is that right?

CAPTAIN HELLMAN: Right.

MR. KEARLY: Five could also be interpreted pre as well as post, can't it? I mean there's nothing in there that specifically says post.

MR. STRUBLER: I interpret that that is pre, because anything post is after the fact and so what we are saying is that there should be some thought by qualified

individuals that, yes, this is not an off-the-wall referral by Dr. Crazy and trained to be perceptive on these things and to ask questions when things seem out of line.

MR. TELFORD: Okay, then you are agreeing with Joe's --

MR. STRUBLER: Yes. I'm just saying what Joe said was -- what my interpretation would be that number five, there is some scrutiny of the prescription to say that it's in accordance with what I understand to be good practice.

MR. TELFORD: Well, what if the referral is all wrong? You're saying it's got to match the clinical procedures manual and therefore only the correct things will happen because only the correct things are in the clinical procedures manual.

MR. STRUBLER: Well, there could be an inappropriate referral, that the physician made an error and prescribed something and he got Mrs. Elizabeth Jones mixed up with Lizzie Jones and got the two reversed and so that is always a possibility that you are never going to prevent necessarily but even that could be prevented with scrutiny.

All my point is, as I said before, I think is very obscure. I agree with Frank and some of the others on No. 4. No.5 is the appropriate. Since we haven't gotten to that I don't how I rated that, so I rated 4 very low and rated 5 rather high.

MR. TELFORD: What if we changed 4, Frank, according to Joe's suggestion, to say you have to ask questions if anything looks wrong. Would that be less fuzzy?

MR. KEARLY: I wasn't -- I can't say I understand fully what you mean.

MR. TELFORD: That's not what 4 says at all now, though. No, no, that's not what it says at all.

MR. KEARLY: What do you as NRC mean by 4?

MR. TELFORD: It means that the authorized user has to go to some trouble in terms of training, in terms of testing, in terms of counselling or the technologist and everybody involved that truly these people understand what they are about to do before they do it.

Now that doesn't mean you have to do that all the time, but at some frequency you have to have training and make sure that these folks are capable of doing or capable of following your directives as the authorized user.

MR. KEARLY: I interpreted 4 entirely differently.

MR. TELFORD: Okay.

MR. KEARLY: All our technologists are trained. They understand how to treat. The information that comes to them is sometimes muddled and I thought that what you're saying is if they don't understand the muddled information they can't treat until it is all clear, which I guess is

similar to what Joe --

MR. TELFORD: Well, if the message is muddled, they truly don't know what to do so they would -- if they followed our guide they would ask questions.

MR. KEARLY: Right.

MR. TELFORD: But the intention of No. 4 is to --

MR. KEARLY: To demand a certain educational level of the staff.

CAPTAIN HELLMAN: Or demand a certain responsibility of the authorized user.

MR. TELFORD: Or maybe a certain responsibility of both the authorized user and the technologist that they are capable of carrying out. We don't want to mess with the authority given to the authorized user.

They've got the authority to issue the directives. I think that is a given. We want the technologist capable of carrying out those directives so that -- you could envision a lot of different cases of when a technologist was disregarding the directives or didn't want to understand or really didn't understand because they have a misunderstanding of what they are supposed to do, so No. 4 just says let's make sure that these folks know their jobs before we turn them loose.

MR. STRUBLER: How do we make sure they know their jobs?

MR. TELFORD: Josie?

MS. PICCONE: I'd like to just summarize what Ken said, I think, and that is if you have 5, 5 presupposes in order to do 5, 4 has to be true, so you don't need 4 if 5 is written the way it is because 5 assumes 4 is there.

You can't have 5 without 4 being present.

CAPTAIN HELLMAN: You could modify 5 to say "Clarification should be sought."

MR. TELFORD: Okay, so we could delete 4 and add an embellishment to No. 5 which says if anything looks wrong, you ask questions about it, basically.

MR. STRUBLER: And get away from the issue of credentialing -- which is about what you are about to get into.

CAPTAIN HELLMAN: That's another sticky issue --

MR. STRUBLER: That's a big one.

CAPTAIN HELLMAN: -- which may be the next level then in just basic QA. I would stay with the certification because that's going to stir up a whole other can of worms you do not need until you at least get this implemented and see if it's working or not.

MS. PICCONE: Is that right?

I mean my summary -- was that your intent?

MR. STRUBLER: Right.

MR. TELFORD: Okay. Does anybody else have

anything to say about No. 4?

[No response.]

MR. TELFORD: Okay. Let's move to No. 5.

I think we have already talked about 5 a little bit. It seems to be pretty obvious. I think people understand the intent, make sure that the directive is carried out, that the administration is in accordance with the directive.

MR. STRUBLER: Again, just to add a further comment I made earlier was that I gave it a high rating compared to No. 4.

MR. TELFORD: Okay.

MR. STRUBLER: In the sense that there are I feel probably many institutions, and this is being changed by each state in terms of requiring registry of technologists, particularly on the radiologic sciences, but there are many places, smaller places that may have a nurse who has been OJed, on the job training, and is doing some of these activities and therefore No. 5 is perhaps very much appropriate so that there are certain schema that are saying these are diagnostic tests that are in accord with good practice and that you should check it before you proceed.

Therefore, I support the No. 5.

MR. TELFORD: You would retain No. 5.

MR. STRUBLER: Would retain No. 5.

MR. TELFORD: Okay. Gene? Do you agree?

Do you want to retain?

MR. GRAHAM: I agree.

MR. KEARLY: I think it's one of the hearts of the quality assurance program. This is the basic double-check rule.

MR. STRUBLER: Yes. Never assume anything from anybody, your superior or anybody else and just make sure that you in your own mind feel comfortable with what you are doing because people's lives may be affected here.

I think that is something that should be very basic to any practitioner or technologist.

MR. TELFORD: All right.

Any other comments on No. 5?

[No response.]

MR. TELFORD: Okay, let's go to 6.

Six says identify the patient.

Joe -- who had their hand up over here? Linda? Oh, Linda.

MS. FRANKLIN: It's just that when we went through all that this morning the thing that kept coming up was on outpatient basis. There didn't seem to be enough redundancy to verify the patient and also written in my little critique here it says that it said no on that. It said "Is ID verbal only?"

Well, I have already said that I have a written script from my physician but the patient signed things for insurance purposes, things like that. The patient checks in with the secretary who gets their name and then I get their name.

What else can you do?

I mean how much more redundant should I be or do they need to sign them off?

MR. TELFORD: Let me see if I understand this.

You have got a patient that comes to you as a technologist and you are going to treat -- you are going to do something for this patient and you have been given the name from the receptionist. Do you have a piece of paper --

MS. FRANKLIN: I've got their name written in the schedule book.

MR. TELFORD: Okay.

MS. FRANKLIN: Because they're an outpatient so they were scheduled. When they come to the office they give their name to the secretary with a script with their name written on it. Then the secretary lets me know the patient is there and I ask the patient their name before I inject.

MR. TELFORD: Okay.

MS. FRANKLIN: So do I -- what else?

MR. TELFORD: Okay. I'm the patient and you call

Mr. Telford and he comes in and you're asking my name.

Okay, do you also ask me my birthdate? My social security number?

MS. FRANKLIN: Oh, I see, okay. No, I don't.

MR. TELFORD: My date of birth.

MS. FRANKLIN: Because I don't have that information.

MS. PICCONE: What you have just described we agree would be redundant.

Do you put all of that in the program that you submitted? That's probably why there was a no.

Did you have all of that when you took the scenario you just went through? If you didn't, if you only said yes, the name or something, that may be why. I think this was one done by the contractor, why there's a no.

What you just described to us appears to be redundant but if that's not what you had on the piece of paper that came in, they wouldn't know what you actually do because no one went out at your site.

MS. FRANKLIN: Well, what I did write was, after identifying the patient, that would be checked against the scheduled patients and the written prescriptions. You know, those are all things that are needed to confirm on a patient.

But I can't, I don't know. They can show me their

Social Security Card, but that doesn't' mean anything to me.

MR. DORING: Isn't it illegal to request a Social Security number?

MR. STRUBLER: I don't think so.

MR. GRAHAM: I don't think they have to tell you what it is, but we use it for a filing mechanism. So it's compulsory.

MR. STRUBLER: I think, also, to follow up on comments made, I'm not sure how redundant this is in the sense, my comment here was of course, you have to identify the patient, and what lengths do you go to to do that and what is going to be required from a regulatory viewpoint. And the episodes that have been related to me of misadministrations where either a psychotic patient says sure, I'm Mrs. Smith, or someone who has been waiting for an hour and getting impatient and says all these patients are having the same study, I'm going to say that's my name, I think that's happened.

And something like this wouldn't necessarily catch that. Because the name is on the schedule, and you ask are you Mrs. Smith; yes, I am Mrs. Smith; all right.

And the question is do you have to say are you here for such and such a study. If the answer is yes, that might be a redundancy.

MR. DORING: Or what are you here for.

MR. STRUBLER: Or what are you here for would be a better question.

MR. GRAHAM: Or, what is your name.

MR. TELFORD: I think we're just after two different mechanisms, two different pieces of information for each patient. We're looking for more than one.

MS. FRANKLIN: After the pilot program started, when the secretary would tell me the patient was there, rather than me going out and saying, Mr. Telford, would you come in, they would identify the patient to me, the secretary, and I would say, which one is it, and then I would go in the waiting room and say, could you tell me your name, please.

Is that adequate? And also --

MR. STRUBLER: That's much different, though, I think.

MS. FRANKLIN: -- my other question is, if three different or however many different NRC inspectors come to my facility, is each one going to have a different level of understanding of that? I mean, is one of them going to say prove to me that you do that; or is one of them going to say okay, you have it written that you do that, I believe you?

MR. TELFORD: The answer to your first question, I think, is yes. My inspectors seem to be busy over here on a burning issue. But they have told me that they are looking

for two different mechanisms to identify the patient. So I think your description satisfies that you've got two different sources.

Now, the answer to your second question is that depends on the guidance that we give to the inspectors.

Now, the inspector might come to your waiting room, unannounced, and sit down. And when you came out of the door and you went over and you talked to the receptionist and said point out Mr. Jones to me, and he saw that happen, then you went over to Mr. Jones and he heard you ask, what's your name; that would do it for him right there.

Or, an inspector might do that but come in and say, show me your procedure. He or she would read that, I do these two things. That may be enough. But any two identifying principals would probably work.

Joe. Excuse me.

MS. FRANKLIN: Do you need to have a log, a document, have each patient sign something?

MR. TELFORD: Some places have the patients sign in. And that would be okay, too. But we're certainly not going to require that.

Joe?

CAPTAIN HELLMAN: Just a comment, John. If you are looking for Number 6, to be done in two different ways,

you're not stating that.

MR. TELFORD: You are absolutely right. And our inspectors have already pointed that out to me. And we are probably going to say "redundantly identify" or something like that. Because that is really what we need.

MR. KEARLY: In teletherapy, where the patient is seen every day for seven weeks by the same technologists, dot dot dot, do we have to be regulated when it's not a problem?

MR. TELFORD: You did it the first time. With a teletherapy patient, you may have positioning tattoos; you may have a photo of the person.

MR. KEARLY: We have a number of things.

MR. TELFORD: You may have three or four things that the technologist could easily look at that day.

MR. KEARLY: But as long as we are not going to be required to document daily that a procedure has been gone through, that you have to look at, if you can take a look at our procedures and that passes, that's fine. But if we have to document something --

MR. TELFORD: No. This is a good thing to do, right? This is an objective. So you would have a procedure in your QA manual that says this is what we do.

MR. KEARLY: That's kind of a question I have with almost everything up there.

If we put policies and procedures in, do we then have to, in addition, document every time we do a step?

MR. TELFORD: Not unless we say something like Number 2 that says dated and signed by.

Notice Number 6 doesn't say you keep a log, you record the two methods that you use to identify, you sign your name that you did those. None of that. Okay. This just gives rise to a procedure that is in your quality assurance manual.

Any other comments?

MR. STRUBLER: Let me ask a question. I'm just wondering whether there are a number of facilities. What you are saying is that you will not accept a technologist to go out and say this Mrs. Jones, please come back.

MR. TELFORD: That alone is not significant.

MR. STRUBLER: And I'm wondering whether there may be places, I think what we talked about here is a good thing, but I'm just wondering, it is going to be impracticable for some institutions where, because of geography or something else, that's not done, and it's over a PA system in which they are calling someone back from the waiting area to another area.

And you're telling everybody you may not ask, Mrs. Jones, please come back, but going out and physically querying, are you Mrs. Jones, or what is your name, I'm

sorry, what is your name, that kind of thing. Because in a busy place or a small place or a different place, I can see where that may not be a reasonable thing to do.

MR. TELFORD: And indeed, that may be okay. What Linda did was suggested two methods of identifying. Now, those are not the only two.

If you wanted to use a PA system and call Mr. Jones to come back, if you used two other means to identify Mr. Jones, other than his name, when he got there, then you've got a redundancy.

MR. STRUBLER: Then you're saying, all right, Mr. Jones, please come back. He comes back. And now you're saying, all right, I have to do one more method. And that method is two credit cards and a license? I'm not sure. And I'm saying that it may prove difficult.

MR. TELFORD: Well, give me a for instance.

MR. STRUBLER: Well, I'm saying do you then say I want to see your driver's license? I'm sorry, I don't drive. I want to see credit. Well, I don't have any credit cards.

MR. TELFORD: Do you have a Social Security number; do you have a date of birth; do you have --

MR. STRUBLER: Well, these things are not, I'm just saying I could perceive that this double, not that I'm saying it's bad, because we want confirmation. But I could

see in many scenarios that it would be not so easy, that you can't go to your receptionist each time and say point out so and so and so and so, when people are coming and going and it's the Noon hour and the receptionist who met the patient wasn't there.

And the question I have in here is how is this to be done? And you are saying there are many ways, do it.

MR. TELFORD: Yes.

MR. STRUBIER: But it may not always be obvious and clear, without challenging the patient, and they're getting upset by having to pull out everything.

MS. FRANKLIN: After you call him on the PA system and he comes to you, then you just say, could I have your full name, please?

MR. STRUBLER: But they're saying that's not acceptable. Recognition of their name --

MS. FRANKLIN: But you ask the patient, also.

MR. STRUBLER: That's not an also. You've already asked them, because on the PA you've asked them to come back. They come back.

MS. FRANKLIN: Right.

MR. STRUBLER: And you ask them what is their name, and they'll say I'm Mr. Jones.

MS. FRANKLIN: Then you ask them to repeat their name to you.

MR. STRUBLER: But that's not double verification.

MR. DORING: You can qualify their last name when they come to you. You can what is your first name, what is your full name.

MR. STRUBLER: All right. That would perhaps be an avenue.

MR. DORING: There's hundreds of different methods.

MR. KLINE: There's quite a bit of range incorporated into that identification. As you mentioned, calling the person over the PA, when they come in, asking are you Mr. Jones.

MR. STRUBLER: Let's say routinely they say "Alice Jones, please come back."

MR. KLINE: Okay.

MR. STRUBLER: Alice Jones comes back. And then what would you do?

MR. KLINE: You say, are you Miss Alice Jones, or you could --

MR. STRUBLER: And they say yes. Is that verification?

MR. KLINE: If they call somebody over the PA, then you come back, then you ask them, is this Mrs. Alice Jones that you are talking to?

MR. STRUBLER: Yes.

MR. KLINE: That's a verification. You have somebody come in from the outside, based on calling of their name. Then you ask them is this that person. That's a redundancy in that process.

MR. STRUBLER: That's no different than you going back and saying "Alice Jones, please come back," and she stands up and walks back with you. I don't see that as any verification.

MR. DORING: Then you can keep on going. This is a pretty simple thing here.

When Mrs. Jones gets to you, if you said the whole name, "how old are you?" You have that information. Where do you live? You have that information. There's a hundred different ways of verifying.

MR. GRAHAM: I just want to support that, and also just to mention, we are all going under the assumption that the patient can answer. We're not really addressing the comatose or the psychiatric patients, that type of issue.

MR. STRUBLER: But those were the misadministrations that that had come from. It is the intent of catching these strange situations of the psychotics that may be out there or that people are just saying I'm Mr. Jones and they are Mr. Jones.

MR. KLINE: During the site evaluations, everybody had a redundancy whether they knew it or not, that appeared.

On paper they didn't note it. But in the brachytherapy and teletherapy --

MR. STRUBLER: Again, all I'm saying is that here is a regulation that is kind of stating the obvious and therefore, is it something necessary that has to be regulated.

MR. KLINE: Well, the case histories will show you that there have been some isolated cases where people were treated and they were not --

MR. STRUBLER: And that's also my point. Your words are well chosen, I think, some isolated cases. And there always will be isolated cases.

MR. KLINE: As a total.

MR. DORING: Perhaps by regulating that, maybe we could decrease that number of unusual cases. If it's being done now, anyway, for the most part, that's different.

MR. STRUBLER: That's my point. It's being done.

MR. TELFORD: Do you want to delete Number 6?

MR. STRUBLER: I'm just stating it's stating the obvious. And we all pretty much are doing it. And even though there's been some episodes which have may precipitated this attempt to be regulated, I don't think it's a necessary thing.

I'm not saying it's bad. We all do it. It's done. Are we for more regulation or less regulation, I

guess it what it comes down to?

MR. DORING: Using that philosophy, we should do away with all of them.

MR. STRUBLER: Let's focus on the more important ones.

MR. KEARLY: Could I raise a potential problem of therapy that ought to be covered by this, but isn't?

MR. TELFORD: Number six.

MR. KEARLY: Identifying the patient is not a real problem with therapy and the technologists. They know the patients routinely. What might be more of a problem is after they set the patient up, come back to treat them, they grab the wrong chart. So, you know who you're treating, you open it up and you don't notice the page that you look at may not be the page with their picture on it, and you administer a treatment perhaps, but usually -- that's a pretty rare thing too. But that --

CAPTAIN HELLMAN: The pill sizes and the tattoos don't line up and they don't figure out what's going on.

MR. BUKOVITZ: But that's not necessarily so.

MR. KEARLY: No. That's not the procedure.

MR. BUKOVITZ: A lot of routine things use the same pill sizes.

MR. KEARLY: In terms of identifying patient and matching treatment to patient, that's a possible error.

MR. TELFORD: What would you do about that?

CAPTAIN HELLMAN: Report to the NRC?

MR. TELFORD: Wrong.

[Laughter.]

MR. TELFORD: Wrong answer.

MR. KEARLY: Again, that would be a rare thing too, but it's more likely than misidentifying the patient.

MR. TELFORD: Okay. It's a little after 3:00 o'clock. Would anybody object to taking about a 15 minute break before we launch into objectives seven and eight?

[No response.]

MR. TELFORD: Okay. Let's take a break.

[Recess.]

MR. TELFORD: We're ready to resume.

Let's pick up with objective number seven, which is to identify any deviation that is made, however small, from what was directed.

Now, the intention here was to merely identify them, have the person evaluate them to the extent that they can determine if it's a big deal, or a muddled message, and they should seek clarification, to enable the person to do the right thing, so they can follow the directive.

So that would be the kind of things before the fact, this would be a mechanism that would identify deviations so that, in the audit phase, these could be

picked up and the licensing management could determine if these need to be addressed or not.

MR. KEARLY: How does it differ from five?

MR. TELFORD: From five? Well, five could be that you -- five, in fact, envisions that was directed was what was administered. So the deviation could be zero.

MR. KEARLY: Right, but it may not be. You found it. Five is the process. It's a double-checking process that you are talking about. And that's the process that you're doing in five. I mean, that's how I see it anyway. Five is a double-check, seven is also a double-check.

MR. TELFORD: Okay. Let's take two cases for number five. First case is, what was administered was exactly what was directed. The second case for number five is what was administered was a little bit different from what was directed. Okay, number five is done, either way.

Number five would give rise to some procedures -- procedural steps that you would have that would say, here's what we'd do to make sure number five happens, but that's all.

Number seven says, after it happens, or even before it happens, let's see if we can identify this deviation.

MR. KEARLY: How can we identify it?

MR. TELFORD: How?

MR. KEARLY: -- if it's in accordance with prescription. If it's not, then you've identified --

MR. TELFORD: Well, I think you could say that number five attempts to eliminate any deviations, but I don't see how that guarantees that's done.

MR. KEARLY: I'm not sure we're thinking of the same clinical process here.

MR. TELFORD: Okay.

MR. STRUBLER: I think he's saying though, that if you went through number five and you still didn't catch something that went awry, and there was a deviation; you thought from number five analysis that it was okay.

MR. KEARLY: How do you know that there's a deviation? You do number five to double check things, right? Or somebody may catch it also from something else.

MR. STRUBLER: Someone else. Yes.

MR. TELFORD: You know there's a deviation because what was administered is different from what was directed by a little bit.

MR. BUKOVITZ: I thought five was more procedurally oriented.

MR. TELFORD: It is.

MR. BUKOVITZ: Okay, so in that case, seven is not so much procedural, but is quantitatively.

MR. TELFORD: Right.

MR. KEARLY: I'm lost.

MR. TELFORD: Okay.

MR. KEARLY: Let me give you two examples.

MR. TELFORD: All right.

MR. KEARLY: On weekly chart checks, if I find that instead of delivering 22 monitor units for field A, 21 monitor units were delivered two days ago, that is a deviation from the intended treatment. And I know why it happened, somebody dropped a number -- changed a digit.

MR. TELFORD: Because 22 is different from 21.

MR. KEARLY: That's how I found it, because 22 is different from 21.

MR. TELFORD: Okay.

MR. KEARLY: And we'll go through a correction procedure and so forth. Now that's -- the process is double-checking. There was a deviation, I know why it happened, in that case. If I didn't know why a problem like that happened, I would go investigate, of course, and it got corrected. Now, that's both five and seven; am I right?

Now, another possibility might be that a wedge was left out when it should have been put in place and the time used was the wedge time, but the wedge wasn't put in place and was reported to me by the technologist who made such a mistake. I know why it happened, and will correct it. I can interpret that as being five as well, because we have a

policy.

You know, the environment that we work in is as important as anything else in the atmosphere, so there's a lot of cooperation and it's a teamwork sort of thing. So you get that information coming back.

MR. TELFORD: Well, number five said use the wedge, but the wedge was not used.

MR. KEARLY: No. Number five says check the charts and listen for problems -- have a procedure for monitoring for problems. That what I see number five as saying.

MR. TELFORD: Okay. But in spite of number five, the wedge was left out. Number seven says identify that the wedge was left out.

MR. STRUBLER: Let me add some of my comments, while we're reflecting on that.

MR. TELFORD: Okay.

MR. STRUBLER: I thought the language a little strange here, "unintended deviation," interpretation that is perhaps open to discussion; in that if a deviation occurs and its unattended you may, almost by definition, never catch it. And, so you're saying, an unattended deviation is different from a deviation, meaning, the physician changes the prescription for some reason.

So I was a little bit confused by number seven, an

"unintended deviation."

MR. TELFORD: That phraseology?

MR. STRUBLER: Yes, the phraseology. If you're just saying that an error occurred, you'd get that from the original prescription; how are you going to catch it and modify it and see that it doesn't happen again.

MR. TELFORD: Try reading it without the word "unintended."

MR. STRUBLER: That certainly sounds much better.

MR. TELFORD: Okay.

MR. STRUBLER: What you are trying to ensure here is that if there are discrepancies or changes or deviations from what was anticipated or prescribed, there is a mechanism by which you can identify and correct.

MR. TELFORD: Right.

MR. STRUBLER: I would just change some of the language there.

MR. TELFORD: In No. 7 you would change some language. For instance, you would delete "unintended."

MR. STRUBLER: At least.

MR. TELFORD: What else?

MR. STRUBLER: At least delete "unintended" or modify it.

MR. TELFORD: Okay. What else would you change in 7?

MR. STRUBLER: That's a good start.

MR. TELFORD: Linda, you had a perplexed look on your face.

MS. FRANKLIN: I was just confused about it too. When I first made my evaluation I just took it to mean after the fact and I took this whole, the whole point of all these things was the program was to prevent and detect errors before the fact, so I just didn't know if it all fit in.

I mean I see the point of it, I just didn't know if it all fit in as far as --

MR. TELFORD: Okay, as far as prevention --

MS. FRANKLIN: -- as preventing the error from happening in the first place.

MR. TELFORD: If you are after prevention, then No. 5 ought to do it.

MS. FRANKLIN: No. 5 or any of these -- No. 7. No. 5 or any of the previous ones. No. 7 in my mind I just read it as all after the fact.

MR. STRUBLER: It's still a reasonable statement --

MS. FRANKLIN: -- preventing error before it happens.

MR. STRUBLER: It's a reasonable statement after the fact. We all know that there are still errors that are going to be made, no matter how many ounces of prevention we

put into this and I think you're trying to achieve saying that you do identify them and see if your error is that you can tighten up on it. You have overlooked and can improve on it to ensure that the same error isn't going to be repeated.

MR. TELFORD: Yes, you're trying to build in a feedback loop that you can operate yourself.

Okay, Jim.

CAPTAIN HELLMAN: Getting to the point that we had during the previous discussions, after we've had these different evaluations what -- or have you all come to any determination as to what will be satisfactory to be identified and evaluated or are you still going to leave that to the individual -- to each user as to exactly what they intend to do with that information and how they intend to document -- the audit phase.

MR. TELFORD: Well, what needs to be documented for No. 7 is the means you use to identify. Now that could be a weekly chart check or a monthly -- some folks do monthly audits or some folks do daily audits. That is a means to identify these deviations.

CAPTAIN HELLMAN: Say I do a weekly chart check and I find, well, that case would not apply -- but I do a daily chart check to find the problem. Say I found a wedge was left out for one treatment, after I just write in there

"wedge left out for one treatment, dose is now so-and-so," what else need be done?

MR. TELFORD: Well, you've identified it. You probably have made some sort of mental evaluation.

CAPTAIN HELLMAN: Yes.

MR. TELFORD: So if you made some sort of a note as to what your evaluation was, you're done but your procedure ought to say that you would do that, take those two steps.

MR. TELFORD: So what am I hearing here? Do we throw this one away or do we modify it or do we retain it?

MR. BUKOVITZ: One thing I seem to be getting from all this is why don't you guys write down what you have been doing all along. Am I wrong?

MR. DORING: No, you're right.

MR. BUKOVITZ: Then my next question is why are we doing this? Just so we can write down what we have been doing all along?

MR. TELFORD: Oh, no. You probably wouldn't believe this but we sat down independently and went through these. I mean we developed these independently.

The way we did it is we said we want the authorized user to be in control, to direct what should happen. Then we said, well, what are the intermediate steps that happen between the time the authorized user says here's

what to do and writes it down and the administration happens?

We looked at sort of the flow path of what happens.

We merely picked the items that needed to happen on the way.

I am delighted that we got the right ones. You say you're already doing it? That's great.

Keep in mind these are just the eight good things to do.

MR. BUKOVITZ: So you're not going to talk about how to do them?

MR. TELFORD: In the Reg Guide we're going to have guidance on how to do them, yes. That's true.

Is your answer that No. 7 you would retain it because you are already doing it, therefore that is good evidence that we ought to keep it?

CAPTAIN HELLMAN: It's so obvious.

MR. TELFORD: Yes, it's an obvious step.

It's so obvious therefore you do what?

CAPTAIN HELLMAN: Well, evidently, the fact that it's stated at all means that some people however have not been doing it. Those are the things you have identified in previous problems, the processes that had not been followed through as they should have been, otherwise you would not

need to state it at all.

MR. TELFORD: Well, if you are going to have a QA program which detects errors, you better have a No. 7 or else how do you detect them and how do you ask people to detect them if you don't ask them to identify them?

CAPTAIN HELLMAN: I agree with you wholeheartedly.

MR. TELFORD: Okay. Am I hearing -- I think I'm hearing that we keep No. 7?

MR. STRUBLER: Changing the language.

MR. TELFORD: Oh, take out "unintended" --

MR. KEARLY: Isn't No. 5 though the identification part? I think that's part of what Ken might have felt nervous about.

You have got two things there: ensure that the deviation is identified and ensure that the deviation is evaluated.

Now No. 5 is ensure that the problem is identified.

MR. TELFORD: Doesn't No. 5 say identify what you are supposed to do and do that?

MR. KEARLY: And ensure that it is being done properly but that means you are looking for problems. Right?

And if it is not being done properly, there is a problem that you have identified.

Then -- in other words, if you erased 7 and added a sentence to No. 5 that said any problems that are identified will be evaluated.

MR. TELFORD: Oh, do it in accordance with but identify anything that is not in accordance with in No. 5 and you would say that -- that No. 7 would not -- would be incorporated in No. 5? Same thing?

MR. KEARLY: I think that's what you're saying.

MR. TELFORD: Okay. That sounds like a reasonable suggestion.

MR. KEARLY: Let me also say that JCAH has concentrated on what I think you are trying to get at with Number 7. That has been almost everything that JCAH is telling us to do. Have a process for problem identification, evaluation, resolution, and re-evaluation. That's what JCAH is making us do up and down, across the board. We have to have that.

MR. TELFORD: That may be what we are calling the audit.

MR. KEARLY: I don't think so. Audit is what you are calling something that is done once a year. Right?

MR. TELFORD: Yes.

MR. KEARLY: JCAH says you have to have an ongoing program that looks at what you are doing clinically. You have to decide what kinds of things go on that have clinical

impact and look at those things which are likely to give you troubles, evaluate them, look for problems within them, if problems come up, propose a resolution. Evaluate the resolution.

And the State of Maryland is extremely heavy on this. JCAH is extremely heavy on this. Therefore, our QA program is designed first around that principal. And then we throw in everybody else's requirements.

MR. TELFORD: And so your audit is ongoing?

MR. KEARLY: That's an audit? That's problem identification.

MR. TELFORD: Okay.

MR. DORING: You wanted an indicator, Number 7 to be an indicator --

MR. STRUBLER: I think that is also saying that this should be a separate statement, because as you point out, JCAH is focusing on that, and that it is really an additional step, that you've approved the procedure in accordance with what should be done, and you find out later that it didn't occur, because a wedge was left out or in this case, you are talking about diagnostic and clinical procedures. But that there was an error that was identified by your process. And so I would probably not put it all together in Number 5, even though it could be, but identify it as a separate procedure.

MR. TELFORD: Okay.

MR. KEARLY: If you guys could determine whether what you really want or what is needed is identical to what JCAH is asking for, then both of you saying the same thing would be helpful.

MR. TELFORD: Okay.

MR. KEARLY: Or one of you saying it and not the other, would also be helpful.

MR. TELFORD: Okay. Let's go to Number 8.

MR. DORING: More specifically what you are saying is take out identified and evaluated, because we're already doing it on another level.

MR. KEARLY: JCAH makes us do that.

MR. DORING: Is that what you are saying?

MR. KEARLY: I'm not saying take it out, I guess. I don't know if, I don't know the regulatory status of JCAH compared to NRC.

MR. BUKOVITZ: Let me add one other thing, since we mentioned that. Since we are really doing it for JCAHO, we are really doing it at least on a quarterly basis, because we need quarterly reports to the QA committees.

CAPTAIN HELLMAN: But not everybody is responsible to JCAHO. Small, independent clinics, some private practices, do not come under that criteria.

MR. TELFORD: Well said, Joe.

MR. KEARLY: But, because a lot of people are, it is really important that you guys get the language looking identical, because you are going to make us do the same thing over again in a completely different way and keep completely different records, it seems to me.

MR. TELFORD: That's a good thought.

MR. KEARLY: If you don't.

MR. TELFORD: Yes. That's one way that we can accomplish the same goal but minimize the impact. Well said. Okay.

Number 8. This one is also obvious, that we want the planning to be in accordance with the prescription.

Would you delete this one, would you modify it, or would you retain it?

MR. STRUBLER: Strangely enough, I don't have any quarrels with this.

[Laughter.]

MR. TELFORD: All right. Anyone else? Any quarrels with this one?

[No response.]

MR. TELFORD: I'll take yes for an answer.

Okay. This is the annual audit on the last --

MR. KEARLY: Oh, good. Let me make one comment.

Treatment planning is sometimes used to refer to clinical treatment planning. So if you want this to be

computer treatment planning, you probably ought to spell that out.

MR. TELFORD: Brachytherapy, teletherapy treatment planning.

MR. KEARLY: "Treatment planning" is used for clinical. I mean, the clinical thing that the physician does is to plan the treatment. The physicians have that as a term for some of what they do as well as what a dosimetrist does at the computer console.

MR. TELFORD: So would you take out the word "treatment"?

MR. KEARLY: No, I would add the word "computerized treatment planning," if that's what you mean.

You're talking about the computerized treatment planning, right?

CAPTAIN HELLMAN: Computerized or manual.

MR. TELFORD: Yes. What if somebody told me they don't have a computer to do their treatment planning for brachytherapy?

MR. KEARLY: I guess what I'm saying is --

MR. STRUBLER: But that's their prescription, their treatment plan is their prescription. So their interpretation I think is a reasonable one. Treatment planning meaning the process after the prescription that dosimetry does or simulation does. Is in accord with the

treatment planning prescription. I mean, we do that, too. We use the term "treatment plan" that the physicians say this is our plan for this patient.

MR. TELFORD: So we could say treatrent plans?

MR. STRUBLER: I have no problem with the say it is. But I understand what Frank is saying.

MR. BUKOVITZ: You know what? Each one of us may be interpreting that a different way. Because if what you are saying is a treatment plan is a little different from what you are saying is a treatment plan, I'm looking at it as, treatment planning as the dose I want to give and how I delivered it, is the end result the same as what I originally intended, both for field placement for teletherapy, source placement for brachytherapy, and was my total dose delivered that I had originally intended or had decided to change along the way.

So how do you mean it?

MR. TELFORD: I think that is what we mean.

We're saying, see, the prescription, you can look at the content, the information content for a prescription, for brachytherapy. And you can look at the information content in the prescription for teletherapy.

If your treatment plan says how you are to deliver what is prescribed, that is your treatment plan.

MR. KEARLY: To be honest with you, if I looked at

that, all I'd say is I want to look at the output from my computer, the computerized treatment plan, and see if that was consistent with the prescription. That's how I would interpret that.

MR. STRUBLER: All of it, I would include in, not just the dosimetry, but the simulation, and in a brachytherapy case you may have the source loading configuration.

MR. TELFORD: Page 1447 under "Prescription," Item C.

This is what a prescription, the information that prescriptions should contain, for teletherapy. The total dose, the number of fractions, and the treatment site.

So your computer output may tell you the dose per fraction.

MR. KEARLY: It doesn't.

MR. TELFORD: Okay.

MR. KEARLY: It doesn't have anything to do with that.

MR. TELFORD: All right. What would it tell me?

MR. KEARLY: It would tell you the relative dose distribution for a particular configuration of treatment means.

MR. TELFORD: Okay. Isodose curves?

MR. KEARLY: That's right.

MR. TELFORD: Okay.

MR. KEARLY: It doesn't have anything to do with total dose, number of fractions. And it shows you what you are calling treatment site. I'll give you that.

MR. TELFORD: Okay. But it would tell you the isodose curve that you want to use; that isodose curve would be selected from that plan?

MR. KEARLY: Yes.

CAPTAIN HELLMAN: If you do an external plan. If you do an irregular field, then you would get a whole different set of values.

MR. TELFORD: Sure. But I was trying to state one example here to clarify a point.

So your plan is going to show you the isodose curves. And if you use that plan, then you would deliver the dose that was prescribed to the site that was prescribed?

MR. KEARLY: In part. It usually doesn't have anything to do with how long you leave the machine on, though.

MR. BUKOVITZ: That's right. But there's another problem.

You may have a set of parallel opposed stilts, and maybe with a two to one weighting, or one to one weighting, and you may deliver half your dose with a different

weighting than originally intended, which will change the dose distributions to the patient, which, in the physician's mind, may be a misadministration. But you don't cite that at all.

MR. TELFORD: Well, what you described was your plan.

MR. BUKOVITZ: Well, but, your definition of a plan is total dose, number of fractions, and treatment site.

MR. TELFORD: Wrong. That's the definition of prescription.

MR. BUKOVITZ: Prescription. Where's your definition of plan?

MR. KEARLY: I consider the computerized plan as part of the prescription, to tell you the truth.

MR. TELFORD: I don't think we have one. Do you think we should have one?

MR. KEARLY: Treatment planning sounds like it needs a definition. Because it does sound like we have some major misconstruations here.

MR. BUKOVITZ: Because treatment plan, according to physicians and physicists, can be two very different things.

MR. TELFORD: Okay. Therefore, we need a definition. Okay.

Assuming we have a definition --

MR. STRUBLER: Let me interrupt for a moment.

MR. TELFORD: All right.

MR. STRUBLER: Let me tell you what our physicians would define as treatment plan, versus their prescription.

A treatment plan is what they, broad scope of what they intend to do. Approximate total dose. Not anything real specific. Approximate fractionation. Palliative or curative. And what the intent is, of what they hope to achieve.

Once that is done, and they get all the rest of the studies and information and the simulation, they will write a prescription, which gives the specifics of the daily fractionation, the total dose, reassessed, modified field, bin arrangement, that kind of thing, and the number of treatments per week.

And we also say that our treatment planning process then is at the point of, after consultation and acceptance of the patient for therapy, that we will then initiate a treatment plan of how best to achieve the physician's broad intent, what they call treatment plan.

And that is our treatment planning process. It includes simulation, dosimetry, calculation of time, honored units, and so forth.

So it is being used in two different, distinct ways. But it is, I think, understood by all concerned,

those distinctions.

Of course, when you are talking about a regulation or something else, we have to be maybe more clear.

MR. TELFORD: Okay. Does that description of a treatment plan meet everybody else's understanding of a treatment plan?

MR. BUKOVITZ: Part A or Part B?

[Laughter.]

MR. TELFORD: I think both.

MR. BUKOVITZ: Well, we're using the same words in two different contexts, though.

MR. TELFORD: Okay.

MR. BUKOVITZ: Because I agree with the way Ken put it, the treatment plan is the overall picture, the overall procedure. And then once that happens, then the physician comes up with the prescription.

There is another definition of a treatment plan that takes over.

MR. TELFORD: Like a final plan.

MR. BUKOVITZ: Right. Yes. But that is the actual configuration of sources and machine time, and water treatments, or whatever.

But the first time the plan --

MR. TELFORD: Okay.

MR. STRUBLER: That's why I don't have a problem

with this wording, personally, because it is not planned or planning. So it's an active process, it's not a passive process.

MR. KEARLY: Then it's absolutely no different from Number 5. Once again.

MR. TELFORD: It's something that you have to do to make sure Number 5 happens.

Is that the way you see it?

MR. STRUBLER: Number 5 is still diagnostic.

MR. KEARLY: No.

MR. BUKOVITZ: Or the prescription. That could be 5(d).

MR. KEARLY: The prescription. Medical uses in accordance with the prescription. It's a part of, one of the things you do, for Number 5.

MR. STRUBLER: You're saying 5 intended by the word, the prescription means also therapeutic?

MR. KEARLY: Yes.

MR. TELFORD: Yes. In particular, about radiopharmaceutical therapy.

See, 8 recognizes that brachytherapy, teletherapy are a little more complicated. You do have to go through treatment planning. You do a preliminary plan and a final plan, as you've described it.

MR. STRUBLER: But then what Frank is saying is

true. If you mean that the prescription, you could say Number 5 in fact includes, is inclusive of Number 8. But then you would have to be a little bit clearer there, the prescription. You have diagnostic, diagnostic twice. You don't have therapeutic at all. And I don't think we should make the presumption that the prescription necessarily means therapeutic.

MR. KEARLY: It says medical use.

MR. STRUBLER: Then you should probably delete "or B" and use number 8 to encompass the therapy.

MR. TELFORD: How about radiopharmaceutical --

MR. STRUBLER: Although, of course, then you have to include the therapy.

MR. TELFORD: Radiopharmaceutical therapy.

MR. STRUBLER: Yes, the radiopharmaceutical therapy.

MR. TELFORD: So you're saying that we could pick up 8, put it into 5 --

MR. STRUBLER: That's one possibility. Or use B as a radiopharmaceutical therapeutic prescription to distinguish it from brachytherapy and teletherapy.

MR. TELFORD: Okay. Would either way be okay?

MR. KEARLY: I'd be happy with just leaving 5 and getting rid of 8. I think it -- you don't think that it would be seen as applying to therapy, number 8? I interpret

it --

MR. STRUBLER: Well, as long as it is clear, one way or the other. I would keep them separate, simply because generally they are separate entities. You have the diagnostic and maybe some radiopharmaceuticals in one department, and the therapy taking place in another department.

MR. TELFORD: Okay. Can we move on to the audit?

MR. KEARLY: You're saying we eliminate the words "treatment planning" altogether in this and say "use" again, so that we don't have any ambiguity. You are to review to make sure that the use you're proposing is in accordance with the prescription.

MR. TELFORD: If you incorporate 8 into 5.

MR. KEARLY: Of if you use 8 by itself within.

MR. STRUBLER: He's saying 8 by itself, use the same terminology.

MR. KEARLY: Just get rid of the word "treatment planning" and use "medical use."

MR. TELFORD: Well, that's an alternative. We could consider that.

MR. KEARLY: Then people like me would not be tempted to misinterpret it as meaning check the treatment plan, which is look at the piece of paper that comes out of the computer and make sure everything was entered right and

it looks okay.

You mean that to be much more general.

MR. TELFORD: Okay.

MR. STRUBLER: You could just use the same terminology -- ensure that the medical use, maybe for brachytherapy -- ensure that the brachytherapy and teletherapy medical use is in accordance with the prescription -- to be consistent with No. 5.

MR. TELFORD: We could do that and by saying it that way, that would encompass the treatment planning.

MR. STRUBLER: Yes.

MR. TELFORD: Include it -- okay.

Shall we go to the audit phase?

The annual audit -- the intent here is to build in a feedback loop that the licensee can use for self-correction. That is, you have this audit that produces the collection of deviations that have happened and the licensee management has an evaluation of that audit. They look at these identified deviations and say, gee, we're got a lot of little things. Do we do anything about that? Or, gee, we had just a few little things and a couple of big things, what do we do about that?

So No. 3 says they'll have a determination that the program is still effective and does or does not need modification but if it needs modification, then they will

see that prompt modification is made in order to prevent reoccurrence of those same mistakes that have been identified in the audit.

Question -- yes, Joe?

CAPTAIN HELLMAN: Well, a comment. I question the need for No. 2. We did not in San Francisco go over this. You said you were going to defer that to this meeting after the -- and I really do not see a need to involve my management in an internal matter other than what may go up to the Quality Assurance Committee in accordance with my JCH standards.

I understand it would be nice to have an audit perhaps. I think that the process I have of just evaluating it and fixing it right there on the spot should be adequate.

MR. TELFORD: What if we took out the word "management?" What you are saying is you'd rather let the QA Committee do it.

CAPTAIN HELLMAN: Or I would like to leave it within my department and furnish anything up -- anything that needs to be brought to the QA Committee's attention, have that option and if I want to keep it within the department to do that as well.

I would definitely go along with eliminating management unless I have a serious problem.

MR. TELFORD: Okay, Tom?

MR. DORING: I think "management," yes, is a word that perhaps we're thinking of as the hierarchy of the organization and you may be referring to management as management within the departmental --

MR. STRUBLER: They say here "Management in this Regulatory Guide means the Licensee's Management" which means the Administration of the hospital or facility.

I agree, that should not be.

I ask a question though. This series -- 1, 2, 3, 4 -- are you referring here to the guidelines which says responsibility, authority and audit, 1.1 and 1.2?

CAPTAIN HELLMAN: 35.35(b)(e)(1), 1449.

MR. TELFORD: Page 1449, the third column, paragraph (b)(1).

CAPTAIN HELLMAN: I mean the Reg Guide is even more stringent and even then I find even more objectionable to the proposals than the Reg Guide.

MR. TELFORD: The intent here is to -- we did talk about Licensee Management. The intent is to say these are the folks we give the license to. We make them responsible. However, if Licensee Management wanted to delegate to the QA Committee, they could do that to make the evaluation or make the determination.

What you are really saying, I think, is that you would prefer to keep Licensee Management out of it in an

overt way because they may not be knowledgeable enough to do the evaluation or make the determination.

You would rather somebody with a more sound technical basis to do that.

MR. STRUBLER: They can't do it in any way, shape or form other than as a broad viewpoint.

CAPTAIN HELLMAN: Now we do have a responsibility to bring problems to Management that are outside the clinical control or that need administrative input.

That is part of the licensing process and the Radiation Control Committee or whatever you have, but I see no need to even bring this to the Radiation Safety or Radiation Control Committee level. I think this is an internal clinical matter that need go no further unless the head of the clinic or department feels that there is a need to do so.

MR. TELFORD: So the modification that you would make would be to let this be done and not say Licensing Management, do it.

CAPTAIN HELLMAN: That is correct.

MR. TELFORD: Any other comments on this? I'm sorry, suggestions?

MR. STRUBLER: I agree 100 percent with those comments and I also question though No. 1, Annual Comprehensive Audit.

MR. TELFORD: Okay.

MR. STRUBLER: Because in some of the guidelines not only the term but who does the audit and is it an external audit by qualified personnel and who are they and you say, well, they can be determined by us, but I think it creates quite a burden on the system regarding financial and also time, particularly if you have documented a quality assurance program and it has been reviewed externally at some period of time or it has been submitted to the state or federal agencies. Then an annual audit, if it is going to be comprehensive, is going to be very time-consuming, very detailed and it's a program in which you have spent a great deal of time, ongoing program, ongoing reviews and evaluation and I don't believe it is a necessary thing for an annual review on that because you are saying look, I haven't done any changes in my system and it is an ongoing active program that I'm involved with, to require an audit every 12 months. I don't know what an optimal time is because it needs to be reviewed obviously but annual and comprehensive creates quite a burden on the system I would say.

MR. TELFORD: The words about the guidance in the Reg Guide, we'll do that tomorrow morning.

This is the statement of what we will do. If we talk about an annual audit, if you're following JCAHO

guidelines you are doing it continuously so therefore all you have to do is compile that at the end of the year and that is your audit.

The comprehensive, if you don't like that term, what would you suggest saying, because you are saying you're doing what JCAHO wants you to do, surely what you are doing there is comprehensive but why is it that "comprehensive" gives you a problem?

MR. STRUBLER: What do you do? Do you write another document and assemble all of the monthly or quarterly reports that you have and just say here? I mean, you've already done your internal audits. You've already documented them in some fashion. Now, you're saying do it one more time at the end of the year.

MR. TELFORD: Oh, no. Oh, no. If you've done 12 of them, that's enough. That's more than enough.

MR. STRUBLER: Well, I agree. But I'm just saying this says an annual audit, and someone will come in, let me see your annual audit. Well, we don't have one; we have the monthly audits. And somebody will say that's fine, and somebody else says no, I want your annual audit.

MR. TELFORD: So you would say, we should say in the guidance, if you are doing these monthly, that satisfies the annual requirement, for example?

MR. STRUBLER: Yes.

MR. TELFORD: To pile those 12 up, that is sufficient for the annual audit. Okay.

CAPTAIN HELLMAN: Actually, the Reg. Guide does not require an annual audit. It requires an audit at intervals no greater than 12 months. If you do it monthly, that should satisfy this requirement.

MR. TELFORD: I think so. You don't mean the Guide, you mean the Federal Register Notice.

CAPTAIN HELLMAN: Yes, the Federal Register Notice.

MR. TELFORD: 35.35. Yes.

CAPTAIN HELLMAN: Requires that it be done no greater than annually.

MR. TELFORD: Yes.

CAPTAIN HELLMAN: Comprehensive can mean many things to many inspectors. I just had one who just nit-picked me line by line on my teletherapy license. If I were to give this to him, I don't think, I think he'd still be there.

So I would prefer to eliminate the comprehensive, because it could mean many things to many people, including some inspectors.

MR. TELFORD: Okay.

CAPTAIN HELLMAN: Unless you define it.

MR. KEARLY: I would look for a definition of

audit itself, and what do you mean by audit. Are you going to say by audit, are you finding problems; is that what an audit is? Or does an audit say how many different procedures do you have in place which are aimed at looking at performance? I mean, there are all kinds of questions you can ask. How many different policies are written down? Do you just look at written policies in an audit? Do you look at the results of tests done? Do you look for problems found? Do you look for evaluations? All of the above? That's the difference between --

MR. STRUBLER: And also the recommendations that the audit should be done by someone other than participating in the event.

MR. KEARLY: Oh, yes.

MR. STRUBLER: In the activity.

MR. TELFORD: That's in the guidance. Did you tell me that the JCAHO calls it it's ongoing review?

MR. KEARLY: We have to evaluate our indicators for whether or not they are truly relevant to the clinical process and likely to find problems.

Do they use the word audit? I can't remember.

CAPTAIN HELLMAN: I'm not sure what the latest buzzword is

MR. KEARLY: I can't remember if that's the word. But that's the process we're supposed to go through.

We're supposed to take a look at the clinical indicators, things that are likely to cause problems with patients, and come up with studies, tests, to demonstrate that everything is all right with respect to such things. And if we are using indicators that are not likely to show problems or might not be related to a high-risk area, they we are to evaluate whether we need to be looking at something else.

CAPTAIN HELLMAN: Close those out and go to something else.

MR. KEARLY: Close those out and go to something else. Right.

MR. TELFORD: Okay. In JCAHO language, an indicator is an action step. It is something that you do.

MR. KEARLY: Indicator is, JCAH doesn't tell us really, what an indicator is. But functionally an indicator is something that you can generally look at.

MR. TELFORD: Okay.

CAPTAIN HELLMAN: In audit.

MR. KEARLY: Right.

MR. TELFORD: So if we said, instead of "audit," if we said, annually make a review of all your procedures, and see if, make a determination that they are all still effective --

MR. KEARLY: How about review your QA program.

CAPTAIN HELLMAN: To see if any demonstrable trends occur.

MR. TELFORD: This is a feedback loop. We are looking for something that may need change, something that is not effective. It's the same spirit, I think. So maybe your suggested modification would be to review, annually review the quality assurance program, determine whether or not it is effective, and promptly make modifications to prevent reoccurrence of any errors identified during the year.

MR. KEARLY: I'd say that sounds very reasonable, to me.

MR. BUKOVITZ: Well, one point. When we have annual conference audits, to me it seems as though you are going to have an annual audit in addition to your other audits.

MR. TELFORD: I can fix that real easily.

MR. BUKOVITZ: Oh, good.

MR. TELFORD: Scratch that thought from your mind.

MR. BUKOVITZ: Okay.

MR. TELFORD: But do you have any other suggestions for either this set of words or the words that I just gave to Frank?

MR. BUKOVITZ: No. I'm in agreement with those.

MR. TELFORD: Okay.

MR. BUKOVITZ: I'm relatively content.

MR. TELFORD: All right. Tom?

MR. DORING: No, I don't have anything else.

MR. TELFORD: All right. Joe?

CAPTAIN HELLMAN: No.

MR. TELFORD: Frank?

MR. KEARLY: Again, I would encourage you to see what JCAH says and try to use their language where what you are talking about is the same as what they are asking for, as well as the ACR recommendations, which probably say something like this, too.

MR. TELFORD: I know what the ACR says.

MR. KEARLY: There is an annual review in there. I can't remember, some kind of -- isn't there a review of the QA program?

MR. STRUBLER: I don't remember.

MR. TELFORD: With ACR, they do a lot of chart checks and they have a checklist that you use.

MR. KEARLY: Right. But they have some overall statements in there, too --

MR. TELFORD: Right.

MR. KEARLY: -- that would be similar to this.

MR. TELFORD: Gene?

MR. GRAHAM: No.

MR. TELFORD: Okay.

MR. BUKOVITZ: I do have one other question, since you are talking about JCAHO, because we are required to set thresholds. And basically, your thresholds are a zero percent occurrence, whereby, if there is a deviation -- well, no, let me back up.

If there is a deviation, a 5 percent deviation, we're allowed to have that, no more than 5 percent of the time. A 10 percent deviation we are allowed to have no more than zero percent of the time.

MR. TELFORD: Those are JCAHO criteria?

MR. BUKOVITZ: Well, we establish what the threshold levels are, as to what we find acceptable. Now, what does the NRC think about things like that?

MR. TELFORD: Those are reporting requirements. That's tomorrow afternoon.

MR. BUKOVITZ: Okay.

MR. TELFORD: Okay. Let's go back to the agenda.

We have one more thing on 35.35. And that is any additions. In some of the evaluation forms that I have seen so far, some volunteers have suggested additions, that we would add, things you would add to the eight objectives.

Do any of you want to make a suggestion for any additions to these eight objectives?

[Pause.]

MR. TELFORD: I'm not hearing any. Okay. Oh.

Frank.

MR. DORING: This is a fantastic start.

[Laughter.]

MR. KEARLY: The only suggestion I had was to replace them all with a simple statement that you shall have a quality assurance program which is consistent with professional society and JCAH recommendations. That would replace everything.

MR. TELFORD: JCAH, ACR, AAPM, all that?

Any other additions?

MR. KEARLY: That's not an addition. That's a replacement.

MR. TELFORD: I got it. Okay. No additions. All right, let's look back at the agenda.

We have an item at 415 for the volunteers' summary comments. This is sort of your final thoughts and conclusions on proposed 35.35, and nothing else, because we haven't gotten to the reporting requirements nor the Regulatory Guide. Frank may just have given us his.

Let me suggest that we go through this and then, as promised earlier, we'll go into the need for a regulation.

Is that acceptable to everyone?

[No response.]

MR. TELFORD: Okay. This is intended to be about

five minute, you know, five minutes or less of your final thoughts and conclusions on 35.35. So I'll start here with Andrew.

MR. BUKOVITZ: Oh. Thanks.

Actually, I guess the bottom line is we really didn't have very much difficulty implementing this. There was more trouble with the realization that a lot of it was being done, but it wasn't documented that we were doing it.

One difficulty with this is, upon discussion of the various objectives, is in determining what we meant. There were differences between myself and the physicians and the nuclear medicine tech. Rarely was it three out of three originally agreeing. It was more like one out of three or two out of three.

Basically, it is, after I come back, is to present what the NRC's or what I would perceive the NRC's final rulemaking would be. Basically, I'm going to go back and say, I don't know.

MR. TELFORD: Is that all?

MR. BUKOVITZ: That's it.

MR. TELFORD: Ken?

MR. STRUBLER: I guess I've already said enough today.

I had similar comments and thoughts when I saw this morning's presentations regarding that many of these

objectives were being met 100 percent of the time in those few facilities, 18 facilities that they evaluated, even though they were not documented, or were poorly documented, or misinterpreted. And I think that is significant in itself to suggest well, is further regulation necessary.

And I think we are all in support of the concept of having a clear and lucid quality assurance program that is doing what it is intended to do, and to have a review of it.

Many of these objectives are fine, and then with the modifications that many of us suggested, I don't think any of us would have any problems in meeting them. It is, I think, perhaps, trying to be consistent with some of the other recommendations that are out there now that are volunteer rather than regulatory that Frank points out, and to be consistent with them so that we are not trying to be redundant and trying to meet the interpretation of various bodies who come into evaluate our systems, and they say no, that's not what we have here. And we say well, that's what we have over here by another agency who is scrutinizing our programs.

So I think that is an important concept. And Frank has mentioned that a number of times.

MR. TELFORD: Anything else?

MR. STRUBLER: Not today.

MR. TELFORD: Okay. Gene?

MR. GRAHAM: Well, lest we forget why we are doing all this, we are all trying, I think, to give good patient care without misadministration. And I think that it is, again, good communication, and without duplication. I think that is the absolute essential. And the ambiguous terms and that type of thing is where we have the most problems, I think, in our profession.

I think from a more positive standpoint it has brought some physicians into line, from my viewpoint, anyway, using this as a kind of a lever. So I think it is from a very positive standpoint.

MR. TELFORD: Okay. Frank?

MR. KEARLY: Ken said it pretty well. I think that the professional societies have put an enormous effort into trying to give us guidance as to what needs to be done. And I hope that what you finally come up with us very much consistent with what they are asking us to do, along with what the other regulators are asking us to do.

And I hope also that the work that we are asked to do in conjunction with this documentation and so forth really has clinical relevance. I hope that we are not just asked to do stuff because an investigator, an inspector needs to see something.

MR. TELFORD: Is that all?

MR. KEARLY: Yes.

MR. TELFORD: Linda?

MS. FRANKLIN: I don't have too much to say. I think that as long as the rules are going to be made, it is commendable that we are asked to participate in it. And as far as the rules are concerned, I pretty much agree with what everybody has said already. They are worthwhile. But anybody who cares to practice good medicine pretty much practices it anyway.

MR. TELFORD: Okay. Joe?

CAPTAIN HELLMAN: Nothing at all.

MR. TELFORD: Okay. Susan?

MS. MOORE: Just basically that we've been following all of these objectives, but need to work maybe at more doctor and patient, or changing our format.

MR. TELFORD: Okay. Tom?

MR. DORING: I agree with Andrew. It has become very evident through the information on the graphs that we don't have enough written documentation to verify that we are doing these things, but we're doing them. It was painfully obvious when I saw the graphs, in comparing the programs that we sent you in comparison to the actual site visits. I think all this is a good idea. I think anything to increase quality is a good idea.

And I am also in agreement with Frank and a few

others that I would, before I die, I would like to see two or three regulatory agencies request the same exact thing of us. Then I can to go my Maker and feel good about it.

MR. TELFORD: Thank you.

Let's take about a one-minute break from the record while I collect my next set of viewgraphs.

[Pause.]

[Slide.]

MR. TELFORD: The outline of what I'm going to tell you is over on the left viewgraph. I'll show you the current requirements to refresh your memory and then I'll talk about some recent misadministrations that are -- I think there's one or two from 1988, most are from 1989, with a couple from 1990.

Then I can give you my punchline on the need for a solution for these problems.

In showing you these recent misadministrations I'll show you the kind of problems that we see, the kind of problems that we are trying to prevent. You can decide for yourself if what have needs a solution or not.

[Slide.]

MR. TELFORD: The current requirements are these six types of mistakes that are in 35.2. As I said, as of April 1st this year agreement states are now required to report these. Prior to April 1st of this year agreement

states were not even required to report misadministrations, so that the information that we have so far, most of it comes from NRC licensees, although we have a few cases that sort of hit the headlines and got reported in a few magazines that were from agreement states.

No. 1 says you have the wrong source.

No. 2 says you have the wrong patient.

No. 3 says you have the wrong route of administration.

No. 4 says you have a diagnostic dosage that is 50 percent different from what was prescribed.

No. 5 says you have a therapy dosage that is 10 percent different from what was prescribed.

No. 6 says you have really a teletherapy or a brachytherapy dosage that's 10 percent different from what was prescribed.

[Slide.]

MR. TELFORD: I have these grouped according to teletherapy, brachytherapy, nuclear medicine, so I'll show you teletherapy first.

This occurred during a period of months from 1978 -- or 1987 to 1988. The years just kind of go together as you get older. You just can't tell the difference between '78 and '87.

It happened in an agreement state. There were 33

patients that were overdosed over a period of 13 months from teletherapy cobalt source.

The probable consequence of course in this case would depend upon each patient.

What happened was that the source strength, the new source strength was not put into the planning computer upon change of the source.

The action taken to prevent reoccurrence here was they now have overcheck procedures to make sure that they input the right source to the treatment planning computer.

[Slide.]

MR. TELFORD: Okay, this was March of 1989, in Augusta, Maine. There was a patient who was given a dose of 100 rads to the brain instead of to the floor of the mouth.

The cause was that the names and the physical appearance and even the planning pictures of two elderly patients were very similar and the patient that was to get the dose to the lower palette was administered the brain dose instead, so the probably consequence is this patient received 100 rads to the brain.

The action taken to prevent reoccurrence was the licensee put in place some new procedures to require positive patient identification and they were going to use a photograph of the patient and oral communication and also identification by a second person.

Now these procedures that I am telling you about were suggested by the licensee but you can see the range of procedures that get suggested by licensees that licensees decide to do on their own when you ask them "What are you going to do to prevent reoccurrence?"

This was March of 1989 in Indianapolis, Indiana. There was a patient that was administered a treatment of 300 rads to 9 sites on the left hip and groin which should have been administered to the right hip and groin.

The cause was miscommunication.

Among the technologists here there was no direct communication from the authorized user to the technologist.

The patient received 2700 rads to the wrong hip and the action taken was the licensee now has a new procedure to verify the treatment site.

[Slide.]

MR. TELFORD: This is July of '89, in Massachusetts.

The patient was administered a dose to the spine instead of to the right lung.

The cause was the technologist failed to confirm the patient's identity, even though there was an available photograph.

The technologist didn't recognize the absence of the positioning tattoos. And the probable consequence was

250 rads to the spine.

And the action taken was the licensee now has new procedures that require each patient's identity be verified by photograph, and in questionable cases, the physician will verify the patient's identity prior to initiation of treatment.

You can tell they are trying to build in a redundancy for patient identification.

[Slide.]

MR. TELFORD: Okay. This is February of 1990. Another teletherapy case. This is in Cleveland, Ohio.

The patient received teletherapy treatment of nine fractions of 278 rads per fraction. And the prescription was modified to terminate after the second day. But the technologist didn't know that the change was made.

The cause was that there was no procedure that required the technologist to review the chart prior to treatment. So a change could be made in the chart, the technologist doesn't see it. So this patient got 278 rads to the spine.

The action taken was to have a procedure for putting a flag in the chart. One thing they're to do is to tape the files shut when the prescriptions are changed, to alert the technologist that a change is made. And this tape that closes the files has a little note on it that says

check for a change.

[Slide.]

MR. TELFORD: This is still teletherapy. It is February of 1990 in Pennsylvania.

This patient received four additional fractions to a spinal field over what was prescribed, resulting in 4,200 rads received rather than 3,000 as prescribed.

And the cause was the staff technologist and the student didn't see the words "treatment completed" written in the patient's chart. And the probable consequence was 1,200 rads to the spine for this patient.

And the action taken here was that the technologist and a student will now initial the daily record individually to reflect that they have each assessed the patient's chart. One can't do it for both. And they have a large stamp now; instead of a handwritten message from somebody, they stamp "complete" in there with large letters.

Now, these are facility specific fixes.

[Slide.]

MR. TELFORD: Okay. Still in teletherapy, March of 1990, in Saginaw, Michigan.

This patient received 13 treatments of 250 rads each to the wrong portion of the spine.

The cause here was the technologist did not consult the treatment chart, but used an anatomical marker

still present from prior treatments. So the patient received 3,250 rads to the wrong site.

The action taken was, in this case, they will have a second technologist will verify the treatment and initial the treatment record prior to start.

[Slide.]

MR. TELFORD: Okay, brachytherapy. January, 1989. New Haven, Connecticut.

Here we had, the nature was that the technologist entered a decay factor of 267 instead of 128.

The cause, the technologist simply misread a number and there was no overcheck procedure. The consequence, the patient received 1,000 rads instead of 500 rads.

The licensee then established new overcheck procedures to prevent recurrence.

[Slide.]

MR. TELFORD: This is January of 1989, Kansas City, Missouri.

The nature of this event was that two cesium sources of strength 25 and 5 milligram were administered instead of 25 and 20.

The cause was that one storage drawer contained sources of two different strengths. In this case, the patient was 56 percent underdosed.

The action taken was they are going to have one drawer contains sources of one strength.

[Slide.]

MR. TELFORD: Okay. This is February of 1990, Muncie, Indiana.

This patient was administered an iridium implant via an endobronchial catheter. The ribbon was inserted in the afterloading catheter for 25 hours, but upon removal of the catheter it was discovered that the ribbon was located 17 centimeters from the top rather than 45 centimeters, as it was supposed to be. It was the wrong location.

The cause was that the patient's vomiting caused a kink in the catheter which prevented the ribbon from going to the proper location. And the probable consequence here is the patient got 1,500 rads to the larynx.

And their action taken was to use a portable X-ray after the implant to determine the position.

[Slide.]

MR. TELFORD: This is February of 1990, another brachytherapy case in Madison, Wisconsin.

The patient was scheduled to receive four exposures of 1,620 rads each. This is a high dose rate device. And the patient received 4,120 rads in the first two exposures instead of 3,240.

The cause was that the distance was incorrectly

entered into the computer. The consequence was the patient received an extra dose of 880 rads.

And the actions taken to prevent recurrence were fairly extensive. Now, they will have dose distributions completed or calculated before leaving the planning computer. They will have a dosimetry and a physicist perform the dosimetry together. But now, they will have a dosimetrist or physician check the plan prior to and they will have a nuclear physician will check the dose printout and distribution prior to.

[Slide.]

MR. TELFORD: Now we move into nuclear medicine.

This was May of 1988.

This was Houston, Texas.

The patient was administered 30 millicuries of I-131 instead of 30 microcuries.

The cause here was the radiopharmaceutical order was verbal. The technologist simply ordered the wrong dose. The technologist ordered 30 millicuries knowing that it was a diagnostic study.

When they got the radiopharmaceutical they checked with again the camera, not a dose calibrator because they don't use one -- the state of Texas is an agreement state, does not require the use of dose calibrators.

You may have a tendency to smile here but, you

know, that's one of the reasons why this rule will be a matter of compatibility for all agreement states. It's things like this.

In this case the probable consequence is the patient gets 30,000 rads to the thyroid and now they have a new procedure, the licensee has a new procedure for requiring that the nuclear physician place the order for the radiopharmaceutical.

One of these days, maybe!

[Slide.]

MR. TELFORD: March of '89 in Boston. The patient received the wrong radiopharmaceutical and the wrong dose. The patient was to receive 1 millicurie of I-123 but instead got 5 millicuries of I-131.

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

The consequence is the patient got 5000 rads to the thyroid.

The action taken is the licensee now has new procedures to verify each diagnostic study requested, which gets the authorized user into the loop, not simply the referring physician.

[Slide.]

MR. TELFORD: In May of 1989 in Minneapolis,

Minnesota they have a patient that received a 3 millicurie dose of I-131 instead of 300 microcuries of I-123.

The cause was the technologist misunderstood the referring physician's request about the radiopharmaceutical and the dosage that was ordered.

The consequence was the patient gets 3000 rads extra to the thyroid.

The action taken to prevent reoccurrence is they have a new procedure now that no I-131 radiopharmaceutical will be administered to a patient without prior approval by a nuclear medicine physician.

[Slide.]

MR. TELFORD: This is October, 1989 in Rochester, Minnesota. The patient got a dose of I-131 that was ten times too large.

The cause was the referring physician checked the wrong box.

The probable consequence is that the patient gets 1000 rads to the thyroid.

The action taken to prevent reoccurrence is that any use of iodine will require the nuclear medicine physician to review and approve the request and write the prescribed dosage on the referral form so this gets the nuclear physician into the loop.

[Slide.]

MR. TELFORD: This is November, 1989 in Arizona.

This is a case that probably everybody has heard about. This patient got 100 millicuries of I-131 instead of 100 microcuries.

The causes were several.

The radiopharmaceutical was ordered by phone. It was then amended by phone. The dose was not measured upon receipt. There was miscommunication between two technologists. One assumed that the other one had already checked the dose and this was the proper dose for this patient and was instructed to give this dose to the patient so the technologist did.

The consequence was of course that the patient's thyroid was destroyed.

The action taken was the state of Arizona in this case suspended use of I-131 to allow the hospital to show how future misadministrations like this could be prevented.

They later allowed the use of 100 microcuries, up to 100 microcuries of I-131 without approval by the state, without prior approval by the state.

[Slide.]

MR. TELFORD: Okay, this is November of 1989 at Honolulu, Hawaii.

The wrong patient received a dose of 9 millicuries of I-131.

The cause was when the technologist called Patient B and another patient responded and took the I-131 dose. The patient that did respond was to get a technetium dose.

The consequence is this patient, the wrong patient, got 9000 rads to the thyroid.

The action taken by the licensee -- it was in this case an NRC licensee -- they will require single technologists to have the responsibility for identifying patients and handle all aspects of I-131 therapy. Also, the technologist, the physician and the patient will sign the therapy worksheet prior to administration.

Okay, the tripler event -- there was a female patient who was given 5 millicuries of I-131. I believe that her thyroid had previously been oblated and this was for essentially a whole body scan.

I believe that the patient was asked was she pregnant? The patient was not asked, however, are you nursing, because she was.

She was released from the hospital. She went home and during the intervening 24 hours or so nursed her baby. the infant was given a rather large dose of I-131. Upon the patient's return they discovered a large amount of iodine in the patient's breasts and immediately began to get suspicious and then brought in the infant and found that the infant had a large thyroid dose.

That would be the nature and the cause and the consequence -- the consequence was the infant's thyroid was oblated in this case.

Action taken I think is still being determined.

Is there anything that you wanted to add on that, Joe?

CAPTAIN HELLMAN: Well, the unfortunate thing -- it was an Army facility -- was that the technologist's check list for the scan also indicated to ask, are you nursing, and the technologist failed to do so.

The other part was that the management failed to report the incident to the NRC in a timely manner, which is why they are having an enforcement conference today.

MR. TELFORD: Okay. Larry, do you want to add anything on that?

MR. CAMPER: Just some numbers. I recall there were about 30,000 rads to the baby's thyroid gland, approximately 17 rads whole body, about 9 rads delivered to the mother's breasts.

With regards to the enforcement conference, probably the most significant thing is that there has been a significant amount of discussion and agreement amongst OGC, which is Office of General Counsel, NMSS, Region V, and Enforcement, that we are going to cite against Part 35 in this case.

MR. TELFORD: Okay.

MR. CAMPER: That's probably all for now.

MR. KEARLY: Do you publicize the events without names, that sort of thing, you know, like the PRP does for the FDA?

MR. CAMPER: This case is public knowledge, because a press conference was held.

MR. KEARLY: But do you have a list of things put out in a journal or something like that?

MR. CAMPER: All of these types of cases are ultimately published. They are available.

CAPTAIN HELLMAN: They're in the NMSS newsletter.

MR. CAMPER: Citations, enforcements, civil penalties, what have you, are all published.

MR. KEARLY: With as much of a description as this? Because this would be really helpful --

MR. CAMPER: Usually.

MR. KEARLY: -- in QA programs, to see what problems people have.

MR. CAMPER: Usually.

MR. TELFORD: Okay. What we saw in 1989 was 12 misadministrations that were either therapy misadministrations or cases that started out as diagnostic but resulted in a therapy dose.

In 1990 so far we've seen 14 misadministrations.

CAPTAIN HELLMAN: Are these the result of increased reporting by the agreement states, or are these simply NRC?

MR. TELFORD: All NRC.

CAPTAIN HELLMAN: All of them?

MR. TELFORD: That's one third. That's 2,000 out of 6,000 licensees, reporting 14.

What we currently have is a requirement to report, not to prevent. So it is difficult for me to imagine how I can show that I'm doing my job.

My job is to ensure adequate protection for the public health and safety. How can I show that the cases like I've just cited, I've just told you they occur and they re-occur. And how can I show that I'm doing my job if all I ask is to have these things reported?

I think I need to say to the licensees, why don't we try to prevent? Now, there may be some good voluntary programs out there. But that's not doing my job. I can't show that I'm doing my job, unless I ask them to prevent.

Now, what I also see going on is that we are observing that we look at one problem, at one hospital, as it occurs. And there are 2,000 NRC licensee facilities, 4,000 agreement state facilities.

What if we went around to each hospital and said okay, you just had a problem, patient id. What are you

going to do about it?

Okay. I could iterate 6,000 times. I could go back in teletherapy 6,000 times. I could go back in brachytherapy 6,000 times. I could go back in nuclear medicine therapy 6,000 times. 24,000 times doesn't make any sense to me.

Why not have a generic solution to require a certain minimum set of standards that tries to prevent errors in medical use?

Those are two reasons that I think we need a regulation, an enforceable regulation.

The third is that I think we need to have the same set of regulation, same set of requirements for everybody. Because those misadministrations that I showed you, you recognize that some of those facilities are quite good, quite famous. You know, just because they reported something doesn't mean they are not capable of doing very good care, but they did have a mistake.

But how about those folks that don't even have the same reputation as those facilities do? Do you think they have the same minimum standards? I think everybody should have the same set of requirements. So this generic solution, one regulation would do that. It would at least be fair, consistent with all the licensees. Even agreement state licensees.

There you have it.

Yes?

MR. BUKOVITZ: Is there a possibility of getting a copy of what you just showed? The reason being is that to define how the incidents happened would make it much easier to implement procedures to prevent these at our own institutions.

MR. TELFORD: For the misadministrations, it occurred from 1980 to 1988. We examined each of those that were in the therapy range. That was the basis that we used to define the prescriptive rule that we came out with in '88.

And, in our judgment, those steps, if followed, would have prevented 80 percent of those misadministrations.

Now, personally, I don't have any problem with giving you a copy of my viewgraphs. But I'm not sure about some of the ones that I've got here that are misadministrations.

Maybe what you are really saying is that a report, the report on misadministrations, you'd like that information.

Larry, can we get that somehow?

MR. CAMPER: I think so.

MR. BUKOVITZ: You don't need names and places of the incidents.

MR. TELFORD: The cause and what went wrong?

MR. BUKOVITZ: Right.

MR. TELFORD: Okay.

MR. STRUBLER: I agree, it would be helpful in our own institution to say look, this can happen to you. And even though, as you say, we all feel we have good programs in existence.

MR. BUKOVITZ: Actually, if I would have seen this 60 days ago, I would have taken a whole different approach to this.

MR. DORING: Yes, that's what I was going to suggest. I wish you had showed us this the first time around, the first hour.

CAPTAIN HELLMAN: You showed it in San Francisco.

MR. TELFORD: We did it in San Francisco. I agree with you. After we did the first five workshops, actually, after we did the second one, I knew I needed this. I didn't know I needed this until the second workshop. And I used it for the last two. It must have been the last two, because we went from the second one to the third one nonstop.

MR. TSE: The last two.

MR. TELFORD: The last two. We used it for the Dallas workshop and the San Francisco workshop, just to show people what we see.

Okay. Let's adjourn for the day. It is 5:00

O'clock. Tomorrow, we want to talk about, first of all, the Regulatory Guide, and in the afternoon we'll talk about the reporting requirements.

Keep in mind it is open season on the reporting requirements. I truly want to hear what you would do, whether you would delete, modify, or retain each of those reporting requirements, because I will confess to you what we're after and seek your advice on how to do it.

Okay. Let's adjourn.

[Whereupon, at 5:00 p.m., the meeting was adjourned, to reconvene the following day, Friday, August 17, 1990.]

REPORTER'S CERTIFICATE

This is to certify that the attached proceedings before the United States Nuclear Regulatory Commission

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were held as herein appears, and that this is the original transcript thereof for the file of the United States Nuclear Regulatory Commission taken by me and thereafter reduced to typewriting by me or under the direction of the court reporting company, and that the transcript is a true and accurate record of the foregoing proceedings.

Mark D. Handy
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