OFFICIAL TRANSCRIPT OF PROCEEDINGS

Agency: Nuclear Regulatory Commission

Title: Pilot Program Workshops for
Purposes and Objectives of
The NRC Quality Assurance Program

Docket No.

LOCATION: Elk Grove, Illinois

DATE: Wednesday, April 4, 1990 PAGES: 1 - 155

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

UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

- - - - -

PILOT PROGRAM WORKSHOPS FOR
PURPOSES AND OBJECTIVES OF
THE NRC QUALITY ASSURANCE PROGRAM

- - - - -

Webb Hotel O'Hare West
2550 Landmeier Street
Elk Grove, Illinois

- - - - -

Wednesday, April 4, 1990
9:08 o'clock a.m.

- - - - -

PARTICIPANTS:

Rita Duffy, Marian Health Center

Bill Erickson, Mercy Hospital

Larry Brennecke, Sina Samaritan Medical Center

Ray Wery, Marquette General Hospital

J. Douglas Bennett, Miller-Dwan Medical Center

Bob Lawalin, Harrison County Hospital

Kevin Nelson, Brookhaven National Lab

Robin Schaefer, St. Joseph Medical Center

Ed Kaplan, Brookhaven National Lab

Joanne Kark, Illinois Department of Nuclear Safety

Anthony Tse, NRC

Darrel Wiedeman, NRC, Region II

Lloyd Bolling, NRC, State Agreements Program

Mary Ann Swan, St. Joseph Medical Center

Alexander Ricci, St. Joseph Medical Center

Tom Stetawakos, Kruse-Lubert

Richard Clouse, Elkhart General Hospital

John Scheu, Elkhart General Hospital

Duanne Zenn, Medical Physics Consultants

Tracy King, Medical Physics Consultants

Kathy Allen, Illinois Department of Nuclear Safety

Judy Bastian, Freeport Memorial Hospital

PROCEEDINGS

MR. TELFORD: Good morning. I am John Telford. I am from Headquarters, NRC in Rockville, Maryland. As a way of introduction, last Thursday we had a workshop in New York. That was our first workshop. We are going to have five workshops around the country for all of the volunteers that are in the pilot program. One thing that we learned from the New York workshop is that we should spend a little more time on the introductions.

Let me mention that we are keeping a transcript of this meeting because that way we can make it part of the official record for the rulemaking process. Anything that we say can be used in the rulemaking deliberations as if it were a public comment. I will show you how it comes in handy later today. One of the things that we thought we would do during the introduction process this time is, while we go around and state our names we can say what our position is, where we work, the name of the facility, and the type of facility and basically its location.

What we are trying to do is, there is something like 2,000 NRC licensees across the country and 4,000 agreement state licensees. We would like a "representative sample" of volunteers in our program. Then you look a little further and you find out that the NRC Region I and III contain most of the NRC licensees in the entire country.

Here we are in Region III today.

Then you look for the agreement state licensees and you find that most of the licensees in the country are in the states of New York, California, Texas, Florida, Illinois. Then you come down another level of magnitude to places like South Carolina and Arizona. Therefore, you say if I am going to sort of represent the country how do I do that. So, what we said we wanted to do was proportionately represent the licensees in each NRC Region, each agreement State, each class of licensee; that is, whether you do therapy, whether you do brachytherapy, or whether you do teletherapy, or just nuclear medicine.

Some people just do nuclear medicine explicitly and we hear from them just for that. It depends on the location, whether you are in an urban area or rural area. We have endeavored to do what is called stratified random sampling, break the country up into strata and all those characteristics that I have mentioned becomes the strata down the line that we are trying to proportionately represent.

I think it will be informative to the other participants as well as to us when you tell us, I'm from a small town or I'm from a big town, and tell us what combination of teletherapy or nuclear medicine that you do. Some folks may be doing all and some folks may be doing

brachytherapy, but they will be doing on a cobalt machine. Just to get us started, did I forget anything?

MR. WIEDEMAN: The size.

MR. TELFORD: Okay, the size of your hospital and maybe in terms of number of beds. Maybe we can start here.

MR. ERICKSON: My name is Bill Erickson, and I am special imaging supervisor at Mercy Hospital in Muskegon, Michigan which is a little bit North but directly across Lake Michigan on the Shore of Lake Michigan. Mercy is a 180 bed acute care hospital, and I guess you could consider it a rural area in comparison with some of the metropolitan areas that I have seen.

The type of nuclear medicine that we do is basically we don't do any therapy other than thyroid therapy which is straight nuclear medicine.

MR. TELFORD: Next.

MR. BRENNECKE: I'm Larry Brennecke. I am the radiation safety officer at the Medical Center. It's about a 700 bed hospital in Milwaukee. We do nuclear medicine, nuclear cardiology and brachytherapy, limited to cesium implants.

MR. TELFORD: What is the size?

MR. BRENNECKE: About 700 bed. It's a pretty big hospital.

MR. TELFORD: A pretty big hospital. Next.

MR. WERY: My name is Ray Wery. I am from Marquette General Hospital, Marquette, Michigan which is about 400 miles due North of here. We are a rural area. What we do basically is all the areas that we are going to be discussing here. I am a physicist and radiation safety officer.

MR. BENNETT: My name is Doug Bennett. I am from Duluth, Minnesota representing Miller Medical Center. I am the director of Medical Physics at the hospital and the radiation safety officer. Miller Dyne is about a 150 bed hospital. We have both nuclear medicine and radiation therapy.

Nuclear medicine is actually quite small. We only do 10 to 20 nuclear medicine studies a month. Brachytherapy is limited to cesium insertions and teletherapy, we probably treat -- it averages between 30 and 40 patients a day on teletherapy.

MR. TELFORD: Size? Did you say that, or did I miss that?

MR. BENNETT: I don't think I said the size. Marquette is about 300 beds.

MR. TELFORD: Okay.

MR. LAWALIN: My name is Bob Lawalin. I'm from the Harrison County Hospital in, Indiana, which is about 30 miles West of Louisville, Kentucky. It is a rural hospital

with 66 beds. All we do is just nuclear medicine.

MS. SCHAEFER: My name is Robin Schaefer. I am from St. Joseph Hospital in Bloomington, Illinois. We are approximately 150 beds. I am a staff technologist in nuclear medicine and radiation safety officer. We do full studies of nuclear medicine and nuclear cardiology.

MR. KAPLAN: My name is Edward Kaplan. I am with Brookhaven National Laboratory. I will be involved in reviewing the plans and responses that you ultimately come up with to this pilot program.

MR. TSE: My name is Anthony Tse. I am the task leader for this rulemaking proceedings, and also for this pilot program. I also work in other areas related to medical rulemaking like iridium 192 and other practical matters. I will be interested in what you say today.

MR. WIEDEMAN: My name is Darrel Wiedeman. I am with the NRC Region III office in Illinois. I recognize some faces around the room, and I recognize names. I just want to personally welcome you to the Webb Hotel in beautiful downtown Elgrove Village. I did the same thing this morning, I drove right past and didn't recognize it until the numbers started changing as I went further South.

I am glad to see most of you made it. I think we are still missing some of our folks from Michigan, but I am sure that the will show up later on. Once again, welcome.

MS. SWAN: My name is Mary Ann Swan. I am from St. Joseph Hospital in Joliet, Illinois. It is about 30 miles South of here. I am the supervisor for nuclear medicine and I do a full range of nuclear work. We do probably over 5,000 procedures a year, a little more than one-third of that being all cardiac work. We are a little bit over a 500 bed hospital.

MR. RICCI: My name is Alexander Ricci. I am the physicist at St. Joseph Medical Center in Joliet. The radiation therapy department has cobalt with two five electroenergies. We have brachytherapy, mainly cesium insertions. There is some radium which is rare, something like a couple of years or something like that. I cover radiation safety for the Hospital and physics for the hospital.

MR. CLOUSE: My name is Richard Clouse. I am the coordinator for nuclear medicine at Elkhart General Hospital. You have probably never heard of Elkhart.

MR. TELFORD: I have.

MR. CLOUSE: It's kind of a suburb from Notre Dame. It's about 20 miles East of South Benton, Indiana. We do just nuclear medicine. We are a 130 bed hospital. We are licensed to do implant therapy, but we only do one. There isn't a lot of interest there.

MR. SCHEW: My name is John Schew. I am a health

physicist and radiation chemist and advisor for a number of hospitals in the Elkhart area. Elkhart is one that I do advise.

MR. TELFORD: I forgot to give you the punch line a while ago after we went through this elaborate selection process. What we were trying for is to get 24 licensees that are NRC licensees to agree to participate in the program. What we ended up with was 22 NRC licensees and 26 state licensees.

Let's go off the record for a few minutes.

[Off the record.]

MR. TELFORD: Now that we are joined by the balance of all of our volunteers, I see that the airlines have finally delivered all of our folks. Let's start with Kevin over here on the introductions again.

MR. NELSON: I am Kevin Nelson. I am from Brookhaven National Laboratory.

MR. STETAWAKOS: I am Tom Stetawakos from Cleveland, Ohio with Kraus Lubert. I am from the satellite facility. All we have is a cobalt unit there, but I am also affiliated with Mount Sinai Hospital where we have a complete nuclear medicine as well as therapy department.

MR. TELFORD: What is the size?

MR. STETAWAKOS: The satellite facility has no beds. It's strictly an out-patient basis that we have our

clients come in, and the hospital is a 450 bed hospital.

MR. ZENN: My name is Duanne Zenn. I am from Ann Arbor, Michigan. I am representing a small clinic that does nuclear medicine, x-ray and ultrasound. In their nuclear, they only do about one to five patients in a week, so it's a very small place.

MS. KING: My name is Tracy King. I am with Medical Physics Consultants, representing one of my accounts which is Kalamazoo Cardiology. We are a group of cardiologists performing strictly outpatient studies, one type of test only.

MR. TELFORD: How may patients?

MS. KING: They are doing probably about eight patients a day. They do a stress and arrest study on almost all patients. They have one technologist.

MS. ALLEN: I am Kathy Allen. I'm from the Illinois Department of Nuclear Safety. We have no beds. I am here to gather information and submit comments to NRC for proposed rulemaking. I am especially interested in meeting any licensees from Illinois that would like to input.

MR. BOLLING: My name is Lloyd Bolling. Iam from the NRC State Agreement Program. I am going to try to answer any questions you might have about how the pilot program and the QA proposed rule will affect agreement state licensees.

MS. DUFFY: My name is Rita Duffy. I am a supervisor of nuclear medicine. We have nuclear medicine, immunology, and therapy.

MR. TELFORD: Earlier I was talking about how we went through a fairly elaborate selection process to finally come up with 22 NRC volunteers and 46 agreement state volunteers who represent a diversity of classes of licensees, types of facilities, a combination of nuclear medicine. I want to say that I congratulate Brookhaven in all its hard work to go through the two or three rounds of selection from solicitation letters.

It turns out that when we send a letter to your Hospital we had to check with the department chairman and somebody else and check with somebody else. And then 10 days later you can tell him yes or no. He had to do that several times and go through many people to come up with all of the volunteers here. Indeed, you can see that some people are from urban locations and some people are from a rural location.

Let's get a couple of details that you wanted to say Ed?

MR. KAPLAN: Yes. Those of you who would like to check out late, the front desk tells me that a 4:00 p.m. checkout is okay. We are going to have to break at 11:30 or so, so that we can use the facilities then to get us from

this isolated area to some restaurant somewhere. I assume we will break from about 11:30 to 12:30 or thereabouts.

For those of you who need reimbursement, during one of the breaks just let me know. I have forms for you. There is a multi-leave form. All you need to do is sign it. Then there's a xerox copy of that which will be a worksheet. Please fill out the worksheet and send that and the signed copy back to us with your original receipts. We need original receipts, and then we will reimburse you.

MR. TELFORD: On your agenda this morning, we want to get a little bit of history and a little bit of how we got to where we are. I know of at least one person in the room that has a joke that you have heard. That's okay. Then we are going to work up, talking about the proposed 35.35 and the rest of what is on the agenda.

We will talk about the pilot program and what it is all about. If we go more quickly that's fine, and if we go more slowly that's fine. It's the reason we don't have very many times listed on the agenda. Let's go to background.

We started working on quality assurance in 1987. The Commission asked for a rule to be able to do something other than just having a definition of what this Administration has in 35.22. It is a little bit of something new for our agreement state licensees, because as

of April 1st the state licensees have to report to this Administration.

MS. KARK: I am sorry for the interruption. I was given incorrect directions and was roaming around.

MR. TELFORD: We have just been joined by our final participant and we will let her introduce herself.

MS. KARK: My name is Jo Ann Kark. I am an employee of the State of Illinois, Department of Nuclear Safety. My title is Nuclear Safety Health Physicist. I am essentially a radioactive materials inspector for the Chicago region.

MR. TELFORD: Okay. Let's go back to the background now. Back in 1987 there was a request to develop what we called quality assurance and comprehensive quality assurance program. So, we wrestled with a definition of how to divide those. We finally did, and we sent a basic rule to the Commission in March 1988. We spoke to the Commission and sent in written comments to the effect that we really don't like to be told how to do this and would rather be told what to do and not how to do it, and a few other things.

But, the Commission responded and requested rulemaking options which the staff gave it, and the Commission said let's have a performance based rule. The staff held various meetings with the Quality Assurance

Subcommittee of the Advisory Committee into the Office of Material Safety and Safeguards. We met with the American College of Radiology in March of 1989 principally because at that time they were developing what they have called the quality assurance program. It is a voluntary program for all of the members. Many of you are members of the American College of Radiology and I am sure that you have seen it by now.

We held a workshop in January. The first day was with people with therapy and the second day was people with nuclear medicine. These were selected licensees that just requested to come in and talk to us about what they thought about the regulatory guide. We asked for their comments. In June of last year we provided our first draft of the proposed rule to the Commission. I am sure it is a mystery to you of how the NRC works.

The way it works is a couple of lawyers, two people from the office of nuclear safety and safeguards -- that's a different office than the office than Tom and I are in. We are responsible for regulation and development, whereas NMSS is responsible for overseeing licensees and inspections across all the regions. I put them together in a room and say okay, we are going to do this.

We discussed, arm wrestled, we worked on it for a long time. Essentially, it wasn't so long really because it

was from October of 1987 until June of the following year that we had total time. The first few months was developing this prescriptive rule which was ultimately rejected by the Commission. We turned around from there and six months later provided the performance based rule.

The reason I am telling you all of this is, the staff develops its best position for recommendation to the Commission. If I were you, I would think of the Commission as the Board of Directors for a Company because they make the ultimate decision. We don't make the decisions, we just provide the proposals. They make all the decisions. The Commission discussed the proposed rule and gave it back to us at the end of June. We submitted another proposal, another draft, in response to their request.

There was a lot of discussion on this proposal rule. Finally, in December and the first of this year we got what we call the staff requirements memorandum which told us the changes that were required in order for the Commission to approve this. We made the changes and it was published on January 16th of this year.

Part of the staff requirement memorandum was to conduct a pilot program about how we went through the selection process. There were several purposes of the pilot program, which I will outline in detail later. But what it really is, is the acid test for this proposed rule. It is a

performance-based rule and not a prescriptive rule. It is going to say here are the eight objectives. It won't tell us how to do it, it will just tell you the what.

Before we go final with this, we wanted to do something other than merely publish it for public comment. We wanted people to try it, to work out all of the bugs that it has and perfect it. Are there any aerospace background in the room. You have heard of the Chicken Test. Rolls Royce is a manufacturer of jet engines, particularly for military aircraft. Before a jet engine is finally approved, it has to undergo the chicken test. Rolls Royce spent $5 million in two years developing a high performance test engine.

It passed all the quantitative tests and had all the horsepower, thrust and everything else correct and everybody was very proud of it. But then they had to go to the chicken test. What you do is go to the supermarket and get about 12 gross of chickens and put them in a large gun, about a six foot diameter barrel and turn on the engine. You point the big cannon at the engine and fire the chickens at the engine. The engine is of course supposed to be running, because if the military aircraft has to take off for maneuvers through a flight or flock of birds it has to keep running.

You guessed it, the engine failed. So, rather

than go final with our proposal and have it fail, I am doing the chicken test. Don't get the wrong idea, you are not the chickens.

[Laughter.]

MR. TELFORD: You are more like the gun. What I would like to do is to talk about the proposed 35.35. You will notice in the agenda that after sections there are questions and answers. We want to make sure that everybody has the opportunity for questions and comments before we move forward.

MR. BENNETT: You started with October of 1987. Why did you decide in the first place that there needs to be such a rule?

MR. TELFORD: Well, that's a 30 minute or so discussion. I gave a talk on the quality assurance program about five or six times last year, and so I dragged out all the Administration books and read some case studies of the patients that was incorrect. The technologist or nurse goes to the waiting room and asks for Mr. Smith. Mr. Smith comes and he gets his dose of radiation and it's the wrong Mr. Smith. Or, Mr. Smith comes in and gets his dose of radiation in the right hip but it's the left hip.

Too many cases of I-123 or low amounts of I-131 that turn out to be large doses of I-131. When I go through those I say this is the problem. Here are the kir f

problems that we can fix. When we started in 1987, what we did is took out this Administration for the last eight years and said these are the problems that we know about and how do we fix these. When we were done we said we can fix at least 80 percent of the procedures that are incorrect.

At each Commission meeting the Commissioners have always come in with the industry that provides this service to the patients to say it's great. They put in a little kicker at the end and say make improvements. We are asking for everyone to make an improvement and not be complacent. It may be that your facility is great and maybe never had this problem. The current requirements in 35.82 say if you make one of these mistakes you have to report it. We don't have anything in the regulations that say you should specifically go after people that have misadministration that say you have to have a program. That's what this rule does.

It says you have to have a quality assurance program to prevent errors. If your facility has a great record, really in the end this rulemaking may be nothing because you are to meet the standards. We have been told many times by many licensees that they are already doing this. On the other hand, the facilities that have a bad record, then what I might call a slow learner. What this rulemaking says is, you have to come up to speed of where

everybody else is.

This is an enforceable regulation that will force I hope forces all 6,000 facilities in the country to come up to one standard. The reason the agreement state licensees are in the program is because this rulemaking is because it is a matter of compatibility for the agreement state licensees. When we talked to the American College of Radiology, what they said is that we don't have national standards. Great, we would like to see some national standards.

Some of the things that we have in the regulatory guide, we simply borrowed from them.

MR. BENNETT: What I am really leading up to is that there are millions of treatments that are performed each year throughout the United States.

MR. TELFORD: That's right.

MR. BENNETT: You have a handle on how many misadministration occur?

MR. TELFORD: Sure. There are seven million diagnostic treatments every year roughly. There are 400 misadministration for diagnostics.

MR. BENNETT: That's from NRC licensees.

MR. TELFORD: From NRC licensees. If we look at the therapy in misadministration or diagnostic procedures that ended up with the high dose of I-131 for instance,

there are about 11 therapy misadministration per year. There are something like 180,000 therapy procedures every year from NRC licensees.

The rate is very low. If that's what you are getting to, I will say it for you. The rate is very low. The industry should be commended for its low rate. However, the NRC has the responsibility to protect the public, and that includes patients. What this rule does it, if it is approved as a final rule, your hospital may treat 1,000 patients a year, one out of 10 years you may have a misadministration. That's about the current rate of misadministration.

But on the other hand, if a hospital 100 miles from you has a misadministration three times a year, all this rule will say is you have to have a quality assurance program that addresses that problem. That is the people that we need to pay attention to. All of the misadministration that I talk about get reported to Congress. Congress has charged the NRC with protecting the public, so they could easily say to us why aren't you doing this job. This rule does that job.

MR. BENNETT: I thought this concept was as low as reasonably achievable.

MR. TELFORD: Right.

MR. CLOUSE: It seems like we are throwing lots

and lots of dollars at accomplishing not an awful lot more. I am certainly concerned about those few people that we are having some problems with, but the amount that you are asking us to put into this --

MR. TELFORD: Let's separate the amount of what you think we are asking for. Let's not jump to conclusions, let's back up one step and say do you have any disagreement with how we are approaching it? In other words, just on the basis of it we are saying let's have performance based rules and let's just list some objectives. You tell us how to best do that in your facility and be custom tailored to your facility.

It is an enforceable regulation so that all the slow learners have to come up to the same speed where you are. Just don't think about it now, because we will talk about that later. Do you have any disagreement with that basic --

MR. STETAWAKOS: May I ask, and correct me, in saying that the whole reason you are doing this is so that you have a recourse for those who have a lot of misadministration that presently you don't have; is that what this rule is telling you? You have a control right now if you want. You know the misadministration and you know who the bad guys are out there, the slow learners or whatever you want to call them.

We are talking about four in 70,000 -- out of every 70,000 administrations there are four that you have a misadministration. Probably 90 percent of the four or three out of four, probably none effective to the patient or a study could be done -- I am not using that as saying we don't need it because we really didn't hurt anybody. I agree with you. As Doug said, you have to keep it as low as reasonably achievable and you don't want to expose somebody unnecessarily.

Still, we are talking about four out of 70 procedures. I don't know that there is an industry in the United States that has a record like that, okay? In the effectiveness of it, is it going to be effective or are you just putting a bigger burden on people so that you have a way of coming back and saying you are a bad guy, you are a slow learner so we are going to fine you.

MR. TELFORD: Let me ask you to not make arguments for or against the amount of burden yet, because we haven't talked about it. At the end of the day you can tell me that. We haven't talked about it yet. Let's talk about theory.

MR. STETAWAKOS: My primary question is, is this strictly so that you have a way of penalizing those who are slow learners?

MR. TELFORD: That is one. In my opinion, that is

one objective of this, it's an enforceable regulation. You could say okay, 10 CFR says you have to -- Part 20 protects workers, and you have to use dose calibrators and there are various parts of 35.100, 200 and 300 that affects licensees. But no regulation says you have to have a program that tries to prevent errors in medical use.

If we just talk theory for a moment and say -- I could give you the answer to that. I am doing it because the Commission told me to. I am not going to give you that answer. The reason is that it would be a copout, and I want to convince you that we are part of the staff that is here and we are real people and have ideas just like you do. We have reactions just like you do.

We are going to be part of the team that turns this proposed rule into a final rule. What you have today in this workshop and the next workshop is, you have access to those people. Let's just talk theory for a moment. I really want to ask you two questions. The first one is, do you disagree with the theory of saying we have to have a rule to bring out the slow learners. The second is, if you don't like that -- and I don't mean to put you in a box or anything -- if you don't like that, then tell me what you like.

The first question for having enforceable regulation -- first of all, don't worry about the rate

because the rule says confidence so there's a lot to be talked about there. It is not absolute. It's just the theory. Do you disagree with the theory of having an enforceable rule.

MR. BENNETT: I don't think you have a problem.

MR. TELFORD: No problem to be solved, okay.

MR. STETAWAKOS: I look at it as a way of -- that's why I asked you the question if it is giving you like a law so you can punish people who are slow learners. I think you could work it in a way where you can punish the habitual offenders if you would, and not have to go through something as elaborate as this appears to be at this time.

I agree that you need to keep it as low as possible an you can't just let it go helter skelter. I think what you are saying is that we need to find these people who are doing it wrong, and this is the only way that we can find them is to make a rule to say that we can find them.

MS. KING: I can understand where you are coming from. Although it is low, it could be lower. I agree. I see a lot of misadministration with patients answering to the wrong name or grabbing -- a lot of them seem to be technologists in a hurry drawing from a wrong vial. That seems to be what I get most of, and this isn't going to eliminate that.

The other thing that we thought about was a lot of these iodine therapies seem to be because the technologist isn't trained properly or doesn't understand what they are doing. Isn't a more productive way of doing things of going toward minimum training for technologists?

MR. TELFORD: Maybe one thing.

MR. WERY: I agree. I think the kinds of misadministration that you at least use as an example are kinds of misadministration that are human based. Whenever you are doing something repetitious day after day, humans will make mistakes. Quality assurance programs are designed so that you try to minimize that.

The other thing that I would like to say though is, I think most places -- at least I would hope that most places that do have misadministration because of human error or whatever, I would imagine that what most of them will do is put some kind of quality assurance system in place to make sure that at least the mistake that has happened is less likely to happen in the future.

I think the NRC has the ability to enforce that now in the form of at least -- I guess I don't know. If you could enforce that in terms of a license amendment, that would force an institution that has misadministration to proscribe a way of ensuring that it won't happen again.

MR. TELFORD: Do you understand what he is saying?

He is saying that if you discovered through inspection of licensee A that has trouble, you could take a regulation like this and give it to them as a license condition. Except, what would you do in a 4,000 agreement state licensees?

MR. WERY: I am looking at it as kind of saying --

MR. TELFORD: You would have to go to a state and first of all enforce a state. Then go to that single licensee or go to all licensees in the state.

MR. ZENN: I think that if you are trying to go after these slow learners, I have to agree that there's an easier way to do it than this elaborate scheme. I was a technologist myself for a few years, and the problems I saw mostly in misadministration is where it is a bad day. I got three patients and I just ran over there, I grabbed something and injected it.

There is no QA that is going to help that. That is almost always what happens, you know, either you are going too fast or you have someone that is not trained. The one that made Time Magazine and everything, where that lady got the 100 milicuries rather than 100 microcuries. I don't know if the technologist was trained, but when I was trained we were told over 30 milicuries you don't let them out of the hospital. That would have been an instant flag to me that you don't give them 100 milicuries and let them walk

out. You check with the doctor and see what is going on.

MS. DUFFY: Well, I agree. I also think that the proposed rule should direct more to the director of the departments.

MR. TELFORD: The authorized user.

MR. ERICKSON: Not really, other than the fact that the economics in medicine in the limited -- the steps that we do in most areas are due to --

MR. BRENNECKE: I was just thinking that when you report in this Administration, it says right on the form accident to prevent recurrence, why couldn't an inspector follow up on that and make sure that the action was accomplished.

MR. WERY: If I could add just one more thing. It was not actually introduced, your eight items that you are working on. The quality assurance items, part of those that you have there, at least as I understand them or can imagine them --

MR. TELFORD: We are at the theory level.

MR. WERY: Okay. Then I will wait on that.

MR. LAWALIN: I agree. I think if we are coming up with an elaborate system, it is just too elaborate right now. We have human error involved here, and I don't think QA is going to deal with the human side of it.

MR. TELFORD: Let's turn the tables. What if you

are a Congressman and I'm the NRC. I come to y and say hey, I got 2,000 licensees, they are busy. They are overloaded. The rate is only one in 10,000 but I'm sorry about that lady down in Arizona that got 100 milicuries. That's the best I can do. Congressman, what do you tell me?

MR. LAWALIN: I am going to ask you if you followed up and make sure there is no more problems with that licensee.

MR. TELFORD: I followed up every year out of the last eight years and every year I come to you and tell you, we had "x" of these cases. You look at me and say, GAO says there were four of these cases last year. There was one guy out of one reactor that got more dose than he had. There are seven cases last year and four of them were medical use licensees. You are Congressman, you look at me and say, why aren't you doing your job.

MR. WERY: I suppose this all follows through.

MR. TELFORD: That's an if.

MS. SCHAFFER: I will regress way back here as John Q public. I don't want my kid being one out of that 10,000. I am going to have to regress way back there. I want some controls on that, especially if you are talking -- whether they be a slow learner or fast learner, having had a QA program in progress for over a year now, you are not talking that major of a problem if the way we have it set up

for each patient I am talking 30 seconds time to go through my checklist and make sure that everything has been accomplished to every person's treatment.

Granted, I only have six patients to eight patients a day, but that is per person, per camera, per room. I think you can slow that way down. As far as I a concerned, when you are talking about my kid, my family or whatever, I was too busy.

MR. STETAWAKOS: Let me ask a question. What is considered minimum?

MR. TELFORD: We are at the theory level. Don't go past that.

MS. KARK: May I make a statement as a nuclear medicine technologist?

MR. TELFORD: As a technologist, okay.

MS. KARK: In a previous life I'm a certified nuclear med tech, and that's part of the reason why I am here. Specifically getting beyond the human error I have seen that and I understand it. One aspect of misadministration that bothers me is -- maybe this is not kosher and maybe it's not legal. However, I have seen it where if there is a misadministration, the M.D. basically can prescribe the dose after the misadministration.

Let's say that the red vial is made up with glucoheptanatin instead of NDP. So, we have a

misadministration. The physician is allowed to say well, we want a bone scan but since we have had a misadministration essentially, let's write a script for a liver scan. Then, you don't have to report the misadministration which it was. From a regulatory standpoint, I would like to see something like that not continue to be possible, that you can't write a script for something after the fact.

MR. STETAWAKOS: That is illegal right there, what was said. My interpretations of the regulations, I consider that illegal.

MS. KARK: Well, it is done.

MR. STETAWAKOS: Well, whether it is done or not, it is illegal. All you are doing is piling up regulation after regulation, trying to cut something down that is illegal to begin with. I don't deny that it might be done, but it is illegal to begin with.

MR. TELFORD: She wanted to make a statement and she made a statement.

MS. BASTIAN: I apologize for being late. I will reserve comments. I don't have the whole gist of the explanation of this.

MS. SWAN: I agree with her. If it eliminates one misadministration -- our plan is, we can do up to 40 scans a day and I have been there a few years. We have never had a misadministration, but we have a good QA policy. It comes

from me -- it's got to come from the supervisor. If you don't enforce it -- they look at the sign right above where they are working and it says think, but they also know how to think through the steps. I think any program is worthwhile if it eliminates that one.

I agree, I wouldn't want my kid getting a dose either. That is just from a -- we have a lot of work and are busy all the time, but that's no excuse.

MR. RICCI: I would like to know what the proposed rule is like for making a mistake.

MR. TELFORD: I like that.

MR. CLOUSE: She says that we need to put more on the authorized user. I work for the hospital, and the administrator's name is on the license. But the authorized user does not work for the hospital and they are in independent positions. Therefore, if I have a human being make a mistake, my responsibility goes back to the hospital I work for and not to the authorized user.

Then we have to decide, is it the authorized user's responsibility to make sure that the hospital disciplines their employees or however this takes place, or is it the hospital's responsibility? Who in that chain from the vice president down, whose responsibility is it?

MR. TELFORD: That's a detail. I can solve that now.

MR. CLOUSE: Okay.

MR. TELFORD: We are talking about theory here.

MR. CLOUSE: I have to agree. I don't want that to happen to my child. I am probably more tolerant than some people. If I was the 100 milicuries, obviously I would be very upset. We have had in the past a couple of misadministration and I will admit that. They were diagnostic. That person no longer works for the hospital, thank goodness. That eliminated part of the problem.

But, human error does happen for various reasons. I have no disagreement with the needing of a proposed rule. I think probably it is going to have very little affect on our institutions, simply because the Joint Commission on Hospital Accreditation already says that you are going to have a quality assurance committee. So, I don't think it's going to have a lot of affect on us financially or perhaps any other way.

I think perhaps it makes my job easier just because -- then I can go to adminstration and say this is the way it has to be. If it takes 30 seconds and if it takes longer, that is my justification. Then the responsibility is less mine maybe and more on the administration. To me, I don't see it as a problem.

MR. SCHEU: My only thought was when I was using your material to outline a quality assurance program, I

didn't find it to be that much work in terms of application. The thought did come to my mind -- as many people have expressed here -- my 20 years in nuclear medicine, I think the majority of the misadministration that I have seen this would not eliminate it because they have all come from just mental lapses on the tech's part making the wrong product and sticking it in the wrong vial which is labeled all day.

It is those errors that I am not sure that we can ever really, truly eliminate.

MR. TELFORD: Okay. But in theory, if you had a choice of attempting to eliminate a few of those by instituting some sort of QA program that would reduce some of those -- we are on a theory question, I guess.

MR. SCHEU: The one that I have produced based on your material, it does not seem like a whole heck of a lot of work. I certainly can adapt that to our system. I am not sure that would eliminate many of the misadministration that I have seen.

MR. TELFORD: Nobody is going to make any claims that this proposed rule is the best proposed rule. In fact, we are here saying just the opposite. We are saying that this is like five cowboys sitting around a campfire stories. The first guy tells a story and the second guy comes along and tells a story to top that one. The third guy tops that one and the fourth guy tops that one. We are the first

here. We don't stand a chance.

We will admit right up front that this is our proposed rule. This is the best we can do with the time that we had. The purpose of the pilot program is to make it better. All of you folks have more experience than we do, and I can't think of a better way to try to develop a final rule that is as good as we can make it. It may be that we can reduce the impact on the licensees by this process or we can make it better. We can go after those things that we can fix and have the wisdom to know that we can't fix some things.

Therefore, don't make it a requirement that says you have to go to zero. I mean, apparently, the Japanese can make cars with zero defects but that's not the question here. We should just go after those things that we can fix.

MR. SCHEU: I have a question though. Let's say this is adapted and becomes law. Is this a mechanism them for the NRC to add to without further review in terms of quality control steps? Once we have this particular material in the law a quality assurance program is necessary? Can more things be asked of that program as time goes on in years without review?

MR. TELFORD: We will get to the answer in a minute. But basically you are asking can you ratchet this law to make it tighter or make more requirements.

MR. SCHEU: Exactly.

MR. TELFORD: You can't make a chance to the 10 CFR unless you go through the rulemaking process. You will see in this requirement that there is an annual -- therefore, you have a slow learner and when they started out they said I have a QA program that meets the rule. They come to the end of the year and they have six misadministration. We are getting into too much detail right now.

All right. We have some folks that think we need to do something and some folks that don't. I asked you to talk about just the theory of the question and not the details, so let's go to the details.

MS. DUFFY: I know that I am a regulator, but licensees have talked to me. They just had a question on the theory of this whole thing. If the rate of misadministration for diagnostic and therapeutic radiopharmaceutical application is so low, maybe the NRC is looking the wrong way. Although they don't have jurisdiction over x-ray machines and x-ray radiation, they feel that a majority of misadministration comes from that area.

The states have jurisdiction, and they feel that NRC is imposing -- they are looking at something that they can control, when really in fact, maybe the emphasis should

be towards the states to control x-rays instead of in some people's words wasting their time with something that is already very low, why not get the hospitals to focus in on something that really does need improvement.

MR. BOLLING: Maybe I can address that a little bit. We had a number of meetings in Washington and meetings with our advisory committee on medical uses of isotopes. That group is made up of some physicians who are nuclear medicine people, therapeutic radiologists, cardiologists and I think we got two or three physicists as well.

They made it quite clear to the Commission -- as many of us who have worked in hospitals know -- that there are other sources of radiation exposure besides byproduct material. The rates of overexposures or retakes for instance in x-ray, nobody even can predict how many they are. The physicians don't know and the technologists aren't talking. So, what we are hoping is that the QA program that we are proposing will spill over into those non-NRC regulated areas.

But we are not going to tell the states that they have to do that. For instance, in many of your hospitals you have a lynac unit right next to a cobalt machine. What is the difference? There is basically no difference. However, when the QA program is instituted through the agreement state radiation control program, we are hoping

that the same kind of measures would be used in the lynac applications as would be in the teletherapy area. Hopefully, the overall rate of misadministration, regardless of where the radiation is coming from, will be reduced.

MR. TELFORD: Does everybody have a copy of the objectives and purposes of the program? What I want to tell you is that for those folks that disagree in theory, hang on to your objections. What I want to talk about now are the details of the proposed rule.

Before we ask you to try out your program, all that we ask is that it meets the objectives. It is a key thing that you understand the objectives. By the way, I plan to take a break at 10:30 because we have to break to go to lunch at 11:30. Bear with me for just a few minutes and we will take a break.

MR. KAPLAN: I just want to mention that instead of coffee being brought in, they are going to keep this thing going outside. If anybody wants coffee, it will be outside.

MR. TELFORD: In this handout it talks about in paragraph A, it says that each licensee should have a written basic quality assurance program and we can stop there. The program has to be written rather than part oral and part understood procedures. It is to prevent the tech from errors in medical use. You all recognize that medical

use is a defined term in 10 CFR, and it means the administration of byproduct material or radiation to patients. We didn't bother to put that on here.

The objective of the program is to provide high confidence -- high confidence that errors in medical use will be prevented. The entire emphasis of the program is on prevention.

MR. RICCI: I suggest that if you really mean to do something to change reality and since there is already high confidence, you should say higher confidence.

MR. TELFORD: Then we say that the program must include the following objectives. Now, I highlighted that on this viewgraph, that we want high or higher confidence to prevent errors.

[Viewgraphs.]

Another step we did not define is high confidence. We don't talk about one in 10,000. If you are a member of a medical society or if you personally want to suggest a numerical definition of high confidence, you are welcome. We will welcome that suggestion. If you think that one in 10,000 is not good enough, tell me what you think is good enough and tell me why.

We purposely left it as a qualitative idea, and of course we mean higher. We really didn't say higher because if we had said higher, that would mean that we thought that

what was the current rate was not good enough. If you have any ideas on what high confidence ought to be, I would certainly like to hear them.

MR. BENNETT: This is the thing that I think I struggle with more than anything. It seems as though if we have one in 10,000, somebody wants one in one million and the next person wants one in a billion or one in a trillion.

MR. TELFORD: How do you get that?

MR. BENNETT: It's the way that regulations occur. It seems as though somebody is constantly -- you are telling us that you are being mandated to do this because Congress is after you to do it.

MR. TELFORD: I believe it, too.

MR. BENNETT: Are they ever going to be happy?

MR. TELFORD: I don't want to hide behind Congress and I don't want to hide behind the Commission. I personally, John Telford, believe that the industry should have a quality assurance program. I agree with other people that say look, if it is me in the hospital and somebody gives me an overdose of I-131, I don't want my thyroid to be played with, no way.

And you are telling me that your technologists are busy or your hospital is understaffed, hey, look out fellow. That hospital is going to get sued up the whazoo from me, and that's personal. Don't tell me you don't want a quality

assurance program. I by God believe it, but that's my personal sermon. That is not really my job. My job is to develop the best rule that we can.

I think it's a false assumption on your part to say one in 10,000, one in 100,000, one in one million or one in a billion. Let me turn it around. If you want to tell us what high confidence is, if you want to tell us that one in 10,000 is good enough and never go further, why? Tell me that, tell me why. I am here to tell you that I will use it to the best of my ability. I will put that into law if that's what you want. If that's what the community wants -- if they want to say okay, one in 10,000, that's good enough -- how do we measure that.

Let's have a moving window for five years or ten years for each facility, because if you treat 1,000 patients a year then you ought to get the 10,000 for ten years. Maybe at least you would go over five years for a window. It's not so easy if you want 10,000 for each facility.

MR. STETAWAKOS: Yes, but I think we ought to look at this from a practical point. Nobody wants anybody -- your child, my child or anybody's child overexposed. I mean, there is a limit to how far you can push this, because then you are going to get to the point that you are going to have more misadministration because of the piled up paperwork because you got administration on one side saying

you got to cut down costs, you got the government on the other side saying we need more regulations and more paperwork. The hospital is not going to hire more people to do all this.

What is going to happen? You are going to make your techs, physicists and you are going to make your physicians even more busier doing paperwork which, inadvertantly could cause more misadministration. You are talking about six-thousands of a percent of misadministration a year.

You say don't bring money in, don't bring these numbers, but you have to think about these. You can't say it's going to be my child and I don't want that to happen. You can't look at it that way.

MR. TELFORD: I didn't say don't bring it in. In fact, I will say bring it in now. I was asking for comments just on the theory of whether or not we should a regulation to prevent misadministration. What the pilot program is all about is to say how can we have each licensee meet a certain set of objectives. This may not even be the best set, but it is our starting set. How can you meet those objectives and let each licensee say how best to do that, such that they can minimize paperwork, they can minimize impact on the facility.

That would be each participant's goal, to try to

minimize the impact of this regulation.

MS. KARK: It has been mentioned that the responsibility for the QA program is administrative, it falls on the user side. Apart from what everyone has said, it is kind of known that the majority of misadministration are due to human error and probably most on the technolog'st level. The QA program, the emphasis is placed on -- do you want to say administrative, physicist, radiation safety committee, et cetera, at that level.

However, in all your data processing regarding the number of misadministration per cases and whatnot, has there been any emphasis on misadministration primarily caused by a particular technologist. It seems to me that from any department that I have worked with, that there is a type of technologist who would be considered to be more likely to cause a misadministration, one that is less conscientious, works too quickly, has a lot on her mind. In fact, there are several of those that I know in Chicago, that they go from one hospital to another. They get fired from one place and they move to another.

From a regulatory standpoint, is it not reasonable to -- is it reasonable to track misadministration per technologist and establish a QA based on an accreditation standpoint rather than a licensee standpoint?

MR. TELFORD: It is very possible for licensed

technologists, if they have problems to take away their license. Our attack here is to sort of go from the top down, and tell each licensee if they should have a quality assurance program, let them solve their problems the best way they know how. The first viewgraph I put up enhances our quality assurance program, and there could be others.

I personally hope that this does it. I personally hope this rulemaking can let licensee's solve their own problems and everybody will be satisfied.

MR. CLOUSE: Backup John to, I guess is a theory in what you said about supposedly the Japanese can make a car that has zero faults. Why do the Japanese, how do they make a car that supposedly has zero faults? It goes back to their attitude, it goes back to the fact that -- I don't remember the term. There's a term for I always try to do better. I always try to my job better. Every time I do it -- I have been here for eight years, but I still always try to do my job better.

Then we were talking about the attitude of what is good enough. As far as they are concerned, it is never good enough unless it is perfect. Obviously, we don't reach perfection but we try. I worked for General Motors back in the early 1970's, and their attitude was, we are doing good enough and we don't need to do any better. I will stand here and say that, because I worked for the company.

They didn't care what they sold you as long as they are making a profit and buying it, therefore, it must be good enough. That didn't prove to be good enough in the 1980's and it's not going to be good enough in the 1990's. I think that there is nothing wrong with striving for perfection. As far as the rulemaking, I don't see that it is a bad thing, although I agree that I don't think it is not going to reach some of the problems.

It certainly isn't a bad idea to try to strive for perfection. You can't eliminate all that human error, but if you can change that person's attitude about the way that they do their job so that they are always trying to do better and are not satisfied with being good enough.

MR. BENNETT: I certainly feel that is a confrontational attitude to some extent, but I don't want to generate that to get it out of context here. My frustration is that I also want perfection. I would like to see zero misadministration anywhere up and down the line. But all of us here are here because we are interested. Some of us might have been mandated to come for some reason or another, but the administrators of the hospitals are the ones that are on the bottom line of the license, the authorized users are the physicians.

I have been in this business dealing with the Nuclear Regulatory Commission and other regulating agencies

for 20 years, and my experience has been they come into the hospital and they don't talk to the authorized users. They don't talk to the administrators that sign the bottom of the license. When those of us that are trying to maintain the programs that we have been directed to maintain go to the authorized users and we go to the administration, they say what the heck are you talking about. I never see any of these folks. They are doing a good job.

MR. TELFORD: That's a very good point.

MR. BENNETT: I think that some of this stuff has to be done, there is no question about it. I think that you have to get to the physicians and talk to the authorized users, you have to visit them when you come to the institutions and make it a point of sitting down with a representative -- a select few of them at least -- and you have to get to the administrators. So that, when you tell us that we have to have that piece of equipment or we have to have a minimum standard, they understand where we are coming from when we ask them for capital equipment requests and that.

MR. BOLLING: When I worked for an authorized user, I worked at several universities and medical centers, large ones in New York. I would never let an inspector leave without seeing at least the assistant administrator, because that was my once a year opportunity to say we need

another one-half FTE or we need some more equipment or something.

I always wanted to let them know that they should view me as their insurance policy against things like misadministration. If you ever have an inspection and the inspector thinks that they can get away without visiting your administrator, I would pitch a fit about it. I would insist that at least the deputy administrator or somebody be appraised of what the program is and how well it is going and all that.

MR. BENNETT: I make a point of doing that each time myself. Some of the inspectors that come out, no way, I don't want to talk to them. I have to get out of here, I have 12 more inspections to do before the day is over.

MR. BOLLING: As a matter of fact, I think one of our standards in the state agreement program anyway, is to make sure that the administrators are seen when you walk in the door and when you leave again. Really, they should be seen twice.

MR. TELFORD: Let me note that we are talking about inspection policy, whereas, what we are supposed to be talking about is rulemaking. We have one of the best inspectors in the NRC here today, so let me let him tell you what the inspectors are supposed to do.

MR. WIEDEMAN: One thing that you said that is

rather shocking is that the inspectors never talk to your administrator. I find that unbelievable. Part of our procedure is to always have an entrance meeting with the administration of the hospital, and we must always exit with the administrator of the hospital or a high level administrative person.

We don't close out with physicists, we don't close out with technologists.

MR. BENNETT: You do.

MR. WIEDEMAN: We will talk to the technologist and physicist and explain to them the problems that we have identified if any at all, but we have always made an attempt --if the administrator doesn't want to talk to us and he's too busy, that's one thing. But we at least try to get somebody who has either an authorized user or administrative staff.

MR. BENNETT: I know that's your policy, but in fact in the field, that's not what is happening.

MR. STETAWAKOS: In 26 years I have never had an incoming inspector go to the administration. I can't say that for the outgoing. They have talked to the department head, but not any higher than that. Never in 26 years have they gone to the administration on an incoming basis. When he comes in and says hi, I'm an inspector and let me see your director. Never.

MR. TELFORD: Let us accept that as a problem to work on. We don't want to doubt your experience. In fact, we want to capitalize on that experience.

Don't get me wrong folks, I don't want to change your attitude or opinion about whether or not we should have this regulation. I want you to keep your suspicions. I want you to hold that close to your heart and don't abandon that. What I want -- that will make you a more careful critic and you will give me better suggestions as to how to improve this program, because you will be looking at it with a fine tooth comb and won't let me sneak in anything that you don't like.

It is after 10:30. Would anybody object to taking about a five minute break for coffee?

[No response.]

MR. TELFORD: Let's break here.

[Brief recess.]

MR. TELFORD: Okay, let's go back on the record. We have previously talked about the fact that the first paragraph of the rule is that you have to have a written quality assurance program. The objective is to prevent errors. That is a very broad statement. In addition to that we say there are eight objectives that we would like you to meet in the program.

In the rule we don't tell you how to do any of

these. We have a regulatory guide that is a draft guide for now, it has been published and is available. I am sure that you have a copy, because it is attached to this handout. Keep in mind that this regulatory guide is not mandatory. You can use or not use the suggested procedures that are in here, whatever you desire.

All that we are asking is that in your program if you tell us that your program meets these eight objective. There is one other part of the proposed rule that actually does not affect the pilot program, and that is the audit requirement, but we will about it anyway. I want to make sure that everybody understands the intention of these eight objectives. You need to understand them because you need to write a program that meets these objectives. When we get through with this discussion, I am going to ask for a show of hands to make sure that everybody understands this.

The first objective. I am sure that what you are bound to do as many medical users have indicated -- other people would call that the authorized user -- selects the patient. The objectives that we have here allude to certain words which we have tried to define on the second page. In those definitions, you will see that we were careful to whether or not the authorized user or in the case of the audit requirement, licensee management, in the case of referrals we say the physician. We are careful to say who

does what.

Does anybody have any question about the first?

MS. KING: Who ensures that the medical use is indicated. Is that an authorized user or technologist?

MR. TELFORD: That is an authorized user, as they decide how to do it. If they delegate -- for this trial period you have the flexibility to say in your quality assurance program how you do that.

MS. KING: You are not saying that it has to -- okay.

MR. TELFORD: It doesn't have to be done any specific way, because this is a performance-based rule. You tell us how. You can make this any mechanism or any procedure that you want to use that you say it is yours. Maybe somehow it is that the authorized user wants to use the referrals or the other departments or authorized user or physician working under the authorized user should sign the prescriptions or the orders for therapy. That is up to you.

MR. ERICKSON: How would I evaluate. This is a quality assurance program, and I need to go back and evaluate that program. If I say that the physician signs the order, then my quality assurance item is that the physician signs the order. It is not saying really that the medical use is indicated.

MR. TELFORD: Let me see if I understand your

point. Maybe you are saying that in the case of therapy if the physician dated and signed the authorized user position, dated and signed the prescription or the I-131. You are asking me I think, is that good evidence that the authorized user has decided that it is indicated in the medical position. I think so, but I want every licensee and every volunteer to say what they want to happen.

MR. WERY: I don't think that the licensee is in almost all cases a physician. So that, the licensee cannot tell the physician or has a difficult time telling the physician how to decide whether a particular form of therapy is indicated for that condition. Let's say a cobalt therapy patient that has back pain history of carcinoma, I am not sure that you can get everyone to agree on what would be -- that it is an indicated use for the patient's medical condition.

MR. TELFORD: You are bringing up the question, is the licensee an authorized user, the physician. But is that true?

MR. WIEDEMAN: Every physician?

MR. TELFORD: Every licensee. Does every licensee --every licensee doesn't have to be an authorized user physician, but they have to have authorized user physicians on their license. The authorized user physician name is on the license, so they are respons ble for the program just as

the management of the hospital is.

MR. WIEDEMAN: Let me throw in a suggestion. In the New York Workshop this same question came up, how do we ensure that medical use is indicated for the patient's medical condition. Several of the participants recommended or thought of the idea that in a hospital situation one good way to do it would be to verify the patient referral by way of chart. If the physician ordered a scan or therapy on the patient, you would verify it by chart that this is truly what he ordered.

Now, I will say that is not 100 percent because sometimes they order thyroid or body scan. In their procedural manual they also indicate on there that anytime there is something ordered that is out of the ordinary, not the routine bone scan or brain scan, then the authorized user will contact the referring physician and say you ordered a body scan, what does that mean. What did you really want. Then you may find out it was a CT scan or MRI or something else. That would be one way of checking it.

For outpatient and some of the small outpatient inics, that would be very difficult to try to do that because you normally don't have a patient chart. However, it was recommended that possibly on your prescription slip or somehow you get the word to that small clinic that the doctor wants a scan on his patient, possibly he could

include at the very bottom or somewhere on that slip a little indication of the patient's history. Why is he ordering this brain scan. What is he looking for; aneurysm, tumor.

That way, your authorized user would have some kind of knowledge about why we are scanning this patient and what we are supposed to be looking for.

MR. WERY: If this outside physician orders a bone scan on a patient for a reason that 99 percent of the medical community would agree is not indicated, --

MR. WIEDEMAN: That is sort of a medical judgment. The referring physician is the one who ordered the bone scan. I would be the first to agree -- I have worked in hospitals. I know that in emergency rooms many times you will get an x-ray requisition where they want spines and skulls and yet the patient may be in for indigestion.

That is a very difficult answer. If the referring physician is sure that he wants a bone scan on that patient and the authorized user has reviewed it and it's in your procedure manual that it is what you will do, and you already have the dose laid out, then that should be adequate.

MR. BENNETT: These are tough enough to deal with, but what do you do when a van drives up to a hospital that has 15 beds and has a nuclear medicine camera inside the

van. They roll in into the hospital, the authorized user is 100 miles away, there is not a radiologist present at the institution where they are and walks in and somebody from the hospital hands them a slip and says we want you do to a bone scan.

MR. WIEDEMAN: A technologist can very easily pick up the phone and call the referring physician and say you ordered a --

MR. TELFORD: What would you do? What would your QA program do? What I would like the QA program to do is say 99 percent of the time here is what we do. Here is how we ensure. There is sometimes when we have a problem or some extenuating circumstances. You say during these conditions here is what happens. The authorized user has delegated someone to make that decision, just tell us.

We want it to be as minimal an impact upon you as it can be. In these extenuating circumstances, you already have a solution to the problem, right? It happens to you every year. We are not asking you to change anything, we are just saying put your procedure down for what you do. If it works, maybe that is something that everybody can use. Maybe we need to -- if we are going to develop some licensing criteria for how to judge these things, but that is for the final rule, we are going to use information that you provide to say that if this happens one percent of the

time but it gives me 90 percent of my problems, that would tell you one thing to do.

That is the spirit of that.

MS. SCHAEFER: Picking up the phone and verifying that order just eliminated that one out of 10,000, because you had that QA policy. It does indicate therefore on your QA program you refer that to a radiologist who will contact the ordering physician if it is done or not done from that phone call. Right there, you come up with that one out of 10,000 that you just eliminated by a phone call.

Granted, that patient is going to sit there for a while, but what is 30 minutes out of your time if you just eliminate an NRC misadministration that is going to create how many hours of your time later on.

MR. BENNETT: I am not trying to justify what happens, but you call and the authorized user is doing a biopsy or is unavailable. You also have to go to three more hospitals that day with your mobile service and somebody is sitting there waiting for an authorized user to call you back. I know what should be done, and I also know what is done.

MR. CLOUSE: I was going to say that's difficult situation and we don't get into that situation because we don't have a mobile service. But the authorized user is the person that is going to make that determination whether he

wants to consult the referring physician or not. Our authorized users believe that is their option.

They are the ones that are responsible, including any kind of an x-ray. If they do not believe that it is medical thing to do, then they refuse to do it. Then they are going to contact the referring physician and say that is not appropriate. They are willing to put that on the line and do that. I am sure there are physicians that won't. All I have to do is pass the buck to my authorized user, and it is up to him if he wants to decide if that is appropriate.

That's an interesting case though, in your case that is very difficult to do because your authorized user isn't there.

MR. BENNETT: But then you are putting all the responsibility on that technologist, because the authorized user then is left completely off the hook.

MR. CLOUSE: No. The authorized user is the one that is going to make the decision. You are saying --

MR. BENNETT: If the technologist decides that this is a reasonable scan and he decides to go ahead with that, the authorized user is completely off the hook.

MR. CLOUSE: No. I have a procedure that the authorized user has allowed me to make that decision unless I see fit to bring it to him.

MR. BENNETT: That would cover all cases?

MR. TELFORD: We are getting into a little bit of details of how we get referrals, how we do diagnostics and how we do --

MR. BENNETT: It is my understanding from the rule that the authorized user is the final judgment. That is his decision.

MR. TELFORD: The intent is to put the authorized user, physician in charge. Let them make the medical judgments. In your hospital, that person is not available to -- your program should say what happens under [illegible] conditions. If it works for you, maybe that [illegible]ething that we can learn from. If it doesn't work f[illegible]ou, that is something we can learn from too.

MR. WERY: Can we measure this by then some kind of exception rule, that if you basically have a policy that says if there are any questions as to whether the indicated use is appropriate refer it to the authorized user.

MR. TELFORD: That would be a fine statement to go in your program.

MR. WERY: How would I measure that though, to make sure that it is actually -- the exception of course, where there is a misadministration you have an --

MR. TELFORD: We are going to get to what we are going to measure and how do we evaluate it.

MR. WERY: That's all.

MR. TELFORD: Let's look at the second one. Let me give you kind of an overview of the second and third objectives. We tried to recognize that business gets done in a certain way in hospitals today. Diagnostic cases often come to you in the form of a referral. A non-nuclear physician let's say had sent this patient to the hospital or from another department within the hospital.

What the objectives talk about is a written referral. If we look at the definition of diagnostic referral on page two, it just says that a written request dated and signed by a physician -- not a nuclear physician but a physician. You have to recognize that most of the diagnostic cases come in this way, through referrals. We wanted the authorized user physician to be in charge. How did we get that person into the loop.

We said that we will have clinic procedures. That is, the study requested in the referrals must match with the clinical procedures manual. The authorized user physician approves of the clinic procedures, so they work in tandem. If what is requested doesn't match what is in the manual, call and find and ask. Find out. Don't go any further, because to give you an example, a referral could come in to give this patient a liver scan and use 10 milicuries of I-131.

The physician -- this is my theoretical physician -- thought that was what was supposed to be done. We went to the authorized user in charge to say that the referral has to match what the manual says, and therefore, the authorized user physician is in control of each and every diagnostic procedure by that mechanism. The other mechanism is the prescription.

For therapy in certain cases, the objective speaks to the prescription. The definition of prescription here, if you don't like the word prescription then don't let that bother you, that can be changed. Its intent means a written record of order for medical use for a specific patient, dated and signed by an authorized user. So, the principal difference is that it is an authorized user physician that directs the therapy be done for the patient. We go on to say what the content of that written order should say.

With that background, objective two says that prior to medical use -- I think these are not the exact words. Prior to any use made for any therapy procedure in all therapy you have a prescription or for any diagnostic, any pharmaceutical procedure involving more than 30 microcuries of I-125 or I-131. We wanted to go after the cases that resulted in overdoses of I-131 to say let's try to help that out by asking for a written directive signed by the authorized user that says this patient is supposed to

get more than 30 microcuries of I-131.

Number three says that diagnostic referral -- you can use a prescription for diagnostic cases. You have that option. Realistically speaking, it is going to be mostly diagnostic referral that is made for any diagnostic procedure at all. Even though iodine 125 or 131, it has to be less than 30 microcuries. All we are doing in those two objectives is saying before you do it, let's give a clear instruction, a written instruction to the technologist. This is in preference to written instruction rather than oral instruction.

MR. WERY: A quick point of question.

MR. TELFORD:

MR. WERY: Both of these are only talking about I-131 and I-125 procedures?

MR. TELFORD: No. Number two talks to all therapy. All therapy, whether it is radiopharmaceutical therapy, brachytherapy, or teletherapy. Number two says we think it is a good objective that your program specifies that any therapies required, first you should have what we are calling a prescription. It is just a written directive.

Number three says prior to any diagnostic procedure, you should have a diagnostic referral that matches the procedure in your clinical procedures manual.

MR. WERY: That is not just for --

MR. TELFORD: We are taking iodine a little bit special. We are saying but whatever you are doing, whether it is diagnostic or whether it is therapy, if it involves I-125 or I-131 in amounts greater than 30 microcuries, this asks for a prescription and not a referral. We are handling all diagnostics of therapy right there.

The basic intent is to have a written instruction.

MR. WERY: It's hard for me to read this because this reads to me that it only is -- at least for the diagnostic ones, that they are only talking about diagnostic procedures involving I-125 or I-131 less than the amounts that you have given. It would not involve any other isotope.

MR. TELFORD: I will accept that, I goofed, all right. I didn't write it very well. Its intent is to say that number three -- all diagnostic procedures, first to get a written referral.

MR. BENNETT: What is number four then? Doesn't number four cover all the rest?

MR. TELFORD: Let's get to four. Let's make sure that everyone understands two and three. Two says that all therapy or either diagnostic therapy which involves more than 30 microcuries of I-125 or I-131 have a prescription. Three says all diagnostics have a referral and make sure that it is described in your manual.

MR. WIEDEMAN: How about an example. The patient is going to have -- are you going to give the patient 10 microcuries of I-131 for thyroid -- fairly common. Think to yourself, would that be a prescription or a referral. IT would be a referral, because it is less than 30 microcuries. The patient is going to have a brain scan, 20 milicuries of technetium, it would be a referral. A patient is going to have a 10 milicuries of I-131 for a therapy for hyperthyroidism, that would be a prescription.

MR. WERY: There is another section in there. Let's take the situation where a patient comes in from a referring doctor for a diagnostic procedure and they do not have the written -- under your definition of a diagnostic referral it uses the word written -- the doctor office is called ahead of time and sets up everything. They do not have this written diagnostic referral.

Can you -- do we have to send that patient home and wait for them to come back with the written -- follow the --

MR. TELFORD: No, no. I call that the extenuating circumstances case. It may be that in your Hospital or in your practice as the authorized user you may know this physician that sent you this patient. Maybe this guy knows what he is doing, if he or she knows. On the other hand, maybe you have never worked with this person before. Maybe

your quality assurance program would say if any doubt to call, or say other extenuating circumstances under which you would accept an oral.

See, you didn't believe me.

MR. WIEDEMAN: The ones that would probably be the most affected on this are the smaller outpatient clinics and the hospitals that have a large outpatient number, and even small clinics that are not hospitals. You get a lot of telephone referrals, so you would want to include that in your manual, how you are going to handle that. Maybe it requires the technologist to contact the physician and say you did want this patient to have a brain scan.

MR. TELFORD: There are a lot of war stories about the patient walks in the hospital and is supposed to get therapy. They walk up to the receptionist and say which way to the therapy department. They send them to the teletherapy department and they are supposed to get physical therapy. So, you write your QA program to handle those problems the way it is best for you.

I am saying to you that I think it is best to have a written directive. If somebody says John, call 492-3795. I am fine for the next three minutes. Thirty minutes later I have to really think hard, what was that phone number I was supposed to call. I would much prefer to have it written down. So, the basic idea is that if we are going to

have a goal to try to meet something in the procedure that we are supposed to do, I like it written down.

There's all kinds of cases of oral directiv and microcuries becomes milicuries and the patient gets overdoses. The basic attempt is to write it down. Does somebody else have their hand up here?

MS. BASTIAN: In number three, I will just use a simple example. We are going to do a diagnostic I-131 scan and we are going to use over 30 microcuries, so we need a prescription. Then, when I look at the prescription description under number A, we are expecting that doctor to write down the radioisotope dosage, chemical form and route of administration.

MR. TELFORD: Yes.

MR. WIEDEMAN: That is your physician, your authorized user.

MS. BASTIAN: Is supposed to write that on the doctor order.

MR. WIEDEMAN: Somewhere, to let you know what he really wants.

MS. BASTIAN: I mean, we have that in our procedure manual.

MR. WIEDEMAN: Great, you are covered.

MS. BASTIAN: We don't need it on the prescription.

MR. TELFORD: The one thing that you may want to do is the definition of the prescription. You say for diagnostic use what is the radioisotope, what is the dosage, what is the chemical form and route of administration. We could have saved ourselves some trouble and said radiopharmaceutical instead of the isotope and chemical form.

MS. BASTIAN: Can we do that?

MR. TELFORD: Sure. IT's the same, right? You can throw two stones with one bird.

MR. WIEDEMAN: One other thing that you may want to consider in your manual is, what would you do in a situation where you get a prescription from a referring physician and it goes to great detail. Give my patient 15, 20 milicuries of I-131 or hyperthyroid. Think to yourself, this referring physician is not named on our license, not an authorized user, how are we going to handle it.

Are we going to do what our procedure manual says or are we going to follow what the referring physician said. You may want to cover this, possibly an answer would be to have that authorized user of your facility contact that referring physician and get it straightened out between them what the dosage is going to be, who is prescribing this and get it straightened out. We have had several reports of misadministration where it was a misunderstanding of what

should be given.

MR. TSE: This is designed -- this particular item is designed specifically to avoid those cases, because this item says if you exceed these 30 microcurie you cannot administer this dose unless you have your authorized prescription. Therefore, diagnostic referral, if you see 35 microcurie I-131 you cannot do that until you get your authorized user.

MR. TELFORD: Is everyone with me on intent of two and three. Number four is if it is therapy or exceeding 30 microcuries of I-125 or I-131, you are working with a prescription. This says make sure that the prescription is understood by the responsible individuals. That means that everybody -- in therapy, everybody that is going to do the treatment planning calculation or the setup for that therapy. Make sure that everybody understands what they are supposed to do.

On the other hand, maybe you have a diagnostic referral. If the referral comes in and it asks for a liver scan and liver scan is defined in the clinical procedures manual, the technologist looks in there and says this is a one to one match and I know exactly what to do. You are making sure that the procedures to be done to the patient are understood by the responsible persons.

You might think of additional procedures for your

people or you probably already have those or for training, and you probably already do that. All this simply asks for is to make sure that what is about to be done is understood. What is to be done and how to do it. You get to define how to do that.

MR. WERY: How do I define understand?

MR. TELFORD: That is up to you. You see, I perceive that if I am familiar with a 36 point program that says one through 36 and by definition you have a good quality assurance program, you might know exactly what to do and you would know when and if you might be second guessed, right? That is not what we are doing here.

We are saying you have to have a QA program, you know. If the final rule comes out and that is what is says, you have to have a QA program. These are worthy aims of any quality assurance program. You get to define how to do it. You will see that there is a feedback from all of this, that you can find out for yourself if you are doing a good job.

MR. WERY: But I think this all goes back to misadministration. If you look at most people that have done the misadministration, at the time that they were doing what they were doing, they probably thought they understood what they were doing. If I have a prescription written by my physician for a therapy or cobalt treatment I look at that and there may be some assumptions or some -- I

shouldn't use the word assumptions.

I read that and I think I understand what he says, and design a treatment plan for that. Certainly I think that I understand it, but it is going to be difficult for me to design a quality assurance mechanism that will measure my understanding of it.

MR. TELFORD: Nobody asked you to.

MR. WERY: How will I know that I am doing what the item mentions?

MR. TELFORD: It is obvious. If it gets done correctly, it was understood. If is not done correctly, something wasn't understood.

MR. SCHEU: Or ignore it. I mean, you could write a good program and if the technologist --

MR. TELFORD: Oh, yeah.

MR. SCHEU: I mean, you put the blame on the technologist. You have provided all the information that he needs and if he makes a bad judgment or if she does, it has to stop someplace.

MR. TELFORD: You wouldn't want us to tell you exactly -- I hope you wouldn't want us to tell you exactly how much written procedures to have and how much training to have. Some technologists just need a little bit, right? They are going to do everything correctly. Other technologists need a lot of care, feeding and training. It

is up to the individual facility as to how much to do there.

MR. STETAWAKOS: I think there is two ways that you might avoid something like this. First of all, after you write the procedure you have all technologists or people involved read, initial, and date that they have read that. Then, you put it in the procedures that if anything is not understood or prescriptions are ambiguous or not easily read, then do not do the procedure until all questions are answered.

MR. WERY: It is very clear how to write a procedure that will probably make this what you want, looking at what you have in your draft guide. I have a hard time understanding how that is really measuring how well people understand. When I think of a QA program, I think of something that is -- if you have an idea of what you want to do, then you come up with some way of measuring it to know if you are doing a good job.

To me, it is a little bit like saying -- having a procedure that says do not make mistakes and having everyone sign that.

MR. TELFORD: I think this goes beyond making mistakes. This defines the objectives of the program that we think would help people prevent mistakes or avoid making mistakes. All we are saying is these are the eight good things to do that would help you not make mistakes. All

this number four says is make sure that the instructions are understood by the responsible individuals. It doesn't speak to measuring, not yet. WE haven't gotten to measuring yet.

All it says is an idea that the instructions ought to be understood. How you make sure that it is understood, that is up to you.

MR. STETAWAKOS: This is really going to sound stupid, but do we really care if they understand as long as they do it right? I mean, that is what we are saying.

MR. TELFORD: If it works for you. If it results in the administered dose equals the prescribed dose, good point. If you never make a mistake, you could claim that your program fits the rule. I have never made a mistake, all administered doses equal the prescribed doses, your program is grade A.

If you have a problem, what we are saying is okay these are good things to do. If you happen to have a difficulty, overcome it.

MR. TSE: There are two points. One is this section talks about establish a QA procedure but this procedure has to be implemented. Therefore, you need to implement your procedure. The second point is that there are cases that technologists do not really understand milicurie and microcurie. That has happened in your facility, how to prevent it. You may want to have training

and you may want to ask them to read it and test them what is a milicurie and what is a microcurie.

I think it is up to the licensee on how you want to test it to make sure that they do understand what the physician wants.

MR. TELFORD: Are there any other points on number four?

MS. SCHAEFER: On the instance that you provided on your treatment planning, I am not real familiar with it. Don't you get the order referring and he gives you the order for treatment and you do treatment planning; you don't treat them without --

MR. WERY: I am talking about the information that comes from our authorized user.

MS. SCHAEFER: Okay. You set up a treatment planning, and doesn't he have to preview that before you actually begin treating?

MR. WERY: Yes. That still doesn't mean that anyone understood.

MS. SCHAEFER: He looks at your treatment planning and he sees if you understood what he said by your treatment planning. Like I said, I am not real familiar with this.

MR. WERY: He may not see an error in my treatment. If I give him a treatment plan that is not in what he has originally wanted, then there is no guarantee

that he will see that.

MS. SCHAEFER: Wouldn't that reflect on the treatment plan?

MR. WERY: It may, but I would like to have a way of measuring that before it gets to him.

MS. SCHAEFER: I would think that if he had a question he would give that to you and say --

MR. WERY: Like I said, I have no problem with writing a procedure that says if you have any question to contact the authorized user or whoever is appropriate at the time. My only problem is, is that really going to do what your item says that you want to get done.

MR. TELFORD: The industry has a great record.

MS. KARK: Can I ask for my own clarification. The authorized user is always ultimately responsible and, yet, say you have bone scan on a chart. That order to turn into a written request to say nuclear medicine can be drafted by a nurse, a floor clerk, a nuclear medicine department secretary. At what level is the authorized user responsible to interpret, understand, ensure, when you have all these other people who are responsible by virtue of job title to put that from chart to prescription.

All these other people are allowed to do that, provided that their interpretation is in accordance with something that is in a clinical procedures manual. That

whole initial interpretation could be completely off.

MR. TELFORD: You are saying the written referral in your referral could be wrong to begin with?

MS. KARK: I guess what happens frequently is, let's say it says brain something and let's say hospital floor staff assumes that it means brain scan when they meant CT; that it is at that initial level that it gets processed incorrectly.

At what level does the authorized user have to go back to ensure that what is being done is what was originally intended by the other physician.

MR. BOLLING: The regulations require that the authorized user do two things; select the appropriateness of the patient for the study and the isotope, the chemical and physical form and so forth. We would expect that even in the case of diagnostics that the authorized physician would review the request. It is just a request at that point, initial it perhaps, and that will be the technologist's que to go ahead and touch the patient.

We would expect that the patient not be touched until the authorized user in some way indicates that he or she has reviewed the request.

MR. WERY: For every diagnostic exam?

MS. KARK: Does the user have to go back to the chart? It is usually from the chart to the --

MR. BOLLING: Whatever technique works. If, in the odd case that they have to go back to the chart, maybe there is some procedure where the technologist goes back to the chart and sees that yes brain image or -- some of the request forms as you know, have multiple things on them, sonograms NMR, CT scans, nuclear medicine scans.

We would expect that the written procedures would address somebody going through and reviewing those things and distinguishing which one is being ordered. Obviously, the physician isn't the one that is going to do that. It is going to be a technologist or nurse. There has to be some kind of screening. Then at the very end, just before the patient gets touched, the authorized user in some way has to indicate to the technologist that this is okay to go ahead with.

MR. TELFORD: I have a question over here.

MS. SWANN: Whenever there is a doubt, a good technician will take that chart either if I am not there, they will take it to the doctor. Sometimes the patient has something that has not shown up on the chart yet, the report is not typed and not there, but they are aware of this. They are more than happy to say that yes, this was recommended this CT or whatever, or I will call the doctor and tell him this is not kosher. Something doesn't match here.

You know, the tech has to do it. If there is a doubt, check. Assume you are right.

MR. STETAWAKOS: I don't think the misadministration are coming when there is a doubt, I think it comes when people think that they know exactly what is going on. I would bet you 99.99 percent of the time when there is a doubt the techs by their training and by their intelligence in this field -- we don't have dummies in this field. I mean, they are very smart people that we are working with.

That is not when a misadministration or an accident is going to happen. It is going to happen when somebody thinks they are doing what they are supposed to be doing. What we are addressing now is not taking care of that particular point. I don't know what is.

MR. TELFORD: We are not intending to take care of it now.

MR. STETAWAKOS: Okay.

MR. TELFORD: We are merely intending currently to list the objectives that we think we ought to meet. How to is either up to you or to be found in the regulatory guide. You might think of some kind of double check procedures that -- the intent of this is to have the authorized user in control, either in control of the clinical procedures manual or control of prescriptions. The authorized users, by one

means or another, ensures that the administered dose is that prescribed. The how to is probably in many ways, and I can see some people already have the answer to the question. We are really not trying to answer that.

MR. STETAWAKOS: Right. But her original question was, you made the point that the original request or prescription is carried out. But the original point that was brought out by the young lady over there is, what happens if you go back to the fourth floor nurse station when some clerk typist wrote out the wrong original prescription which would fit the situation that is coming down in nuclear medicine but is not the one that is wanted.

That is the question that was coming up. That is a human error that I don't think is going to take place unless you turn around and have every referring physician contacted for every single procedure that is ordered or signed.

MR. TELFORD: That is not my answer. My answer to her question is that in a real case, we have written directives for everything. Somehow the authorized user makes sure that those directives are correct to begin with. Whatever is required in your hospital to make that happen is up to you. I am trying very purposely not to tell you how to do your business. That is the opposite intent of this

proposed rule.

The intent is to say here is the good objective. You figure out how to do it. There may be some cases in which you would say you want to have a written referral, I can't force some people to do that. Okay, put it into your quality assurance program under what conditions you would accept an oral directive. We have a case for emergencies, we have that covered. We just say do it, and write it up later.

But there may be what you call extenuating circumstances. You have decided that you can meet the objectives of the rule by following some procedures which vary from the obvious ideal written ones. If the case of the original referral being incorrect, that's a problem in your hospital. You fix it and tell us how you are going to fix it. I can't deal with that. All I am saying is, let's have it correct to begin with. I am not here to tell you how to fix that.

MR. WERY: If you look at where many of us in the room are stuck though, the situation is that we are working for an institution. The authorized users are not employees of that institution. What I would like to see I think is a very -- I think probably with the size of group of the smaller places, it is probably the most common. What I think is that everyone knows what the idea is, that the

patient -- we are talking about a nuclear medicine exam -- would be interviewed by the authorized user before the examination.

I think that everyone would like that. I would love it. The people that I would have to sell that to are my radiologists that are practicing nuclear medicine. They probably would not be too excited about that. I am an employee of the hospital and trying to write these rules. If I write the rule that every patient will be interviewed by the radiologist before the exam, I am going to have problems.

The hospital, if they want to back me -- if I want to go to the hospital administration and say if we are going to do this we are going to cut down on my diagnostic administration. I can think of a case. If we had a lot of diagnostic misadministration that would probably give a mechanism for the hospital to get behind me and try to do something. In the real world, no one has a lot of -- very few people have a lot of diagnostic misadministration. I am bringing this up to someplace that we haven't had any or very few diagnostic misadministration.

How do we convince the authorized users?

MR. TELFORD: Why did you stop with that one procedure? Aren't there other acceptable procedures?

MR. WERY: I'm sorry, I missed it.

MR. TELFORD: You said I want every patient to get examined by the authorized user physician. Is that the only way to do it?

MR. WERY: I think that the authorized user can interview that patient better than the technologist.

MR. TELFORD: Okay, fine. But aren't there other alternatives?

MR. WERY: Yes.

MR. TELFORD: Why did you put yourself in that box? I didn't put you there. You put yourself in that box. Why don't your QA program have other alternatives? There are certainly alternatives given in the guide.

MR. WERY [illegible] have to choose something.

MR. TELFORD: Okay.

MR. WERY: If I want to choose the best thing, it is going to be the nuclear medicine physician interviewing patients.

MR. TELFORD: That is your choice. If that is what you want in your program --

MR. WERY: I can't do that.

MR. TELFORD: Please do it.

MR. WERY: I can't. I don't have the clout.

MR. TELFORD: Aren't there other alternatives?

MR. WERY: Okay.

MR. BENNETT: It is difficult to judge what are

acceptable alternatives because we feel we know what you would like us to do.

MR. TELFORD: Okay.

MR. BENNETT: We probably would also like to do that, but in practicality most of the time the radiologist may not be there. In many of the small hospitals, they may be there one-half day a week. There are things that are going on all the rest of the week and you can't have him review the request.

MR. TELFORD: All that we are requesting that your program just to say what you are going to do in this case. Are you going to do the best that you can?

MR. RICCI: In a way, that statement is going to change reality.

MR. TELFORD: Pardon me?

MR. RICCI: Why do you want us to state it? It isn't going to change anything. You just have it on a piece of paper then.

MR. TELFORD: If you are saying that you are just going to put into your program exactly the way you do business today, that's fine. All we are asking is that you tell us that your program meets the proposed rule. Just be that sufficient to meet the proposed rule, that's all. I didn't ask you to have every patient examined by the authorized user physician.

MR. BENNETT: Our making that statement is a value judgment on our behalf, and it really doesn't hold any water when you come around and inspect and say that you told us that you met our requirements and this doesn't meet out requirements. That is a difficult thing for us to say.

We may in all honesty think that it does meet your requirements. But then you come along and inspect us and say this doesn't meet what we intended you to do.

MR. TELFORD: You fast forwarded here to 1992. I mean, when we have a final rule and when we have inspections going on, we are not there yet. The purpose of this exercise is to say find out what will work in hospitals. If we can give you the objectives, then you can tell us via your QA programs what works in your institutions. We can learn from that.

Maybe we need to modify the objectives -- maybe we need to modify the guide to go along with the final rule and we will have inspection criteria. There is a part of the pilot program that will affect that too. You are trying to look at 1992 and we are not there yet. All this really says is, whatever procedure that you think is sufficient to ensure that this happens in your hospital, we say it's okay and try it.

MR. BENNETT: I am here representing one institution, but I can't help but think about the 20 others

that I know of that live under different circumstances. What we might be able to live with in one institutions where the radiologists are there every single day is not going to work out for some of these folks that have 10 or 20 beds and have a radiologist once a week and they are trying to conduct business.

They want to have the service because if they don't the patient has to go 50 to 100 miles to get it. So, I am really troubled here in trying to establish a criteria for one institution that I might later on be imposing on another institution that I know they can't live with.

MR. TELFORD: No, you are not imposing on anybody. As a matter of fact, the small folks, we have them in this program. Remember, we have 46 plus 22, we have 68 volunteers across the country. We have some folks just like you are describing that are volunteers.

MR. BENNETT: These are hospitals that aren't licensees. They have services provided to them by their other licensee.

MR. TELFORD: They are not an NRC licensee or agreement state licensee?

MR. BENNETT: That is correct.

MR. TELFORD: So, what's the problem?

MR. BENNETT: They get services from authorized licensees.

MR. TELFORD: You are talking about a mobile scanning service?

MR. BENNETT: Yes.

MR. TELFORD: They fall under the Part 35 also.

MR. WERY: The hospital is not licensed.

MR. BENNETT: No, not at all.

MR. WERY: It is the mobile service and their authorized user that are the licensee.

MS. DUFFY: Are there any participating in the pilot program?

MR. TELFORD: I hope there area.

MS. DUFFY: The mobile service is the QA, not the-

-

MR. CLOUSE: On the basis of the fact that they held the license, but unfortunately we haven't been able to get in contact with them to get them to participate.

MR. BENNETT: I have been hearing that any referring physician who writes a request for a nuclear medicine study to be performed, that prescription has to be reviewed by the radiologist before the study be performed.

MR. CLOUSE: I think it has to be reviewed by the radiologist designee. My radiologist says you review it, and if you have a problem then tell me. He is willing to take that responsibility. At some point, it is the person that is actually going to inject that patient that is going

to have to read the order and decide if it is appropriate.

MR. BENNETT: I could live with that if I thought that was allowable, but I thought that you were interpreting that every study should be reviewed by a radiologist prior to this study being performed.

MR. TELFORD: He is stating the ideal case. Here are the eight objectives for the diagnostic cases we would like a referral, we would like a written referral. If you don't get a written referral, you tell us under what conditions you will accept verbal referrals and you tell us what you are going to do. If you want to follow this gentleman's suggestion, that is fine. I don't think you people believe me.

This is a performance-based rule. We are only going to ask you to address some objectives. We will not tell you how to do it. On other hand, we are not hanging you out on a limb and saying you gave me the objective but you didn't tell me anything about how to. We have a regulatory guide. You can use it if you like. To be perfectly honest, I think you are putting yourself in an inappropriate box and saying I can't do it. I say back to you, you have carte blanche to do anything that works.

MR. WERY: You said anything that works. If I write this up just as we are now doing things --

MR. TELFORD: Anything that meets these eight

objectives. If your program however it is, if it meets those objectives and you are willing to tell me my program meets these eight objectives, okay.

MR. WERY: In which way am I reducing the chances of a misadministration of my administration.

MR. TELFORD: Don't worry about that now. We haven't even gotten through half the discussion on the pilot program and you people are pinning me on 1992. Will you please hold off for a while.

MS. DUFFY: I just have a general type of question. Is it the intent with this pilot program that hospitals participate in the ways that they feel that they can implement these eight objectives. If they submit that to you, you review that and see how it goes after a month. Then, you plan to incorporate some of these changes into your draft guide so that other hospitals can see other ways to accomplish the same goals?

MR. TELFORD: Let me call everybody's attention to the objectives. There is a discussion here of the pilot program. The objective is in the outline. Number two, what the participants can expect in the pilot program. Number three, what is expected of the participants. Maybe I should have done that first, then maybe you would have asked me what was in the rules.

[Laughter.]

Please hold off on those kind of questions until we get through the agenda.

MS. DUFFY: I thought that could answer his question.

MR. TELFORD: Yes, it can, but it takes about an hour of discussion. Is everybody with me down through the fourth objective. You at least understand the intent of these objectives. I am sure that any medical uses in accordance with the prescription or a diagnostic referral is in the procedures manual. All that says is that make sure that the administered dose is what was prescribed. Again, we have used prescription by itself and we are using referral and manual in tandem.

MR. WIEDEMAN: John, one other thing is terminology. Terminology in the medical field is inconsistent. Marquette General Hospital to them, that may mean a whole body scan means one thing which may be different over at St. Joseph's hospital. Thyroid scan means something to one hospital and not to another.

So, it should be described in your clinical procedures manual what these different procedures are and everyone should understand from the technologist right up to the people that order the scan.

MR. TELFORD: Okay. Number six, very obvious. Make sure that you identify the patient and verify that

patient's identity. In your program you just specify what you do in your hospital to verify that. Maybe ask them their name, maybe ask them their social security number or birth date and maybe you ask for their mother's maiden name or all the above. Maybe you take picture, I don't know. Whatever you want to do. The objective is just to identify the patient. Make sure that you have the right Mr. Smith.

Number seven is identify any unintended deviation. The unintended deviation is the difference of the administered dose and what was prescribed or, in the prescription or the administered dose versus the referral in the manual. This is identify them and evaluate them. Only now are we getting into measurements of seeing how feedback could work for this program.

MR. STETAWAKOS: May I ask one question there?

MR. TELFORD: Sure.

MR. STETAWAKOS: If the authorized user feels that the referral is not adequate or appropriate for the patient but another study is and he cannot --

MR. TELFORD: The physician.

MR. STETAWAKOS: Right, the authorized user physician, the nuclear physician gets the referral and says this isn't appropriate for this patient. I think we should do this study. The referring physician is unavailable. Now, he can change that prescription, but do you have to say

that is a variance now or not?

MR. TELFORD: I don't think you said it. You said the authorized user changes the prescription.

MR. STETAWAKOS: That is correct.

MR. TELFORD: So, the thought is that the prescription on the record is the one written by the authorized user, not the person.

MR. STETAWAKOS: You are going to make that distinction between the two.

MR. TELFORD: Yes.

MR. STETAWAKOS: Okay, that's fine.

MR. TELFORD: Number seven, all that is really after is unintended deviations of -- it is a teletherapy. Today the patient was supposed to get 200 RADS but they got 250. Nobody said that's a big deal, nobody said that's a sin, just identify and evaluate. That is all that number seven says.

All I am saying to you is that I believe that these eight objectives are a good first cut at the basis for a quality assurance program. Any program needs some feedback, needs to know what mistakes were made, what their magnitude is, what do they mean. The next question is, what do we do about them now? We are not to that stage, we are just to the stage of identifying and evaluating.

Anybody else on number seven?

MR. KAPLAN: In New York someone mentioned the question about intended deviation.

MR. TELFORD: I think this case here is unintended deviation from the original prescription --

MR. KAPLAN: That was corrected by rewritten --

MR. WIEDEMAN: I think also in New York it was brought up about a boost dose in teletherapy, where a physician prescribes 200 RADS per fraction for each day for so many days. The patient is going to start -- you see him on Friday and it's a long weekend with a holiday on Monday. He decides I am going to give him 600 RADS today for over the next four days because we are closed down for the next four days. That is an intended deviation.

Unintended is where someone made a mistake and I just wanted to make the distinction between the referral and the authorized user, whether you are going to consider that intended or not. I would have considered it an intended deviation, not needed writing up. I wanted to clarify the point and make sure that all my question was intended for.

MR. TELFORD: Does anyone else have anything on number seven?

[No response.]

MR. TELFORD: All number eight says is make sure you treat it in accordance with the prescription. That is our last objective, to say to get your planning in

accordance with the following description and at least you are going in the right direction. It doesn't say how to measure departures from treatment planning or whether we want to look at the 80 percent curve or what, we are not there yet.

All this says is for goodness sakes, let's have the treatment planning follow the prescription. We are about one-third of the way through this agenda here from what we thought we could get done in the morning. It is key that you understand these objectives so that I can then talk about -- we can discuss and you can ask questions about the whole pilot program and what we are going to accomplish and how that is all going to be used.

There have been a lot of questions this morning. Does everybody understand the intentions of these eight objectives? If you don't understand this, you don't have a prayer of running a program to meet them. Seriously, does anybody have any final questions or uneasiness about what the intentions of these objectives are?

[No response.]

MR. TELFORD: Let me ask for a show of hands then. Does everyone understand the intention of these objectives and you understand these sufficiently well that you can write a program to meet their intentions?

MR. RICCI: I understand them as well as their

vagueness on points. They are not clean cut. I can claim that I understand them and you can claim that they are clear, but neither statement is absolutely true.

MR. TELFORD: Well, I don't mean to differ with you, but I am not going to claim that they are clear.

MR. RICCI: So, how can you understand something that isn't clear, that isn't specified.

MR. TELFORD: That is what I am here for.

MR. KAPLAN: Is it that they are unclear or is it that these --

MR. RICCI: There are no human statements that are clear.

MR. KAPLAN: I mean, institutions are different and this is a performance-based rule which has to be taken home and applied at your institution. That is where the vagueness is, you are not being told prescriptively that this is what you should do here and this is what you should do there.

MR. RICCI: The objective itself is vague.

MR. TELFORD: Okay, let's do it again. Number one, be sure that you indicate the patient's medical condition. What is unsure about that, what is unclear?

MR. RICCI: We had a discussion already in the past. Everybody has been agreeable that they understood exactly what you meant. If you want to restart the

demonstration you are just wasting time, because you would just have more of the same words.

MR. TELFORD: It is not a waste of time. We simply can't go on until everybody understands the intention of these objectives.

MR. BENNETT: I think maybe I can help. I can agree that those objectives are good objectives and these are objectives that we should all work to go, and I understand that the objectives well enough to agree that they are good. If we can meet these objectives, I think you will meet your overall objective of misadministration. The only questions I have is, how am I going to meet those objectives.

I don't think that is a problem and that is not really what you are asking about, are you?

MR. RICCI: If you cannot give an operational definition of some -- we can't agree with the principle, and that only means so much as the principle means and let's see what it is going to meet when we operate on it.

MR. BENNETT: Right. I can agree with the principle. I can agree that these are all very good objectives, and I don't have any problem with that. I certainly have a lot of questions as to how can I really meet those objectives.

MR. TELFORD: I didn't ask you that. All I asked

you is, do you understand them. I didn't really ask if you if they are any good, I just asked do you understand them. I am claiming that they are good -- I don't even want you to buy into that. All I am saying is that I have written down eight objectives that I think ought to be in every quality assurance program.

I am asking a basic question. Do you understand them, and do you understand them well enough that if you were given free reign to design a program to meet them can you meet them? It is just like I am asking you to paint a house. Paint that wall and paint it white, and use flat paint, use a roller or brush. I didn't tell you how to do it, I just said I want the wall white.

MR. BENNETT: Yes, but you told me to make sure that everyone understands all the procedures. I understand that everyone should understand the procedures, but I do not have a way of making sure or even evaluating that everyone will understand every test that is ordered.

MR. WIEDEMAN: Let me throw this in. Keep in mind, you are not being asked to design a plan that will work for everybody in the whole world. You have to look at it from your institution; what will work for us. Don't worry about that little community hospital or that community hospital over there. You have to look at what will work for us. If you go down the objectives and say this will work

fine for us but not for the other person, I wouldn't worry about that right at this point.

We are also looking at the small little community hospital and small little clinics, the teletherapy departments that run an outpatient therapy department, and we are going to get all that, various different programs. Some of them will be very extensive programs, probably a foot thick. Others will be a three page document and maybe a one page document, maybe a memorandum. We are going to see all types of programs.

MR. TELFORD: Does anybody have any questions about the eight objectives? If one of them is not clear to you, speak up, please.

MR. RICCI: Yes. How do you define understanding of responsibility. How are you going to make it clear?

MR. TELFORD: Understand, I will let Webster explain understand. I think everybody in this room is more than intelligent enough to define understand.

MR. RICCI: No matter -- there is no one making an emotional issue out of it, accusing people of not being intelligent. I am insinuating that it is a matter of facing reality, that you can't define clearly understanding.

MR. TELFORD: This gentleman sitting next to you made the point that if a patient is getting the administered dose that is prescribed, by definition and by example the

people responsible understood what they were supposed to do and they did it. Do you have any problem with that?

MR. RICCI: Not with that.

MR. STETAWAKOS: I think one of the basic misunderstandings that I can see -- maybe I am completely wrong -- I think that people here are thinking possibly that we are responsible for writing a program that the NRC is going to turn around and incorporate into a law or rule or regulation. If I am understanding this correctly, that is not what you are going to do.

You are going to take our programs, look at them and see if they do work, if they are functional. If they do appear to take care of the problem that you perceive that is there, and if so you will incorporate parts and say this is not how it should be done but this must be done setting up programs like we are going to set up, not that they are the programs. I think that is where the haze comes in, and people are afraid of writing as for fear that they are going to be subjecting others to something that they have to do. That is not what you are trying to do.

You are seeing if this program can work within reason.

MR. TELFORD: Well, I am here to learn from everybody.

MR. STETAWAKOS: Essentially, that is what I just

said; that you people are here to see if it works and learn from out setups.

MR. RICCI: One other thing that one could learn and the NRC as well, it is not worth asking for the moon if the moon cannot be reached.

MR. STETAWAKOS: That is what this whole program is about though.

MR. RICCI: I am saying that stating -- asking for the understanding when it cannot be defined is silly. That is too much for something that can be defined and seeked.

MR. STETAWAKOS: Maybe that is one of the things that is going to fall out from this whole this is, you are going to find out that it can't be understood and that's a result of the program or they are going to find out that you can't reach the moon and that's a part of the program.

The program isn't designed from what I perceive it as setting the law for everybody to follow, but to see if the law can be followed if it is going to be any good. If it is not, they don't want to incorporate it. That is what I perceive, and I don't know and maybe I'm wrong.

MR. TELFORD: You are right. I have eight objectives here, and this is my draft. This is the best that I can do, folks. This is the first lot. It is not going to live you know, somebody is going to come along and tell me how to do it better and I guarantee you that it is

going to be one of the volunteers. If not that person, a whole lot of other people. When I get done I may have four of these that survive. I may have 12, I don't know.

What I hope to have is something better. If one of these turns out to be not effective, it's out. If it doesn't do us any good, it goes out. If there is one missing and we don't have it, it goes in. I am trying to spoon feed this one step at a time and you are real nervous, so you are not going to be comfortable until we get through a lot more. I have to believe at this point whether I have made this sufficiently clear or not.

MR. RICCI: That is not -- let's not get victimized. We may be a bit nervous but I don't think so. You might be a bit aggressive and you might not think so. Let's avoid taking emotional issues from this stand.

MR. TELFORD: Well, I am going to ask individually if you understand these objectives. If I get a good number of people that tell me they don't understand them, we will take it up more this afternoon. My question to you us, do you understand the intentions of these objectives, not necessarily that they are good objectives -- I make that claim and not you. All I am asking you is that -- if I said to you that I think these are eight objectives that ought to be in the quality assurance program, at least you understand the intentions of what I am trying to tell you.

MR. RICCI: I don't understand number two.

We chose to separate diagnostic procedures from therapy procedures, so we have a two and a three. Two says the therapy without a prescription or anything, either diagnostic or therapy, involving greater than 30 microcuries of I-125 or I-131. That is two.

MR. WIEDEMAN: One of the things why this was incorporated is because there would be no mistakes on iodine. You won't have that microcurie, milicurie problem. You won't have that -- it just makes you think twice as soon as the word iodine comes up.

MR. RICCI: But three also says that you will have a prescription.

MR. TELFORD: You can have either prescription or referral.

MR. BENNETT: Prior to any medical use that a prescription or -- it doesn't say may, it says or -- prescription for a diagnostic referral.

MR. TELFORD: It's your choice. It's up to you. For diagnostic procedures you can either referral or prescription. Some places will want to have a prescription for everything. Number three says you should have a choice for diagnostic procedures.

MR. WIEDEMAN: In the hospital diagnostic referral many times is a requisition, the requisition form. It

usually covers all the information required.

MR. STETAWAKOS: The third one includes radiopharmaceutical doesn't it?

MR. TELFORD: If it is diagnostic procedure that involves less than 30 microcuries of I-125 or I-131 or any other radiopharmaceutical in any amounts as long as it is diagnostic.

MR. WERY: Can we assume that maybe in some future draft of this that it will be clear as to other an the I-131 and I-125 that it will be --

MR. TELFORD: I appreciate that. If the language is not clear, it means that --

MR. KAPLAN: I am not suggesting that you do it, but suppose one were to look at two and say put a comma after the word procedure so that any prescription is required for any therapy procedure, comma, and any diagnostic with therapy -- I just inserted the word therapy -- radiopharmaceutical procedure. Would that help --

MR. TELFORD: That helps the situation.

MR. BENNETT: It doesn't read easily that way.

MR. TELFORD: I didn't write it very clearly.

MR. STETAWAKOS: I think if you made that two sentences everything -- if you eliminated the and and put another one in there. The first part of the sentence says any therapy you need a prescription, period. The second

sentence says any diagnostic procedures involving iodine needs a prescription, period.

The problem is that it is a compound sentence. If you made it one into a simple sentence, it would come out easier. That is the simple thing right there.

MR. TELFORD: Right.

MS. KARK: There are three objectives stated in two; diagnostic and the exception for iodine. It's really three almost three separate. Why not separate them out to be clearer.

MR. STETAWAKOS: You just get rid of the and.

MR. TSE: The question is that you know what the sentence is supposed to mean. We can always fix the wording. That is a separate point. The intention just like you said, brachytherapy, teletherapy, radiopharmaceutical therapy, plus anything that exceeds 30 microcuries of I-121 and I-131 even if it is for diagnostic purposes you need a prescription, no substitution. A referral will not be sufficient under this particular objective. That is the intention and we can always change the wording.

MR. BENNETT: Number three then, you are also talking about all diagnostic but specifically in addition to all diagnostics you are honing in on less than 30 microcuries.

MR. TELFORD: Right. Less than 30 microcuries,

you can use referrals. Greater than, you use prescription. Number three is, all diagnostics.

MR. CLOUSE: Anything under 30 microcuries has to be a diagnostic, it can't be a therapy.

MR. TSE: Over 30 microcuries still could be diagnostic.

MR. CLOUSE: Right.

MR. TSE: You say all diagnostic and you are not so clear.

MR. CLOUSE: I see what you are saying, yes, with that one exception.

MR. TSE: That one exception, right.

MR. ERICKSON: Can I just get one clarification on iodine. Is that three iodine.

MR. TELFORD: That's a good point. As stated, yes it includes it. Again, whatever you do in your facility you just say in your quality assurance program. We are up to two and three. What about the rest of them?

MS. BASTIAN: My question is still, I am not really clear about this prescription asking for all of those things. You said before it was just to use the pharmaceutical that we don't need to include all these?

MR. TELFORD: If your prescription states radiopharmaceutical, I think it is correct to say that would include isotopes.

MS. BASTIAN: Although the ordering physician won't know that what all those things are on a diagnostic. I am talking about diagnostic on a prescription when it says for diagnostic use.

MR. TELFORD: If you are using a prescription for a diagnostic procedure, yes, that is the answer. But the objectives say you can use a diagnostic referral for a diagnostic procedure.

MR. WIEDEMAN: Example. Let's assume that a patient shows up at your outpatient clinic and they have a prescription in hand signed by Doctor Referral. It says treat for hyperthyroid. Now, the first thing you would have to do -- I would assume this would be in your manual -- you would go to your authorized user and say doctor referral has given us this slip here for his patient sitting out there, and it says treat for hyperthyroid.

Now your authorized user will write a prescription telling you that I want to give that patient 15 milicuries of I-131 sodium iodine liquid form and any other specific requirements that he wants. Now you have a written prescription from your authorized user.

MS. BASTIAN: What about for a bone scan?

MR. WIEDEMAN: A bone scan is a diagnostic study. If you elect to use prescriptions in your facility, Freeport Memorial Hospital, that would be your own. Correct me if I

am wrong, but you usually have requisitions from the floors. That would be your diagnostic referral. You would not use a diagnostic referral for an iodine therapy.

You could get the word to the nuclear medicine department that the referring physician wants that treatment done on his patient, but now you are going to have to go back to your authorized user and say we just got a referral from the floor and they want this patient's thyroid treated. Now, your authorized user will have to write a prescription telling you specifically want he wants and the amount of material that he wants to give.

MS. BASTIAN: I understand, thank you.

MR. RICCI: Understand all the objectives clearly -- rather clearly, except for number four where the statement that -- understanding is to remain vague forever and could be replaced by something regulation defined.

MR. TELFORD: Do you have a suggestion?

MR. RICCI: Not yet.

MR. TELFORD: Okay. Does anybody object to breaking for lunch. We are only about an hour late. Let's go off the record.

[Whereupon, at 12:22 p.m., lunch recess was taken, to reconvene at 1:30 p.m., this same day.]

AFTERNOON SESSION

[1:55 p.m.]

MR. TELFORD: Let me start with a discussion of the pilot program. There is an overview.

[Viewgraphs.]

These are the objectives. Can you see this?

MR. KAPLAN: You don't have those handouts?

MR. TELFORD: Do we have those before us? I will just speak to these. We would like to understand how licensees would develop their specific quality assurance programs for their facilities that would meet the performance objectives of the proposed 35.35. In other words, we are planning to learn from you how you develop the program for your institution so that you minimize your own internal problems, you minimize the administrative burden or you minimize these factors in your proposed rule in your facility.

Number two is to understand how licensees conduct their program in actual practice. I will tell you about the fact that we are going to have some site visits. In fact, the letter that you received suggested to you that there was some number of sites that would be visited and maybe it is your. I don't know which ones they are yet but I can tell you how many.

The performance objectives in 35.35 have the

effect of preventing or catching mistakes which could lead to misadministration. During this trial period we may find that if you are following some type of over check procedure that the regulatory guide suggests, you may find that you are catching mistakes before they become problems. That would be important to know.

Lastly, if you properly implement 35.35 then we can provide high confidence that we can prevent errors. The answer to that question is highly subjective, I think. Ed will tell you about an evaluation form that we will use that would provide input for questions like that. This is the slide that tells you about complete overview of the program. I just realized that I should be using this slide.

Back in January we started sending out letters to volunteers that had been selected through this process. It took us until March 9th to find a sufficient number of volunteers, because some of the folks that we wrote to no longer worked there, we had some letters returned. It took a long time to get approvals. We didn't want to twist anyone's arm. We wanted to say we are going to run this pilot program and we would very much like you to participate. If you are nervous about it, don't do it. It took us a while, from all of January and all of February basically.

The second item that I have is, during March as it

turns out part of April, the plan is to have volunteers review the proposed 35.35 and modify their QA program if they need to, but reach a determination that your program needs proposed 35.35. The March and April period is for understanding and modification of your program if you need to.

Three is the pretest workshops. The March 29th date was in New York and April 4th which is today, we are in Chicago. The sixth will be in Atlanta, and the 18th we will be in Dallas. The 20th we will be in San Francisco. I don't request that the volunteers bring copies of their modified quality assurance programs to the workshops. You will have a little more time than that. During April and up until the time when we actually start the 60 day trial, you can modify your internal procedures, you can do any training that you need that might be somewhat different from what you are currently doing. For the next more than a month, you will have for that.

On May 14th we would like for you to implement your modified program for 60 days. So, from May 14th through July 13th, we would like for you to actually conduct the 60 day trial of trying out your modified programs which you say meets the proposed 35.35. You have until then to do any procedure modification, any training. I don't think we say on here, but we would like to have a copy of your

quality assurance program by May 7th. The reason for that is because if your hospital is chosen for the site visits, then our QA team that will go to those sites needs to have those programs so that they can evaluate the program on paper before it goes to the site evaluation.

Following the 60 day trial period we will have a post-test workshop, which we will come back to Chicago and all those fine places at a hotel near the airport. It will probably be a two day workshop in which the volunteers will discuss their experience with their modified program, their evaluations -- that's a very important part. I don't want to say too much about this because Ed is going to talk about it. Give us a grade on what you think of -- give us an A, B, C, D, E, F kind of grade on each of the objectives of the rule, each of the other parts of the rule, and any parts of the regulatory guide that you use.

Where you give us a D and an F tell us why. Maybe tell us why for all of them. You will have plenty of time to tell us about your evaluations and your suggestions for improving proposed 35.35. We will tell you that the recordkeeping requirements -- we are not going to discuss them today. They are rather lengthy, and I might even say complex. I want to talk about them at the next workshop, because I would guess that you have a lot of input into how to do that.

After you have tried out the proposed rule and had actually gone through a 60 day trial period, in the next workshop we will talk about the reporting requirements and what, based on your experience overall, what should be included. We will talk about what I am calling the QA team, we will talk about the criteria used to evaluate the QA team quality assurance programs. Sort of as a mock licensing exercise, but in a no-fault kind of way, the criteria that we use to do the QA team site evaluations and the results from both of those.

So, you will get an inside view as to, if this becomes a final rule, you will see how it might be licensed and how it might be inspected. You should definitely understand that and get through it at the next workshop.

That probably covers some of the stuff on this viewgraph. We want you to understand the criteria that we used and then you can understand the kind of evaluation that we qave that program. Keep in mind, this is a no-fault kind of way. We are just confessing to you, this is the way we will do it so that we can have a better understanding. We will talk about the results of those 18 programs as time permits. We will cover the ones that are in this group.

This is the criteria for the 18 site visits, understand the criteria and then to find out the results. If this were final, this is what an inspection might look

like. We want to try out this proposed rule, try to make it better. I want to listen to all the suggestions from the 68 volunteers to suggest how to do this better.

Here is what we expect of you. One is to develop a program that meets the proposed 35.35, assuming that you have already done that. Two, attend pretest workshop, you are here. Three is prior to the 60 day trial period, doing training or modification of your everyday procedures and actually conduct the 60 day trial period, and then evaluate it and evaluate the proposed 35.35 and the guide. Attend the post-test workshop and tell us what you think.

Questions. I think you had a couple of questions left over from this morning about measurements. One of the things that you can measure is, if you discover that the procedures that you have used in your hospital are effective and catching problems before they become real problems, catching little mistakes along the way, that is a measurement of your program, it is a measure of its effectiveness. What we want to learn is, what is the best way to put that into the requirement.

If we state certain objectives, that will cause the licensees to have a program that meets those general requirements. If we put it into the regulatory guide, we make it available as guidance to all the licensees. I don't think that we can measure the frequency of the occurrence of

misadministration during the 60 period because if they happen on the frequency of one of every 10,000 out of 68 volunteers, you know, we may have one or two. It is only one at that institution. I don't for a minute think that we are going to be able to measure that.

What I really want to measure is the evaluation of the proposed rule, your opinion. Are the objectives worth anything? You may look at number one and say I don't need that, this is an example. After you tried it out you could tell me why. You do something else in your institution or it just plain was not helpful. So, that is what we want to hear.

After we get the evaluations -- the evaluations you do -- assuming the trial program ends July 13th. WE would have about a two week period in which you would do the evaluations. We will try to make it as easy as we can on you and we will give you a form, blanks to fill in. We don't want to stop there, we want to talk about all those things at a post-test workshop. If you want to make public comments to send it in writing, you can. Send it to the secretary of the Commission before April 12th when we close the public comment period. If you don't do that because you are part of the pilot program, whatever you say now and whatever you say at the post-test workshop will be part of the public record.

Therefore, you have two opportunities to get in your opinions.

MR. TSE: You can in late this, because in the Federal Register Not[illegible] we say that we will receive something late. We cannot guarantee the consideration. At this time of course we will.

MR. TELFORD: I think a very positive statement to make is that I guarantee it. If you send it in in writing we are here to listen. What this is, is a giant experiment to try out these objectives of this program, and to milk it and try it. Then we want to fix it. You are the people that are going to tell us how to fix it.

I was kind of going through the schedule. The 60 day trial period ends on July 13th, you will have about a two week period to fill out your evaluations. Then we will have the post-test workshops that will begin probably toward the end of July. This is pretty early in the schedule. I would think this would be somewhat close to the early part of August.

Does that make sense to everybody? Is starting the 60 day trial period on May 14th, is that going to be a problem for anyone?

MR. BENNETT: How closely do you expect us to monitor it personally, on a day-to-day basis?

MR. TELFORD: Well, it's up to you. Whatever

frequency will give you enough feedback so that you can tell us how it is working is okay. We are going to go through 18 programs with a fine tooth comb, sort of like in a mock licensing way, so that we can then come to the next workshop and tell you what are the strong points are, what its weak points are, and what needs work. We are doing this in a no-fault way.

We will go to 18 sites. Some of the sites, I think we are going to have four people go and most of them it will be two people. Two of the people are Darrel Wiedeman and Dr. Tse. They will show up at 18 sites and they will give you advance notice. The basic question they are asking for themselves is, are you implementing the program that you have written. This is a way for us to actually look at 18 sites and say how well do they implement it.

All of the programs, all 68 of them, we will go through their written -- evaluation of the written program and you will get feedback from us, so you should get something out of this.

MR. WERY: There is no determination made before we start the program though, whether the program that we submit to you would be appropriate or not.

MR. TELFORD: All I am asking is, you tell me your program meets proposed 35.35 and I accept that. Now, it has

been asked before, what if you send in a program in May 7th and on May 30th you decide that you have a better procedure, send it in. Send us a copy of the change.

MR. WERY: Some of the items not that are in the first eight items but at least are listed on the proposed guide, it talks about things that would normally be done once a year.

MR. TELFORD: Yes.

MR. WERY: Do you expect anyone to do that?

MR. TELFORD: Like the source change --

MR. WERY: The annual survey.

MR. TELFORD: If that occurs -- I mean, it is probably going to occur somewhere among all of the 68 volunteers. Somebody will change a source as chance would have it. You don't have to do that. First of all, keep in mind that the guide is merely suggesting how to, so you don't have to do that. Personally, I would greatly appreciate it if some of you would try out some of those things so you could give me some feedback as to whether or not they are any good or whether or not they should be modified.

It is one thing to mentally contemplate using something like that. It is another thing to actually test it out and try it yourself. Of course, that is the whole objective of the pilot program, so that people can actually

test out the proposed rule.

Mr. SCHEU: When your team comes out to check, what are some of the things that they are going to check for? Are they going to look at patient records?

MR. TELFORD: Records, I forgot to say that. The only thing that you need to keep a record of are the prescriptions, the administered dosages, and the referral manual and the procedures manual. The program assumes the existence of the procedure manual. Most people have one. Actually, you could go a little further and say we need one to carry out the program if you are going to have referrals.

If you are always going to use prescriptions, theoretically you don't have to have one although I would guess that 90 percent of the people do. We are not asking for any --to create any new copies of records or anything like that. You probably already keep those records now. When the people appear they may say may I see a certain sample of records. They will sit down and look through them, and maybe they want to do the comparisons like objective number seven, identify the unintended deviations. Maybe they will look at what was prescribed and what was actually administered and they will identify some unintended deviations perhaps if there are any at your hospital and ask you what you think about it.

Darrel.

MR. WIEDEMAN: I think you basically said it all. I know there was some concern that people -- it is bad enough that it comes out every once in a while and someone inspects my facility anyway. Now, he is coming out and we volunteered. I just wanted to let everybody rest assured, we are not out there to do an inspection to look for violations. However, if I do see a violation I will bring it to your attention.

If it is a serious violation such as you store your brachytherapy sources in a lunch pail in an unlocked closet, I will probably ask you to do something immediately. When it comes to the agreement states, we will probably have agreement state representatives with us. The non-agreement states, it will probably just be the team itself.

We will listen to your comments and suggestions, and we will try to work very diligently with you to see that the program is workable.

MR. STETAWAKOS: When you say keep these records, you don't mean duplicates of the records. The records are a part of the patient's jacket. It is all right to leave them in there, but keep a list of the ones that were under the trial.

MR. TELFORD: That is right. You got it.

MR. CLOUSE: Also, on our referrals, if we take phone referrals then if we do not have a prescription do the

joint commission requirements -- we fill out a form and send it to the physician and have him sign it and send it back to us. That would suffice for a referral.

MR. TELFORD: Yes, because you are telling me that you are going to put that in your quality assurance program. That is the way that you are going to handle that.

MR. CLOUSE: That is an after the fact thing, because he called in and said I want this and we sent him that record to sign.

MR. TELFORD: You are defining the conditions under which you do that, and just keep a record that you did it. That is your program.

That brings us up to Lloyd Bolling is going to speak to the next subject. I will turn it over to Lloyd.

MR. BOLLING: I guess some of my remarks probably have to do with the non-agreement states as well, and that is that if you have some requirements in your license right now or there are some requirements in the current regulations and they appear to conflict with what you are proposing or are going to try in the pilot program, make sure that you have satisfied the current regulations that you are living under and propose what you like. Make sure that your current regulations are okay.

If you have any leaking sources, if you have any misadministration or anything like that, operate under your

rent regulations. I think Illinois has adopted some regulations having to do with misadministration, but I don't think they are quite as comprehensive as these are. Iowa, I don't believe that Iowa has done theirs yet. I think there may be one licensee here from Iowa, so you are in the clear as far as your regs are concerned.

MS. DUFFY: What if you are up for license renewal?

MR. BOLLING: You might want to talk to your RAD control people at the state and see if they would be willing to buy off on any of these changes. Don is very up on what is going on here. We have been talking to him and sending him the literature as well as copies of the proposed amendment. He has commented on them.

As far as I can see, none of the agreement states has a lot of problems with this, although there have been questions. See if he wouldn't buy off on some of this as being part of your renewal package.

MS. DUFFY: Thank you.

MR. TELFORD: The people from Illinois, can you think of any examples of anything that conflict or would be in addition to?

MS. ALLEN: I can't.

MR. TELFORD: I was told in New York that they lacked prescriptions or something written for everything.

So, when we say oral directives are okay under some circumstances, they say no. I don't think anybody here is from New York. Are you through, Lloyd?

MR. BOLLING: Yes.

MR. TELFORD: The next item on the agenda is to talk about the regulatory guide.

MR. TSE: John, what about the evaluation form. Perhaps they can go --

MR. TELFORD: I'm sorry, we will do that next.

MR. KAPLAN: I would like to mention that we recognized the diversity. After all, we did this sample so some of your rural and some of you urban, public, private, and we would like to have some way of looking at your guides in some consistent fashion. What we are asking you to do is to provide us with a roadmap that tells us where in your guide, the guide that you provide us with, each objective is that is to be satisfied.

If you decide to go with your guide and not with the regulatory guide, enclose a cover sheet that makes it clear to us which part of your procedure satisfies which particular objective that was listed by John. It is very important.

MR. NELSON: My name is Kevin Nelson, and I am from Brookhaven National Laboratory. As John has mentioned earlier today, we are helping with the pilot program. I

guess what I would like to start out by saying is that I appreciate all the comments that you have been giving today. This will be part of the record along with the comments that you make on the evaluation form.

I encourage you all to write down any comments that you may think about. As Ed just mentioned, we went to great lengths to make sure that not only the larger institutions are represented but the smaller institutions also. It is very important to us and to the program that we get comments from everybody so that we can make this as good a rule as we possibly can.

If we agree on the theory of the rule and on the objectives, the next thing we need to ask is how we are going to evaluate whether these objectives are being met in your QA program. The way that we have decided to look at it is, look at the reg guide that has been provided to you. The reg guide will give you a little bit more description than the objectives, and we feel is better in evaluating the entire QA rule itself.

You will be sent -- this is an old form, so don't pay a lot of attention to this. There are a few things that I want to go through on it. You can see up on the top we have a row here which would reference the specific point in the reg guide. So, for as many points as there are in the reg guide, I believe 5.11, there will be a role that will

take care of that specific point in the reg guide. We also have listed here several impacts that you may feel as a result of this specific reg guide or this portion of the reg guide.

They include benefit, economic impact, personnel availability, the impact on medical care covered under existing requirements and acceptability. What we want you to do for each point in the reg guide is, look to see what that point is asking you to do and compare that to what you are currently doing or will be doing and evaluate that point. The way that we evaluate it is, for each point that we have up here we have again this row, these points listed here, and we have those listed from one to five.

We want you to rank that point. That information would be provided up here rated from one meaning excellent to five being very poor. After you have done that, then overall we want you to rate the total benefit, the economic impact, the personnel availability for the whole reg guide for rule combined. We have also asked that if you feel that the specific point that you are looking at or the overall benefit is very poor, let's say a four or five, we have also asked you to write those comments down on a comment page.

We will be sending with this modified test result sheet and this comment sheet, a list of questions that we would like you to ask if you find out that one of these

areas is given either a four or five. The types of questions for instance, personnel availability, how many more additional people would it take you to do this specific element in the reg guide; what would be the cost for you for those additional people.

It is very important again, to answer these questions in a fair way. Obviously, we would like to think that some of these things are very beneficial and we have several one or two. I guess we would rather not see something where everything is just a five because I think we all can agree there are very beneficial aspects I think to this rule and to this reg guide. Maybe as an example, I can give you -- on 3.2 in the reg guide, we will talking specifics a little bit later on, so I would rather not get into questions about specifics at this point.

But, 3.2 indicates the administering the radiopharmaceutical, the authorized user under the supervision of an approved user will personally make and date a prescription. Some of the comments that we have heard in New York are that people had a question concerning I-125 or I-131 used for renograms where a dose is typically two to three hundred microcuries. A lot of people had a concern about whether a prescription was needed during that particular step.

This is the form that you would use to address

that question. We would look up here under 3.2 and you would go down and answer each of the questions as far as the benefit, the economic impact, personnel availability, impact on medical care and so on, you would rate that from one to five. On the section, if you had a problem with that as far as having people there to make prescriptions at that particular point, you would address it on that and also the comment page.

Again, it is very important that you take the time to write these comments down, because that is the only way we can make this a good rule, a good as rule as we can possibly make.

MR. STETAWAKOS: You mentioned something about to get a five it's going to go -- I take it you meant to who when you said --

MR. NELSON: When we receive the comments back and begin the timetable for this, that you would submit this and the comments page along with this page back to us sometime after July 13th, from July 13th to July 31st. We will look at everybody's response and then that will be brought up, I would imagine, at the next workshop that would be provided to the NRC.

It's very important that that information is gathered and looked at very carefully because that's really the major way we evaluate this rule and direct value.

MR. STETAWAKOS: Will those comments be given back to us, though, for just to review or look at at that meeting or before that meeting or anything or not?

MR. TELFORD: For the 18 programs that we evaluate, some of them will be from this group so when we talk about the Q-18 part of the program we also want to hear from those people, their evaluation of the proposed ruling, so what you will hear most probably is the evaluation from everybody so you'll hear it at the workshop and eventually you'll get it.

MR. NELSON: Other questions?

MR. WERY: On the rad guide -- on the whole rad guide or just on the process of evaluation of it?

MR. NELSON: Well, we will have a slot for every section on the rad guide. You would only fill out those -- I guess if you only did nuclear medicine type procedures you would obviously only fill out those points that relate to that.

MR. WERY: Are you going to talk about any specifics of the rad guide?

MR. NELSON: I think that's next out on the agenda.

MR. TELFORD: Would anybody object to taking about a ten-minute break before we go into the guide?

(Recess.)

MR. TSE: I'm going to talk about the regulatory guide. Because of the lengthy documents each of you have already read these and we want your comments.

MR. WERY: You use the term several places there "physician under the supervision of an authorized user." What do you exactly mean by that?

MR. TSE: An authorized user generally has a license. Some residents are not authorized users and are capable of doing something under supervision. That provision is very important.

MR. WIEDEMAN: Let me clarify two things. The license conditions two ways for authorized users. The first one will say the condition of your license will say licensed material will be used by or under the supervision of Dr. Joe Blow. That's one way.

Small clinics, single facilities, the license condition will probably say licensed material will be used by Dr. Jones in his physical presence -- used in the physical presence of Dr. Jones. That means only Dr. Jones can use that material.

Most hospitals will say by or under the supervision of. That way, any resident that's in training, any other physician or radiologist that is in the group, they can use material under his supervision. They don't have to be physically there but that authorized user should

be available for consultation if there's a problem that comes up. It's defined in part 35, supervision.

MR. TSE: Now I think we could flip through the pages and if you have any --

MR. TELFORD: One of the places I had some problem with is the part where it says audits and all that. Do you have -- In one place it might be in radiology we would have a radiologist coming in there or something like that but if you had somebody in administration, they're going to audit a program that you've set up and they're not going to know anything about really.

They don't know anything about radiation therapy or nuclear medicine, for the most part, if you have an administrator coming down there.

Now what kind of an audit are you expecting out of them? Are they going to come down and say, yes, you've checked this, you've checked that or here's an initial here and there's a signature there?

Just how intense is this audit supposed to be?

MR. TELFORD: I think that's page 54. Let's see if we have any comment before that.

MR. TSE: Does anybody have questions on page four? On page four it says that audits will be conducted by personnel who is qualified so in management's view if this person knows what the procedure is but she's not involved in

doing that I don't think she would be qualified to audit it.

MR. CLOUSE: As an example, John does not -- he works for the hospital indirectly as a consultant and yet I am the person in charge of the procedure so he would be qualified then, you're saying, to come and audit me because he's not actually doing the procedure.

MR. TSE: That's correct and the management also have to determine he is qualified. If he does not know the procedure he cannot find the errors.

MR. WERY: But if he has set up the procedures that he is doing, can he audit whether those procedures are effective?

MR. TSE: I think probably if he set up the procedures that he is auditing himself he would probably not be effective to find the errors and probably it should be somebody else.

MR. WERY: I think your example is straightforward. If I set up a procedure for our technologists that something is countersigned or something, I can make sure that things are countersigned but the audit procedure seems to ask someone to look to see if that item that I'm talking about being countersigned is a legitimate item to oversee the whole thing and someone should be looking at what I have done there.

At least at our institution I'm not sure who that

would be.

MR. TSE: I suppose you only have one person.

MR. TSE: It's intended that somebody will review his own procedure. It's very likely that this will occur and will not be able to see the faults.

Anything else on page four? Now page five, these are the specific elements for radiopharmaceutical.

MR. TELFORD: You may want to point out that section two are general elements for all procedures, all medical use, therefore they should read those into everything else.

MR. BENNETT: The audit -- excuse me for going back but I just recalled that in 1981 or '82 there was a great guide that was put out that recommended or at least a go-by for an audit that could be performed. I have copies of that but I don't recall where it even came from.

Actually I believe it was written and adopted -- It was adopted by the NRC but written by someone outside of the NRC. Are those types of things still available?

MR. WIEDEMAN: Yes.

MR. BENNETT: Just for my benefit so that I could provide people with some kind of suggested guidance, where can I get that?

MR. WIEDEMAN: The Region 3 office. You just call and say please send me a copy of the rad guide.

MR. BENNETT: And that program has not been modified?

MR. WIEDEMAN: I couldn't say that. I'm not sure.

MR. TSE: Does anybody have any questions on page five?

MR. CLOUSE: I do have a question. Presently at our hospital -- Under 3.5 it says after administering, the qualified person will make, date and sign the written record on the patient's chart.

Presently what is happening is they are using the report for the record in the patient's chart. The transcribed report that the doctor dictates on that exam is being used as the copy on the patient's chart.

The prescribed dose is not going to be in the patient's record, only the administered dose.

MR. TSE: You have described it somewhere.

MR. CLOUSE: Yes. As long as we have that prescription, then we have a record. That would not actually be in the patient's chart. That would be in a radiology copy of a file.

MR. BENNETT: Can I get a point of clarification? If a physician writes a prescription let's say for ten millicuries and the prescription is written before the isotope is ordered, the isotope is received and when it comes in it assays at 10.8 which is over ten percent --

well, I guess it's not over ten percent -- let's say it comes in at eleven or something over ten percent of what the original prescription was written for.

You tell him that before it's administered and he says that's okay, we'll change it to 11.8 or 12, whatever it is, is that legit?

MR. WIEDEMAN: As long as it's changed before it's administered.

MR. BENNETT: For most diagnostic that's what's done. I'm thinking more of therapeutic. Therapeutically they come to us with a request and I won't order anything until I've got a written request.

Then when it comes in it might be more than or less than ten percent from what he originally ordered and before we administer it we tell him what we got and he then modifies the prescription.

MR. WIEDEMAN: The example that you presented is very, very common and especially in the upper peninsula of Michigan where there are few airports in between.

The physician orders a ten millicurie dose, well, you hope that whoever your supplier is when they shipped it out on Friday afternoon they would have shipped maybe 15, 16 millicuries so by the time you would get it on Monday it would be down to about ten.

Sometimes they become very efficient and sometimes

very slow and maybe it will end up being eight millicuries.

As long as the physician is aware that it's eight millicuries and he changes his prescription, that would be acceptable.

I can remember some places in Iowa that the nearest airport is maybe 300 miles away, 400 miles.

MR. TSE: Any further questions on page five? We'll go to page six.

MR. WERY: On 4.5 the description you have, after implanting brachytherapy source radiograph will be obtained and used as the basis for calculating and delivering dose.

That's not how it's done anyplace in the country.

MR. TSE: We already heard that.

MR. WERY: Also the prescription for brachytherapy source, we often will have the case where we will have -- the implant of the source holders will be done in the OR and the patient will come to our department and we'll put in the dummy sources, radiograph those sources, the physician will look at the radiograph and he'll give us a loading, how much, what strength sources to use and how many sources and he wants to start the therapy right there.

He may not have calculated in his mind or we may not have done the computer calculation or whatever that he wants to figure out exactly when it will be removed at that point but he will still want to start the implant at that

time and we know whether it's going to something on the order of 48 hours and we'll have six hours or so that we'll want to start.

At least if I'm writing this for our institution, I will have -- I would want to write it in that form so it actually won't -- before the administration of the source, when I put in the sources I won't have a prescription saying the exact time that it will be removed but I will have a prescription that will say exactly what sources to put in and I'll follow that prescription.

He will have told me what sources to put in but he will not have determined the exact dose that he wants yet. If you know the dose, you know the time so --

MR. TSE: You might know the dose but you still do not know the --

MR. WERY: Right. In our institution, the way it's normally done the dose is started to be administered as we're going through that process is there a problem with doing it that way as long as I spell out what I'm doing?

MR. TSE: It could be a difference in interpretation.

MS. KING: But doesn't that prescription have to have the dosage? You're saying time -- Are you saying the dosage isn't written down, either, or just the time isn't written down?

MR. WERY: Either one.

MS. KING: Doesn't the prescription -- Isn't the definition included in the dosage? Isn't that a conflict?

MR. TSE: The definition, the prescription is the total dose.

MR. WERY: But you're saying you don't even have a dose.

MR. WERY: I don't have a dose When I start -- When I put in the sources, I do not have at that point a dose or a time.

MR. TSE: Does the physician?

MR. WERY: No.

MR. TSE: So the physician does not know how many rads you're supposed to give?

MR. WERY: No, not at that time. That's the way it's currently done.

MR. STETAWAKOS: He's not talking about does rate. The doctor has to know how much he's going to deliver.

MS. KING: He should have but it's not written down. That's what you're saying.

MR. WERY: That's what I'm saying. If I push him, he may be willing to do that but at least the way it's done now I do not.

MR. BENNETT: Does he tell you he would like you to start out with the old voids with 10-10 and then 15-10

and then --

MR. WERY: Yes, he gives me that. I've got the exact loading that he wants. I'm following his prescription for the loading at that point.

MR. TSE: He knows it's going to be more than one day so -- Maybe you should change it. You should have some idea.

MR. RICCI: The total dose will depend also on the dose distribution. That's why he'll not know ahead of time what the does is going to be.

MR. TSE: He can always change it later.

How about page seven?

MR. STETAWAKOS: I have a real problem and this will be addressed in the other sections, where you say before 50 percent of prescribed dose has been administered a qualified person will come back and do the calculations over again.

Places don't have that many people there that are qualified to do it. How are you going to have these checks?

The physicians that I work with aren't qualified to check my calculations. The techs certainly aren't qualified from their training. Where are you going to find somebody to come in here and do that?

MR. TSE: If you look at the checks. The check is correct use and so on.

MR. STETAWAKOS: Yeah, but they're still not going to know. If you're saying adding and multiplying -- if you're telling them, okay, the output at one sonometer is 52.9 MR per hour or R per hour at that point, they might be able to take and multiply that times the time, but to really do a check -- It's almost impossible at some places to do that. I know it is in ours because there's nobody else there to do it.

MR. TSE: First, this is a suggestion. You do not have a person able to do those, maybe you check yourself.

MR. STETAWAKOS: That's what I do. I do it myself. In fact, I use two different methods. I'll use one method for the original and then I'll come back with a second method. If this says somebody independent has to come in there, that isn't doing any good.

MR. TSE: That's true.

MR. WIEDEMAN: This particular statement in here was taken with the intent really of very large institutions with a group of medical physicists and a battery of dosimetrists that that's all they do all long is calculate and it's a dual verification. One guy does it by way of computer, another one does it by longhand or calculator.

MR. TSE: Perhaps we can suggest another way you could check. You could do it by one method and then check it by a different method.

MR. STETAWAKOS: Can we assume you mean that for all the places? It says have an outside source come in there and check, or someone other than the individual?

MR. TSE: Here?

MR. STETAWAKOS: In this guide, 3535. There's two or three places that says you should have this checked by someone other than the person that did the original calculation.

Some of that is easy, like when you're doing therapy doses where the tech does the calculation and the physicist can come behind them and do it, but some of them, like this or some of the other calculations or calibrations, you don't have people that can do that.

So can we make the same assumption that you just made that you can do it yourself as long as you try to do it in a different in a different manner, thus making yourself a separate inspector, so to speak?

MR. TSE: Yes because this is just a guideline. In fact you should make those suggestions at the next workshop so we can include several ways of checking.

MR. WIEDEMAN: You would think you would have a problem in your hospital. You can think of small clinics, a pharmacology clinic where they may have a consulting physicist that comes in once a month to do monthly outputs. How is he going to do that?

He wouldn't be able to have somebody else because he can barely have enough time to treat his patients and then his technologists may not even know the basics of doing dosimetry.

Once again, like Tony said, this is a recommendation. It's not a requirement. There are other alternatives to come up with.

MR. TSE: Any other questions on page seven? Now teletherapy. Any questions on page eight?

Are there any questions?

MR. WERY: Item 5.4 on page eight. After administering a dose fraction, a qualified person, whatever, will personally make, date and sign a written record in the patient's chart describing the dose administered and will record the agreement or lack thereof between teletherapy administration and prescription.

I think you want something there, and I'm not sure exactly what you'd like. The way we do it, and probably a lot of other places, is the dose that is prescribed is recorded in the chart, but I'm not sure that that is recording the agreement or lack thereof with the prescribed dose. Do you know of a system that will do this?

MR. TSE: Okay. Your question is, if I have a chart, I know what my prescribed does is, I put down my administered dose, and do I need another column to say

"Agree" or "Does not agree." Was that your question?

MR. WERY: More or less.

MR. TSE: It may not be necessary to do that because we see the two side by side. Maybe you will need another column.

MR. WERY: But you'd like some kind of reference so that the person could evaluate whether the dose he gave was a misadministration or not, effectively.

MR. TSE: It may not be a misadministration. Maybe we need somehow to let the physicist know or let his physician know. A misadministration has certain window.

MR. WERY: Yes, some.

MR. TSE: But even below the window, you still want to see what's happening.

MR. WERY: Okay.

MR. STETAWAKOS: And the dose doesn't need to be entered in absolute terms as such, but the mentioning of the monitored units, for instance, instead of the dose in rads would be adequate.

MR. TSE: I think, if it's equivalent, it doesn't really have to be so specific.

MR. STETAWAKOS: Right.

MR. TSE: Any other points or suggestions on page eight?

[No response.]

MR. TSE: If not, we'll go to page nine.

MR. WERY: Yes. Let me read my note here.

MR. TSE: Okay.

MR. WERY: You talk about computer-generated dose calculations and checking them. Actually, you give -- I think it pretty much is given here that you say, in 5.6.2, computer-generated dose calculations will be checked by examining computer printouts to ensure the correct inputs for the data information. That is fairly self-explanatory. Alternatively, the dose will be manually calculated to a key point and the results compared.

For this and other things like that, are we sort of free to [illegible] some kind [illegible] number that will be an acceptable agreement? If I do a computer calculation and do a hand calculation to a point, it's not very likely I'll get exactly the same number. I'll have some kind of difference.

MR. TSE: But if you exceed a certain number, you may want to alert your -- put a flag on it until you see what's happening.

MR. WERY: So we can feel free to put some kind of what we think is a reasonable limit on it. Okay.

MR. TSE: But I imagine it would probably not be more than ten percent or so.

MR. WERY: No.

MR. TSE: Any further questions on this one? Does

anybody have a question on 5.7?

MR. STETAWAKOS: No. We said that we could do the same things we said before in 4.8.

MR. TSE: No, I said 5.7, which is the independent check.

MR. STETAWAKOS: Right. That's what I was asking you before, if we can follow the same procedure as we did under 4.8 for brachytherapy check.

MR. TSE: I thought that was different. This is the full calibration measurements.

MR. STETAWAKOS: Right. Okay.

MR. TSE: The other one is a check of the calculations.

MR. STETAWAKOS: Right. But can you not do the same thing here, I mean if you don't have anybody else?

MR. TSE: This one is already provided.

MR. STETAWAKOS: Because what I do is I have two different systems for calibration. One day, I'll use the one system, and then I'll come back and use the other system that had two different factors, correction factors, to see if I come out with the same thing. To me, that's an independent check. Now, I don't know if it would be to you.

MR. TSE: Well, it would not be under part 7.1 because the wording here is that it has to be done independently.

MR. STETAWAKOS: You're right, it says by a different man in that, but I'm saying that I think it should be accepted as that due to cost constraints and the fact of finding some way to come in there and do it.

MR. TSE: Right. That's the same kind of situation.

MR. STETAWAKOS: Right.

MR. WIEDEMAN: Another independent check, if you did the full calibration and you have a victorene 570 condenser R meter, to me, that's an independent check.

MR. STETAWAKOS: That's what I'm saying. What I have is I've got two systems. They're both victorenes, but I've got an NEL probe, and I've got a PTW probe. So, to me, that's two, and they both have two very different correction factors. One's a 9.52 and the other one's a 1.19.

MR. WIEDEMAN: They should probably match within about five percent.

MR. STETAWAKOS: Well, closer than that, actually.

MR. WIEDEMAN: That's even better.

MR. STETAWAKOS: Okay. That's why I'm asking if you consider that an independent check because I think it would be realistic to be able to consider that.

MR. TSE: Okay. Any other questions on page nine?

MR. WIEDEMAN: I might add that 5.72 is normally done by the therapy technologist. I don't know how you do

it at your particular facility, because they are not the one that did the full calibration. That would be, of course, the medical physicist.

MR. STETAWAKOS: Yes.

MR. WIEDEMAN: And as we said earlier, another independent check would be, of course, the TLD monitoring program through ND Anderson.

MR. STETAWAKOS: Unfortunately, they don't do that within that 30 days of change the sources. That's the problem.

MR. WIEDEMAN: There's a problem.

MR. STETAWAKOS: They do it like once every six months or quarter maybe at most.

MR. WIEDEMAN: I believe the University of Wisconsin is another -- I'm not sure of how many -- at one time, we had about five or six, but then the Government cut back on the funds. Pittsburgh used to do it, too.

MR. TSE: How about page ten? Does anybody have a question on page ten?

MR. WERY: Again, for item 5.10, if we think that there are other tests that might be better to compare the computer versus the measured data, we can substitute those tests described and substitute them into our program and hopefully they will be acceptable.

MR. TSE: Right. But how do you do that, the

other tests? You also have to do a measurement.

MR. WERY: Yes, comparing the measured data versus the calculated data.

MR. TSE: Right. It does not have to be exactly as it says here. In fact, we can comment on those things, whether those are appropriate, in your view, or perhaps you have a better way of doing it, and simpler.

Page eleven is very short. You were talking about the schedule. Are there no more questions on that?

MR. TELFORD: Well, we started slowly, but we're picking up steam, and we're about to finish here. I want to just talk about the schedule. Can everybody start the 60-day trial on May 14th? Is that a problem for anybody? Are you all with me? Can you do it on May 14th? Okay. Good.

Let me go over the records one more time. The only records that we're asking you to keep during the 60-day trial is what you have now, which is the prescriptions, the referrals, administered dose and the charts, and the procedures manual, so that when the QA team arrives and says, "May I please look at some of these records," we can put a pile on the table. Yes?

MR. STETAWAKOS: One question on referrals. Would you consider -- whenever we get a referral, a lot of times the doctor just sends the patient to the office and says, "Okay, I want this patient to have radiation therapy because

we think it's indicated." Okay. We check it all out, yes, it is indicated, and then we don't get anything in writing from the physician, but we in turn send what we call a consult back to the physician saying, you know, "Thank you for referring Ms. J. Jones." Would you consider that documentation of a --

MR. TELFORD: Sufficient record for a referral?

MR. STETAWAKOS: Right.

MR. TELFORD: Yes.

MR. STETAWAKOS: Okay. So our letter back to the physician is sufficient record that the referral --

MR. TELFORD: As long as we have a copy of that and a copy in your response.

MR. STETAWAKOS: Right. Well, definitely a copy of that will be in the patient's jacket and a copy -- well, the original goes back to the doctor.

MR. TSE: John, I thought you said therapy --

MR. STETAWAKOS: Yes.

MR. TSE: If there's therapy, you need a prescription.

MR. STETAWAKOS: No, no, no, no, no, I'm not talking about prescriptions.

MR. TSE: Oh. Okay.

MR. STETAWAKOS: I'm talking about the referrals in radiation therapy.

MR. WERY: You don't need them in refer

MR. TELFORD: To start a therapy, you just need a prescription, and it's from the authorized user.

MR. STETAWAKOS: Okay. Now, are we talking about isotope therapy, or are we talking about -- when I say isotope, nuclear medicine therapy -- or are we talking about teletherapy?

MR. TELFORD: All therapy.

MR. TSE: All therapy.

MR. STETAWAKOS: Okay. Well, then I misunderstood.

MR. TELFORD: When you said a referral, I was thinking diagnostic.

MR. STETAWAKOS: No, no. I'm talking teletherapy. I can understand that part, but see, what we do is we always write a prescription on the treatment jacket, but we also respond to the physician who referred a patient to us saying -- but you're saying that's not necessary for this program?

MR. TELFORD: No.

MR. STETAWAKOS: See, that's where I'm getting mixed up with the referrals and the teletherapy.

MR. TELFORD: Okay.

MR. WIEDEMAN: Remember earlier, I said there was some discrepancy in medical terminology that different facilities use?

MR. STETAWAKOS: Yes. No, they always write a prescription, and the chart, the front part of the chart has the prescription in it. Okay.

MR. TELFORD: The chart's got the record.

MR. STETAWAKOS: Right. Okay. Well, then, that's no problem.

MR. TELFORD: Any questions?

[No response.]

MR. TELFORD: Okay. Well, concluding remarks, then. Those people that have an early flight start first. Let's start with those people that have a five o'clock flight. You and you, and you. You, too? All right. We can start over here, then.

MR. KAPLAN: Before we do that, how many people actually brought QA plans with them?

MR. TELFORD: Can you leave a copy with Ed?

MR. KAPLAN: I was going to suggest that if they are in a form that's compatible with the eight objectives, then it makes sense for us to take them. But maybe, if they're not, and you could spend a day or two just putting together this roadmap that goes on top of it and then sending it in, perhaps with the reimbursement, that might be more efficient. So, whichever way you'd like.

MR. TELFORD: I'd suggest that if you have a copy and you don't mind leaving it, leave it, but then do this

one-page roadmap so that you say, "Section X of our program satisfies Objective 1; Section Y satisfies Objective 2." That's what we're looking for so the program can be evaluated. Just something as a roadmap, literally. Nothing detailed.

MR. SCHEU: Where do we send it?

MR. TELFORD: To Ed. His address would be on the letter that you received, Brookhaven National Laboratory, Dr. Ed. Kaplan.

MR. TELFORD: Well, we're up to concluding remarks. I wanted to begin by saying that I thank you all for coming. I appreciate your patience and look forward to your participation and suggestions and evaluations. Let's start over here with the folks that have an early flight. Take five or ten minutes and say whatever you want to say.

MS. KING: Well, at my facility, there is a very small percentage of out-patient, and they have no QA program as of yet, so we need to develop that. I guess it seems a little more lenient than I thought when I walked in here, although I guess the final rules aren't being made yet. We'll wait and see what the final rule is. It doesn't seem as bad as I had initially thought.

MR. ZENN: I would tend to agree it doesn't seem that bad. It seems that most of this QA is really for therapy, as my major concern, and since the clinic I'm

representing right now doesn't do therapy, I'm not sure that this will actually help them out with cutting down any kind of real problems with misadministrations. I think it's a good idea for therapy, but I have my doubts about diagnostic.

MR. SCHEU: I don't anticipate much of a problem or workload us because much of what has been discussed we've sort of implemented to begin with. How much it's going to relieve the misadministration problem, I don't know, but I am certainly willing to work to see whether it will help.

MR. CLOUSE: I don't know if I can add much to that. Again, we do some therapy. Whether it will actually effect misadministration, I'm not sure, but if it in some way does prevent that from happening, then that certainly would be worthwhile in having a program.

I think we found in radiology and diagnostic radiology that having a quality control program did significantly lower the number of our repeat rate. But certainly I believe it's worthwhile. Of course, again, we're talking about a much larger number in diagnostic radiology.

MR. STETAWAKOS: I don't really have any more comments other than what we've already said.

MR. TELFORD: Let's skip over to here.

MR. BENNETT: My only comments might be I think that the group of people that you have here are very

interested and concerned about the program. I would like to see the authorized users involved in this kind of thing up front. They always seem to be in the back room and not really directly involved in developing these things initially. Maybe indirectly, but the comments usually are "Why did you get me into this mess after the regulations are enforced?"

MR. SCHEU: May I add to that? Do users ever receive bulletins or notices?

MR. TELFORD: Yes.

MR. SCHEU: They do?

MR. TELFORD: Sure.

MS. KING: It usually is received by the administrator, though. Who it goes to from their desk is --

MR. SCHEU: The licensee gets it but I'm talking about the user. Is there every communication between the NRC and the user? They seem to be buffered from all this.

MR. WIEDEMAN: The address that's used to send out a bulletin or a notice is the same that's written in the upper lefthand corner of your license. If it says, "XYZ Hospital, Attention: Radiation Safety Officer Joe Blow or Mr. Williams, Administrator," that's who it's sent to.

MR. SCHEU: I think things that deal with quality assurance and patient care may -- we may think about somehow getting mailings to them directly: "Hey, buddy, you're

responsible. This is your program. Get with your people and put it together.

MR. WIEDEMAN: We're in the process -- we have a system called LMS Licensing Management System. It's a computerized program where we can enter the license, license number, docket number, address, and down at the bottom, it'll list the authorized users and the radiation safety officer of that particular license. We don't have that program up to speed, but sooner or later, we'll be able to glean out of the LMS system licensees, radiation safety officers and users, and we will be able to direct mail and different various things to them directly.

MR. STETAWAKOS: Well, when you applied for a license renewal, or that, you have in their contact person. Why don't you just take that and feed it into your computer and have it flagged as a contact person? I mean, the person who writes the license is usually the one individual whose responsible for it overall.

MR. WIEDEMAN: Well, yes and now. You have to remember, a lot of the applications for a byproduct material license for a medical are prepared by consultants, and, you know, they are being paid for their service. They'll say, "If you have a question about this application, contact me for the answer." They are not the radiation safety officer, and, you know, when the mail arrives at that facility, it's

returned because they don't have anybody by that name. So we go by, really, the RSO because that requires an amendment to their license to change the RSO.

MR. STETAWAKOS: Right.

MR. RICCI: I think it's a useful program, a useful study. Insofar as sensitizing the user, I think it should be more of a local concern than an NRC one because then you'd be less effective in sensitizing people whom are sensitized best by direct contact. Radiation safety committees can play a big role in that, and they exist.

A well-specified quality assurance requirement would again sensitize more of the users, and I think it can be done fairly well. They can let us do our job in a professional standardized way better than now.

MS. SWAN: I don't think we're going to have a problem with keeping records or doing any of the QA. A lot of them exist already in our hospital, and we're lucky enough to have the authorized users there all the time. Even on call situations, they are there. So I don't think this will be any problem at all.

MS. BASTIAN: At the facility I represent also, we have -- most of the objectives are met through our written policies or else unwritten policies which can merely be documented. I don't see it being a problem to address the objectives.

MR. BOLLING: Well, I'd like to thank everybody for showing up today. I think that just the size of the audience indicates a willingness to work with us, and I find that every time that we meet with licensees, licensee to regulator, we get to know each other a little better and the discussions get a little frank. That's okay because that's what we're here for.

MR. WIEDEMAN: I just want to once again thank everybody for coming today, and I'm looking forward to working with you. If you have any questions, you've got my phone number, and I'll be glad to try and answer. If I don't have the answer, I'll refer you to someone that does. So, once again, thank you.

MR. TSE: Well, I appreciate your coming and helping us out. This is one of the items we talked about earlier, is the proposed regulation, including this quality assurance part, an also the misadministration part. John already said that we're going to discuss that at the next workshop, so I'm going to give everybody a copy so you can take a look. Thank you for coming.

MS. KARK: I don't have any further comments.

MR. KAPLAN: I'd like to express my appreciation for your cooperation. It's been hard lining up people who will take the time to participate. I think that the participation, your participation is really essentially to

see to it that this proposed rule is meaningful, and it is to the delivery of medical care.

I wrote a note to myself here that I think it's important that the authorized users back at your facilities get involved, that you actually make them do things for you so that you -- you know, if they start complaining, write those down on those comment sheets. We'll be sending them to you in a few weeks, the sheets that Kevin showed you. But it's so important to get these authorized users involved in the pilot project. Right now, they're not, you're right.

If I could stress that it would make our lives much, much easier if we could follow a roadmap that you provide us with to your QA plan, that would be very useful, and we look forward to getting them on the 7th.

About the utility of this program for nuclear medicine diagnosis, I'm not sure I understand some of the questionable aspects that you had made, but I certainly hope that we can somehow see whether or not this makes sense for that area, too.

So, thank you for coming.

MS. SCHAEFER: In 1988, our hospital established a QA policy, and we've had a year to implement it and do it. Our users have helped to come up with their indications; our administration is part of the QA management team. So, I have had a year to see us develop and implement it.

Looking back at the year of surveys that we have done monthly, monthly evaluations, I've seen it work, and I have seen areas in our department drop at least 80 percent in clerical errors, the non-indicated studies, the children that we have saved not injecting, just sending them to alternative treatme and areas of other studies that were more applicable.

I'm all for it. I think it's worked. Again, it took us a year to really develop it and get it to this stage, and looking at this, we're going to be able to make it even better.

MR. NELSON: I'd like to thank you all for coming. Much of what I would say -- I'd like to reiterate what Ed has said, and that we appreciate all your comments. Much of what you have said has already been mentioned by your peers in New York.

I want to stress, though, that it's very important, if we want a good QA program, that we get comments from not only the large facilities, but also the smaller facilities, and I think this group, the NRC group that's working on this, listened to these comments very carefully and will take all of the comments into consideration when they look at this.

As Ed mentioned, we're going to be sending a comment page or a questionnaire page out to you in the end

of April. This is the form and it'll look somewhat like this. We're going to make some modifications. Please take some time and put your thoughts down and your comments down on that, and we'll evaluate those then and have them ready before the next workshop in August.

MR. LAWALIN: I can only echo what was said across the room. Coming from a real small hospital, we only do nuclear work, so there isn't a whole lot of change in this proposal for us. I don't see any problem implementing it. It seems like most of it is directed primarily towards therapy and that type of work. So, I don't see any problem.

MR. WERY: Yes. I think the information that we've gotten here will allow me to write the program quite easily, again incorporating what we have in our current QA policy and procedures or whatever into what is there. I don't think that will be very difficult.

I'd like to echo just briefly just to emphasize again the importance of authorized users. I think everyone else has said things as much as I'd like to say, but I think that would be a real benefit, to get the authorized users involved as early as possible in this. That's about it.

MR. BRENNECKE: I don't have any comments.

MR. ERICKSON: I really don't have any comment other than the fact that I appreciate the opportunity to participate in this program. I think it's a real effort.

It shows a real caring from the NRC that they get input and they have some concerns about how rules and so forth do effect us both. I do see that concern.

MR. TELFORD: Thanks again for your participation today, and thanks for coming. I'll see you all next time. Good luck.

[Whereupon, at 3:57 p.m., the hearing adjourned.]

REPORTER'S CERTIFICATE

This is to certify that the attached proceedings before the United States Nuclear Regulatory Commission

in the matter of:

NAME OF PROCEEDING:

DOCKET NUMBER:

PLACE OF PROCEEDING:

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.

Ronald C. Standish

Official Reporter
Ann Riley & Associates, Ltd.

Enclosure 1

Purposes and Specific Objectives of the Quality Assurance Program

§ 35.35 Basic quality assurance program

(a) Each applicant or licensee under this part shall establish a written basic quality assurance program to prevent, detect, and correct the cause of errors in medical use. The objective of the basic quality assurance program is to provide high confidence that errors in medical use will be prevented. This basic quality assurance program must include written policies and procedures to meet the following specific objectives:

(1) Ensure that any medical use is indicated for the patient's medical condition;

(2) Ensure, prior to any medical use, that a prescription[5] is made for any therapy procedure and any diagnostic radiopharmaceutical procedure involving more than 30 microcuries of I-125 or I-131;

(3) Ensure, prior to any medical use, that a prescription or a diagnostic referral[5] is made for any diagnostic procedure not involving more than 30 microcuries of I-125 or I-131;

(4) Ensure, prior to any medical use, that the prescription or the diagnostic referral and clinical procedures manual is understood by the responsible individuals;

(5) Ensure that any medical use is in accordance with a prescription or a diagnostic referral and clinical procedures manual;

(6) Ensure, prior to any medical use, that the patient's identity is verified as the individual named on the prescription or the diagnostic referral;

(7) Ensure that any unintended deviation from a prescription or a diagnostic referral and clinical procedures manual is identified and evaluated, and

(8) Ensure that brachytherapy and teletherapy treatment planning is in accordance with the prescription.

[5] If, because of the emergent nature of the patient's condition, a delay in order to provide a written prescription or diagnostic referral would jeopardize the patient's health, an oral instruction may be acceptable, but a written record (containing the information specified in § 35.2 for a prescription or diagnostic referral) shall be made in the patient's record within 24 hours.

Enclosure 2

Relevant Definitions in Proposed Section 35.2

§ 35.2 Definitions

"Basic quality assurance" means, for the purposes of this part, the aggregate of those planned and systematic actions designed to prevent the occurrence of any error in medical use produced by, made by, caused by, or attributable to any individual acting on behalf of the licensee (including omissions or commissions).

* * * * * * * * *

"Clinical procedures manual" means a collection of written procedures in a single binder that describes each method (and other instructions and precautions) by which the licensee performs clinical procedures; each diagnostic clinical procedure approved by the authorized user for medical use includes the radiopharmaceutical, dosage, and route of administration.

* * * * * * * * *

"Diagnostic referral" means a written request dated and signed by a physician before a diagnostic medical use that includes the patient's name, diagnostic clinical procedure, and clinical indication.

* * * * * * * * *

"Prescribed dosage" means the quantity of radiopharmaceutical activity as documented before administration of the radiopharmaceutical, either (a) on the prescription or (b) in the clinical procedures manual if the procedure is performed pursuant to a diagnostic referral.

* * * * * * * * *

"Prescribed dose" (a) in teletherapy, means the quantity of the radiation absorbed dose stated on the prescription, as documented before administration, or (b) in brachytherapy, means the quantity of the radiation absorbed dose or equivalent stated on the prescription, as documented before administration and as revised to reflect actual loading of the source or sources immediately after implantation.

* * * * * * * * *

"Prescription" means a written direction or order for medical use for a specific patient, dated and signed by an authorized user or a physician under the supervision of an authorized user, containing the following information: (a) for diagnostic use of radiopharmaceuticals: the radioisotope, dosage, chemical form, and route of administration; (b) for radiopharmaceutical therapy: the radioisotope, dosage, physical form, chemical form, and route of administration; (c) for teletherapy: the total dose, number of fractions, and treatment site; or (d) for brachytherapy: the total dose (or treatment time, number of sources, and combined activity), radioisotope, and treatment site.

* * * * * * * * *

U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REGULATORY RESEARCH

December 1989
Task DG-8001
Division 8

DRAFT REGULATORY GUIDE

Contact: A. Tse (301) 492-3797

BASIC QUALITY ASSURANCE PROGRAM FOR MEDICAL USE

A. INTRODUCTION

The NRC has proposed amendments to the regulations at 10 CFR Part 35, "Medical Use of Byproduct Material." A new § 35.35, "Basic Quality Assurance Program" (54 FR , November , 1989), if promulgated, would require medical use licensees to establish and implement a written basic quality assurance (QA) program to prevent, detect, and correct the cause of errors in medical use.*

This draft regulatory guide, published for public comment concurrently with the proposed regulation, provides guidance for licensees on developing a written basic QA program that would be acceptable to the NRC staff for meeting the proposed regulation. Medical use licensees may use this guidance as they develop a basic QA program specific for their clinical situation.

The NRC staff will start a pilot program during the public comment period to determine the impact and efficacy of the proposed basic QA program and procedures developed by participating licensees and to determine whether the rule and procedures would interfere with or could be incorporated into licensees' medical practice. Based on public comments and the results of the pilot program, the NRC staff plans to revise this regulatory guide as necessary. The

*"Medical use," as currently defined in 10 CFR 35.2, means "the intentional internal or external administration of byproduct material, or the radiation therefrom, to human beings in the practice of medicine in accordance with a license issued by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico." This definition applies whenever this term is used in this regulatory guide.

This regulatory guide is being issued in draft form to involve the public in the early stages of the development of a regulatory position in this area. It has not received complete staff review and does not represent an official NRC staff position.

Public comments are being solicited on the draft guide (including any implementation schedule) and its associated regulatory analysis or value/impact statement. Comments should be accompanied by appropriate supporting data. Written comments may be submitted to the Regulatory Publications Branch, DFIPS, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Copies of comments received may be examined at the NRC Public Document Room, 2120 L Street NW., Washington, DC. Comments will be most helpful if received by

Requests for single copies of draft guides (which may be reproduced) or for placement on an automatic distribution list for single copies of future draft guides in specific divisions should be made in writing to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Director, Division of Information Support Services.

final regulatory guide may contain more general guidance on the design and implementation of a basic QA program, or it may contain specific QA procedures that were developed and tested by licensees during the pilot program.

The NRC will publish a final regulatory guide when the final regulation is published, which licensees may use to develop a basic QA program. The NRC staff is soliciting comments on this draft regulatory guide to ensure timely publication of a useful, practical, and effective final regulatory guide.

Any information collection activities mentioned in this draft regulatory guide are contained as requirements in the proposed amendments to 10 CFR Part 35 that would provide the regulatory basis for this guide. The proposed amendments have been submitted to the Office of Management and Budget for clearance that may be appropriate under the Paperwork Reduction Act. Such clearance, if obtained, would also apply to any information collection activities mentioned in this guide.

B. DISCUSSION

Radiopharmaceuticals contain small quantities of byproduct materials and are used in nuclear medicine to locate tumors, assess organ function, or monitor the effectiveness of a treatment. Larger quantities of radiopharmaceuticals are administered to treat various medical conditions (e.g., hyperactive thyroids). Sealed sources containing byproduct material are used in radiation therapy to treat cancer. Teletherapy machines can be adjusted to direct a shaped radiation beam to the part of the patient's body that is to be treated. In brachytherapy, smaller sealed sources with less radioactivity than teletherapy sources are inserted or implanted directly into a tumor area or applied to the surface of an area to be treated. An estimated 7 million diagnostic nuclear medicine procedures are performed annually in the United States. In addition, there are about 30,000 radiopharmaceutical therapy patients, about 100,000 cobalt teletherapy patients, and about 50,000 brachytherapy patients treated annually.

Every year the NRC receives reports of misadministrations in medical use. These misadministrations usually involve errors produced by or attributable to an individual, such as using the wrong radiopharmaceutical, treating the wrong target organ, using the wrong calculation, or treating the wrong patient. They may result in treatment or doses very different from what was prescribed.

Although the occurrence rate of such misadministrations is low, the NRC staff believes that most such misadministrations could have been prevented if an appropriate and effective basic QA program had been followed by the licensee involved.

Section 35.35, if adopted as an amendment, would require medical use licensees to establish and implement a written basic QA program to prevent, detect, and correct the cause of errors in medical use. To provide the flexibility needed by medical use licensees to practice medicine, this requirement is proposed in the regulation without specifying detailed QA procedures. This flexibility is to prevent or reduce any interference with the delivery of medical care.

Implementation of QA procedures based on the guidance contained in this regulatory guide does not in itself satisfy all QA requirements and recommendations pertaining to medical use. The QA procedures in this draft guide pertain only to preventing, detecting, and correcting the cause of errors in medical use. There are other QA procedures in 10 CFR 35, with the focus on QA for equipment such as a dose calibrator or teletherapy machine. Examples of the existing QA requirements include 10 CFR 35.50, "Possession, Use, Calibration, and Check of Dose Calibrators"; 10 CFR 35.51, "Calibration and Check of Survey Instruments"; 10 CFR 35.632, "Full Calibration Measurements"; and 10 CFR 35.634, "Periodic Spot-Checks."

C. REGULATORY POSITION

This regulatory guide provides guidance for developing a basic QA program acceptable to the NRC staff for complying with the proposed regulation, § 35.35. The NRC staff believes that most errors in administering byproduct material could be prevented by implementing a basic QA program designed by the licensee based on guidance contained in this guide. However, a licensee may propose a basic QA program based on other sources of guidance. The NRC staff would review such a program on a case-by-case basis.

The licensee's basic QA program is to contain the elements listed in the following sections, or alternative elements approved as license conditions.

1. RESPONSIBILITY, AUTHORITY, AND AUDIT

1.1 The responsibility and authority to establish and implement the basic QA program, as well as audits, evaluation, and corrective measures, will be documented in written policies and procedures. The management ("management" in this regulatory guide means the licensee's management) will regularly review the efficacy and adequacy of the basic QA program.

1.2 The basic QA program will include scheduled audits at intervals no greater than 12 months to evaluate the adequacy and effectiveness of the basic QA program and applicable management controls. Audits will be conducted following approved written policies and procedures by qualified personnel who are not involved with the activity being audited. The audit schedules and the audit personnel qualifications will be determined by management. Audit results will be documented, reviewed by management, and available for NRC inspectors. Deficient conditions requiring corrective action will be followed by management and re-audited as necessary. Audit reports will be distributed to appropriate management and organizations for review and follow-up.

2. GENERAL ELEMENTS FOR ALL MEDICAL USE -- DIAGNOSTIC AND THERAPY
(See Regulatory Positions 3, 4, and 5 for additional specific elements for radiopharmaceutical therapy and diagnostic use involving more than 30 microcuries of I-125 or I-131, brachytherapy, and teletherapy, respectively.)

2.1 Records (i.e., prescriptions,* diagnostic referrals,* and other written instructions or records) relating to medical use will be legible and written clearly, precisely, and in a manner to minimize the likelihood of misunderstanding.

2.2 All workers involved in medical use will request clarification from an authorized user or a physician under the supervision of an authorized user if any element of a prescription, diagnostic referral, and other written instruction or record is unclear, ambiguous, or apparently erroneous.

*The terms "prescription" and "diagnostic referral" are defined in proposed 10 CFR 35.2.

2.3 All workers will stop the medical use on a patient and seek guidance if there is an apparent discrepancy in records, observations, or physical measurements that may result in a diagnostic or therapy event (except in emergent situations). The worker may resume use after resolving the discrepancy.

2.4 Before medical use, the person administering the byproduct material will verify that the medical use is in accordance with the prescription or the diagnostic referral and clinical procedures manual.*

3. SPECIFIC ELEMENTS FOR RADIOPHARMACEUTICAL THERAPY AND DIAGNOSTIC PROCEDURES INVOLVING MORE THAN 30 MICROCURIES OF I-125 OR I-131
(See Regulatory Position 2 for general elements.)

3.1 Before writing a prescription, the authorized user or the physician under the supervision of an authorized user will personally review the patient's case to establish that the medical use is indicated for the patient.

3.2 Before administering a radiopharmaceutical, the authorized user or the physician under the supervision of an authorized user will personally make and date a prescription.

3.3 Any change in the prescription will be made by the authorized user or the physician under the supervision of an authorized user, will be recorded in writing in the patient's chart or in another appropriate record, and will be dated and signed.

3.4 Before administering a radiopharmaceutical, the identity of the patient, the radiopharmaceutical, and the dosage will be confirmed by the person administering the radiopharmaceutical to establish agreement with the prescription.

3.5 After administering a radiopharmaceutical, a qualified person under the supervision of the authorized user will make, date, and sign a written record in the patient's chart or other appropriate record describing the dosage administered, and this person will record the agreement, or lack thereof, between the radiopharmaceutical administration and the prescription.

---

* The term "clinical procedures manual" is defined in proposed 10 CFR 35.2.

4. SPECIFIC ELEMENTS FOR BRACHYTHERAPY
(See Regulatory Position 2 for general elements.)

4.1 Before prescribing a procedure, the authorized user or the physician under the supervision of an authorized user will personally review the patient's case to establish that the medical use is indicated for the patient's medical condition.

4.2 Before administering byproduct material, the authorized user or the physician under the supervision of an authorized user will personally make and date a prescription.

4.3 Before implanting the sealed sources, a qualified person under the supervision of an authorized user will verify that the radionuclide and source strength of the sources to be used are as prescribed. (Note: The licensee may use any appropriate verification method, such as checking the serial number behind a shield, using a radiation detector, or using clearly marked storage spaces for each type of sealed source.)

4.4 Any change in the prescription will be recorded in writing in the patient's chart or in another appropriate record and will be dated and signed by the authorized user or the physician under the supervision of an authorized user.

4.5 After implanting the brachytherapy sources, radiographs will be obtained and used as the basis for calculating the delivered dose (this may not apply to sources used for surface application).

4.6 After implantation, a qualified person under the supervision of an authorized user will promptly update and sign the patient's record to reflect the actual loading of the sealed sources and record any change in the prescription.

4.7 After administering the brachytherapy dose, a qualified person under the supervision of an authorized user will make, date, and sign a written record in the patient's chart or in another appropriate record describing the

administered dose; and this person will record the agreement, or lack thereof, between the brachytherapy administration and the prescription.

4.8 Before 50 percent of the prescribed dose has been administered, a qualified person under the supervision of an authorized user (e.g., a physicist, physician, dosimetrist, or technologist) who did not make the original calculations will check the dose calculations.

4.8.1 Manual dose calculations will be checked for:

(1) Arithmetic errors,

(2) Correct transfer of data from the prescription, tables, and graphs,

(3) Correct use of nomograms (when applicable), and

(4) Correct use of all pertinent data in the calculations.

4.8.2 Computer-generated dose calculations will be checked by examining the computer printout to ensure that the correct inputs for the patient were used in the calculations. Alternatively, the dose will be manually calculated to a key point and the results compared.

4.8.3 If the manual calculations are performed using computer outputs or vice versa, the manual portion of the calculations will be checked as stated in 4.8.1 and the computer portion of the calculations will be checked as stated in 4.8.2. Particular emphasis will be placed on verifying the correct output from one type of calculation (e.g., computer) to be used as an input in another type of calculation (e.g., manual).

4.9 If the prescribing physician determines that delaying treatment in order to perform the checks of dose calculations (see Regulatory Position 4.8) would jeopardize the patient's health because of the emergent nature of the patient's condition, the prescribed treatment may be provided without first performing the checks. The prescribing physician will make a notation of this determination in the records of the administered dose. The checks of the calculations will be performed within two working days of the treatment.

5. SPECIFIC ELEMENTS FOR TELETHERAPY
(See Regulatory Position 2 for general elements.)

5.1 Before prescribing a teletherapy procedure, the authorized user or the physician under the supervision of an authorized user will personally review the patient's case to establish that the medical use is indicated for the patient's medical condition.

5.2 Before administering a teletherapy dose, the authorized user or the physician under the supervision of an authorized user will personally make and date a prescription and approve a treatment plan that includes the treatment modality, the treatment volume, the portal or field arrangement, the total dose at a specified location, and the dose per fraction or the number of fractions.

5.3 Any change in the teletherapy prescription will be recorded in writing in the patient's chart or in another appropriate record and will be dated and signed by the authorized user or a physician under the supervision of an authorized user.

5.4 After administering a dose fraction, a qualified person under the supervision of an authorized user will personally make, date, and sign a written record in the patient's chart or in another appropriate record describing the dose administered; and this person will record the agreement, or lack thereof, between the teletherapy administration and the prescription.

5.5 A weekly check will be performed to detect errors in the daily cumulative dose summations and in implementing any changes in the prescription that have been made in the patient's record.

5.6 Before 25 percent of the prescribed dose has been administered, a qualified person under the supervision of an authorized user (e.g., a physicist, physician, dosimetrist, or technologist) who did not make the original calculations will check the dose calculations.

5.6.1 Manual dose calculations will be checked for:

(1) Arithmetic errors,

(2) Correct transfer of data from the prescription, tables, and graphs, and

(3) Correct use of all pertinent data in the calculations.

5.6.2 Computer-generated dose calculations will be checked by examining the computer printout to ensure that the correct inputs for the patient were used in the calculations. Alternatively, the dose will be manually calculated to a key point and the results compared.

5.6.3 If the manual calculations are performed using the computer outputs or vice versa, the manual portion of the calculations will be checked as stated in 5.6.1 and the computer portion of the calculations will be checked as stated in 5.6.2. Particular emphasis will be placed on verifying the correct output from one type of calculation (e.g., computer) to be used as an input in another type of calculation (e. g., manual). Parameters such as the transmission factors for wedges and the radioactivity of the sealed source used in the calculations will be checked.

5.7 Independent checks of certain full calibration measurements will be conducted as follows.

5.7.1 After a full calibration measurement that resulted from changing the source or whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay, an independent check of the output for a single specified set of exposure conditions will be performed. The independent check will be performed within 30 days following the full calibration measurement.

5.7.2 The independent check will be performed by either:

(1) An individual who did not perform the full calibration by using a dosimetry system other than the one that was used during full calibration (the individual will meet the requirements specified in 10 CFR 35.961 and the dosimetry system will meet 10 CFR 35.630(a)), or

(2) A teletherapy physicist (or a physician, dosimetrist, or technologist who has been instructed by a teletherapy physicist) using an accredited thermoluminescence dosimetry service available by mail that is designed for confirming teletherapy dose rates and that is accurate within 5 percent.

5.8 The annual full calibration measurements will include the determination of transmission factors for the beam modifying devices (for example: trays, wedges, stock material that is used for making compensators, blocks, boluses, and the recastable block material).

5.9 Before 25 percent of the total prescribed dose has been administered, a physical measurement of the output will be made if the patient's dose calculations include (1) field sizes or treatment distances that fall outside the range of those measured in the most recent full calibration, or (2) a beam modifying device (except blocks, boluses, or stock material) not measured in the most recent full calibration measurement.

5.10 Before the first use of a computer program for dose calculations or after performing full calibration measurements pursuant to 10 CFR 35.632(a)(1) and (a)(2), depth dose calculations will be made with each computer program that could be used for therapy dose calculations for the following exposure conditions: (1) an open field in air at eight angles to the isocenter: 0 degree and seven other angles with 45-degree increments; (2) a field with and without the wedge of greatest angle into water at a 45-degree angle; and (3) an irregular mantle field into water. The results of the computer calculations will be checked against phantom measurements with the same exposure conditions. (For computer programs involving relative dose calculations, additional manual or computer calculations may be needed to determine doses.)

5.11 If the prescribing physician determines that delaying treatment in order to perform the checks of dose calculations (Regulatory Position 5.6) or physical measurements (Regulatory Position 5.9) would jeopardize the patient's health because of the emergent nature of the patient's condition, the prescribed treatment may be provided without first performing the checks of dose calculations or physical measurements. The prescribing physician will make a notation

of this determination in the records of the administered dose. The checks of the calculations or physical measurements will be performed within two working days of the treatment.

D. IMPLEMENTATION

The purpose of this section is to provide information to medical use licensees and applicants regarding the NRC staff's plans for using this regulatory guide.

This draft guide has been published for public comment to encourage public participation in its development. Except in those cases in which a licensee or an applicant proposes an acceptable alternative method for complying with specified portions of the NRC's regulations, the guidance in the final regulatory guide reflecting public comments will be used by the NRC in the evaluation of basic QA programs for medical use.

DRAFT REGULATORY ANALYSIS

A separate regulatory analysis was not prepared for this draft regulatory guide. A regulatory analysis was prepared for the proposed amendments to 10 CFR Part 35 (54 FR), and it examines the costs and benefits of the proposed rule as implemented by the draft guide. A copy of this regulatory analysis is available for inspection and copying for a fee at the NRC Public Document Room, 2120 L Street NW., Washington, DC, under file 54 FR .

TENTATIVE SCHEDULE FOR PILOT PROGRAM
(Note: this schedule reflects periods of time, a more detailed schedule will follow in about one month.)

Mid-January	Notice of proposed rule published in Federal Register
End-January	Finalized list of attendees; arrangements made with hotels at sites of workshops (tentatively NY, Atlanta, Chicago, Dallas, San Francisco)
Beginning-February	Send workshop details and information packets to participants.
End-February	First set of workshops (1-day each)
Beginning-March	Revised information (incorporating workshop results) sent to participants
May 7th	Participants QA programs sent to BNL
May 14th	Start pilot program
July 13th	End pilot program
July 31	Participants' evaluation information sent to BNL
Mid-August	Second set of workshops (2-days each)

NRC considers results of pilot program and workshop comments in revisions to proposed rule and draft regulatory guide.