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

UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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MEETING WITH THE AGREEMENT STATES

ON THE

PROPOSED QA RULE AND REPORTING REQUIREMENTS

Embassy Suites Hotel

Salon C

Irving, Texas

Tuesday, December 18, 1990

The above-entitled proceedings commenced at 9:10 o'clock a.m., pursuant to notice.

John Telford, Discussion Chairman, presiding.

PRESENT:

John L. Telford
Anthony Tse
Brad Pounds
Larry Anderson
Bob Doda
Steve Collins
Betsy Salus
Jon R. Sharp
Robert R. Kulikowski
William P. Dundulis
Larry Camper
Ed Kline
Lloyd Bolling
David Zaloudek
David Wood
Rita Aldrich
Rick Kelley
Kirksey Whatley
Terry Frazee

PROCEEDINGS

[9:10 a.m.]

MR. TELFORD: Let's go on the record. Good morning. My name is John Telford. I'm from the NRC Headquarters. I'm the Section Chief that's in charge of this rule-making effort.

I've met with some of you before at a meeting back in March of this year. I've seen others of you at the workshops that we had as a part of our program. A few of you I've seen at the State meetings.

Today we're here for what we call the Q.A. team. We're going to review and talk about the proposed rule.

I'd like to start with allowing you to introduce yourselves to first. For the record, state your name and the State you represent. I'll start over here with Terry.

MR. FRAZEE: I'm Terry Frazee, from the State of Washington.

MR. WHATLEY: I'm Kirk Whatley, from the State of Alabama.

MR. KELLEY: I'm Rick Kelley from Arkansas.

MS. ALDRICH: Rita Aldrich, from New York State Department of Health.

MR. WOOD: David Wood, from Texas.

MR. ZALOUDEK: David Zaloudek, Louisiana.

MR. BOLLING: Lloyd Bolling, NRC State Agreement

Program.

MR. KLINE: Ed Kline, Office of Nuclear Regulatory Research, Headquarters.

MR. CAMPER: Larry Camper, Section Chief, Medical and Academic Section, NRC Headquarters.

MR. TSE: Anthony Tse, from Research, NRC.

MR. ANDERSON: Larry Anderson, State of Utah.

MR. DODA: Bob Doda, NRC Region 4.

MR. COLLINS: Steve Collins, Illinois.

MS. SALUS: Betsy Salus, Illinois.

MR. SHARP: Jon Sharp, Texas Department of Health.

MR. KULIKOWSKI: Rob Kulikowski, City of New York.

MR. DUNDULIS: Bill Dundulis, Rhode Island Department of Health.

MR. POUNDS: Brad Pounds, representing the Society of Nuclear Medicine.

MR. TELFORD: Okay. Let me call your attention to the agenda. I put on here the purpose of the meeting.

The purpose is to talk to all of you about the rule, about the reporting requirements, and the Guide.

What I had in mind was to go through the rule, to sort of explain to you its intentions, what it tries to say, what it does not mean.

Then, to have a discussion any apparently conflicting State requirements, or any State requirements

that you would like to bring up that you think might be of interest and might be applicable to what we're trying to do with this part. And then have a round table discussion on how to modify what we have, so that it's sort of mutually agreeable as the way to put.

So, I've broken this into large chunks. The first chunk is the rule. The next chunk is the reporting requirements.

Tomorrow we will continue our discussion on the reporting requirements. Then following that, we the Regulatory Guide.

So, is this an acceptable agenda? Would you like to modify it in some way?

You won't hurt my feelings, now.

MR. COLLINS: If we come up with ideas later for modification, can we introduce them?

MR. TELFORD: We're not going to be too formal. We're going to be pretty informal. What we're going to worry about is what we're going to do today and see how far we get. So, I just wanted to make sure it's acceptable to you as to what we're going to cover and how we're going to go about it.

MR. FRAZEE: John, will you be able to bring us up to date on some of the other meetings that have gone on as we go through each of the sections?

MR. TELFORD: Sure. Some of you have already seen a lot of this.

MR. CAMPER: Let me make a preliminary comment before you go into your detailed schematic.

I'd like to say to each of you -- I've discussed with a number of you, at the Agreement States meeting in Nevada, some concerns that each of you had about your degree of participation as Agreement States in this particular rule-making process to date.

I came away from that meeting in Reno with genuine concern that we go to the Agreement States' representatives and that we get input. At that time those discussions I shared with a number of you the fact that we were meeting with organizations like AABM, American College of Physicists, and the College of Radiology and what have you, as well as most pilot meetings with the participants in our pilot program.

We wanted to make sure that, as a result of those discussions that I had in Reno, that the Agreement States felt they were having maximum opportunity to input as to the rule.

A number of changes have taken place as a result of our meetings during the last several months with some of these organizations. I'm sure that John will agree that we can share with you some of those findings and some of the

projected changes, and what have you.

We are currently re-writing the rule at this point, literally as we speak, almost. And we intend to present the staff version to our Advisory Committee at these meetings that are coming up in January.

So, this forum for the next two days is an extremely important one for both us. This is the opportunity for those of you in the Agreement States to have a direct impact and to work directly, in a workshop format, one on one, sleeves rolled up, with those individuals -- four or five as a team -- actually writing the rule here.

So, we're looking forward to the dialogue, and we think this meeting will be as productive and as fruitful as the others have been.

I think that some of the things learned and some of the things that we're contemplating changing at least at our level -- and I emphasize the staff level -- I think you'll find are positive and constructive. So, we are encouraged. We hope that you'll give us a lot of good input. This is the opportunity to do it.

So, please, speak openly and candidly as fellow regulators and see if we can come up with something here that makes some sense.

Bill?

MR. DUNDULIS: Larry, at Reno, you had indicated

that the Commission had called for tracking this with a Commission Paper and basically a final Rule by March '91.

Based on the other discussions and this meeting, is that still your target?

MR. CAMPER: That's correct, it is.

Kirk?

MR. WHATLEY: Since you're re-writing the Rule and none of us have had an opportunity to look at it, are we going to have an opportunity to look at it?

MR. TELFORD: We will discuss -- pardon me?

MR. COLLINS: Before publication, possibly, the final rule?

MR. TELFORD: Two answers. What Larry is saying is that there are five people, five staff members, who are re-writing the Rule. Four of them are here. We are Tony Tse, Larry Camper, Ed Kline and myself. But we have one missing member. We have had some working sessions.

What he's saying is that we are willing to share with you our thoughts. And, as I go through this, I will indicate where we're thinking changes and exactly what we're thinking of changing. It will be laid out for you.

MR. WHATLEY: Will we have an opportunity to see it and comment on the Rule before it's --

MR. TELFORD: Well, there will be an ACMUI meeting. That's my second answer. ACMUI meeting is January

14 and 15. It's a public meeting and at that time we can say to the public, including everybody, this is our version of the Rule.

MR. WHATLEY: Will the Agreement States be invited to that meeting?

MR. CAMPER: It's a public meeting.

MR. TELFORD: You're invited, certainly.

MR. COLLINS: All members of the public.

MR. CAMPER: It is a public meeting of the Advisory Committee.

MR. BOLLING: Yeah. We'll most likely pay for at least two people from the States to go that meeting. Somebody from the Conference and somebody from the Organization of Agreement States.

MR. COLLINS: In the spirit of cooperation, as expressed in your statute and in our agreements, we would like to work with you on the draft of this Rule.

MR. CAMPER: That's what you're doing today.

MR. TSE: That's why we're here.

MR. COLLINS: We haven't seen a copy of the draft Rule. We would like to work with you on the draft Rule and be able to view the drafts and make comments as we go concurrently with ACMUI. That's what we would like, I think.

Almost two thirds of the medical licensees are in

the Agreement States.

MR. CAMPER: Well again, I can only emphasize that the re-writing of the Rule is taking place. We had sessions where we were actually sitting down dealing with some of the language and what have you.

As John has indicated, we will share with you today and tomorrow our thoughts and where we're headed.

This is the opportunity to discuss it and to work on it and have some input right now. This is working session, I could say.

MR. COLLINS: And it's very good.

MR. TELFORD: Let me go a little further and let me say yes to your question.

What you're literally saying is that at some point in January or February the Agreement States would like to see a draft. We're trying to work that out.

MR. CAMPER: Right.

MR. TELFORD: This is a good beginning. Let's make sure we have a good finish. Let's make sure that you guys see a draft.

But the reason that we're all a little nervous is that, at some point, when we start to run off this review process, the staff at this level kind of loses control in that somebody else in a higher level of management want so get in their input. They're way above us.

So we want to share with you and be totally honest as to what we're starting with and what our inclinations and objectives are.

But, yes, we will try and put you into the review process.

Yes?

MR. KULIKOWSKI: Larry --

MR. CAMPER: Thank you, John, for clarifying the point. He's right. The reason we're a little bit hesitant, please understand, we lose control of thing, just like he said, as it starts up the road.

It's our intention to give to the Agreement States a copy. It's our intention. I suspect that we'll be successful in doing that.

Also, too, recognize that this particular rule-making process and some of the changes that we're going to be suggesting as a staff, as it moves up through our organization we're going to have to do a considerable amount of discussing and negotiating and what have you. So, we're a little sensitive about this.

But it is our intention to share with you a copy of the draft and to solicit your input.

MR. COLLINS: Is there any problem whatsoever if there's a need to address this, or if it would be beneficial to address this on a level lower than the Commission, let us

know. Because we'll address our concerns to the appropriate level to get input, if that's a problem.

MR. CAMPER: I appreciate that, Steve. I need to make one more comment, too, about your ACMUI comment.

The ACMUI meeting is a two day public meeting. The ACMUI has an extremely full agenda, of which the Quality Assurance Rule is one item. We have to stick to a very strict agenda to cover all the items. It's not going to be a situation where we can turn it into a forum for exchange between the States and ACMUI and what have you.

I understand your point, and your interest in this point we'll make. But, unfortunately, due to the nature of that Advisory Committee and the intense agenda, and the public forum and what have you, it's a different kind of scenario. We'll have to deal with it accordingly.

I'm sorry. Bob?

MR. KULIKOWSKI: Still on the ACMUI. Now, I talked to a member of your staff a couple of weeks ago and he has to, I guess -- trying to get myself into that meeting to make some comments. However, I was asked by your staff member to send a letter to John Mclean outlining what my comments would be.

It seems to me that that sort of, at this point, I'm at a loss to send a letter like that. I don't know what the changes are that are going to be affected. It's no

sense commenting on a Rule that was published in January 1990, when it's been changed, when you're contemplating changes. I'm not going to get up there.

MR. TELFORD: Let me guess that, on Thursday --I don't know exactly what to say.

MR. KULIKOWSKI: Okay, but they've asked for this letter two weeks ago to be submitted.

MR. TELFORD: That's all right. Well, don't worry.

MR. CAMPER: Let me explain to you as I did in Reno, Robert. Going -- we would encourage you. I'd like you to speak at the ACMUI meeting. I'd particularly like you to speak because of your experience in New York City. As you said, the decay rule is already on your books. I think it's meaningful and important.

But if you want to speak at the meeting -- and I would like you to do so -- I do need a letter requesting a opportunity to speak because it's part of the procedure. You understand.

MR. KULIKOWSKI: I understand.

MR. CAMPER: With regard to what you want to say, I would think that between discussions between you and I individually, and discussion with this Q.A. team, as well as this interaction for the next two days, I think you'll be able to come away with an understanding and some ideas of

what you might like to say.

So, over the next two days be productive to that end.

MR. KULIKOWSKI: When I talk to Norm around Thanksgiving time.

MR. CAMPER: I understand.

MR. KULIKOWSKI: He outlined very specifically what I should say in the letter to John Mclean. One of the things was what I wanted to say. That's putting the cart before the horse, if you will.

I have no idea. Why should I comment on something that was published a year ago when it's now going to be changed, probably substantially.

MR. CAMPER: Well, I think perhaps after the next two days that you will away with a better idea of what you might like to say. And I would encourage you, please, mail that letter into us right away. Because we'd like to have you speak there. I think you'd have a good perspective to add.

Yes, Kirk?

MR. WHATLEY: You mentioned that you'd like to share some things that were sensitive. Help me understand, what can be sensitive about a Q.A. rule that you cannot share with Agreement States, with the people in this room? I don't understand that.

MR. TELFORD: Let me explain. That's not the implication at all, Kirk.

The implication is that we can share with people in this room. During our office appearance process we can, of course, send you a letter saying this is the draft, don't let anybody else have it. This is pre-decisional information. We want your comments.

But, only because it's pre-decisional information are we a little nervous. And it's something that we routinely do, to send drafts to the States. I believe we did this during the proposed Rule, and we will do so during the development of the final release.

So, that's what my words meant.

MS. ALDRICH: John, I feel like I'm in a time warp. We're talking about this as being a good beginning. We had a meeting in March, which was three months after the Rule was published.

I have a feeling that the comments you're going to get today, if we are assuming we're talking about the same animal, are essentially the same as the ones you got in March.

We have no indication that those comments made any difference at all. In fact, I wonder whether that meeting, those comments, also a follow up letter I sent afterwards to Mr. Miller are even formally entered as comments. Could you

tell me whether that is the case?

MR. TELFORD: That is the case.

MS. ALDRICH: They are formally entered as comments?

MR. TELFORD: Yes.

MS. ALDRICH: It would have seemed to me that, after that meeting and whatever changes you might have made in response to it, that we would have had some second meeting, or something would have happened.

All of a sudden, here we are now at the time when the Rule is being written as we speak. There again, what's gone on in the meantime? You know, we're talking nine months, and we have no indication that that made any difference.

The other thing is that you talked about including the States in development of the Rule, that we had received some draft materials before that -- January '90, or I think it was published actually in December '89 Rule.

Nothing that we saw prior to the publication of that Rule was anything like the Rule that was published. So, no, we did not have any participation in what was published for consideration.

MR. WHATLEY: Just -- There are a lot of the Agreement States that are not here. I think most States never have seen it. I didn't know until this morning that

the Rule had been, or was even being re-written.

As I understand it, the opportunity for the Agreement States to comment will basically be at this meeting here. Most of the Agreement States were not even aware that there is a new Rule to comment on.

MR. TELFORD: Well, let me first respond to Rita's remarks.

Rita, I use the phrase good beginning because, with the group sitting here it will, I think, be a good beginning to have a real impact to what the final Rule is going to look like.

At the meeting we had n March, there were four States invited. The Office of State Programs invited those four States. We certainly listened to those comments and we'll have to wait 30 minutes or an hour until we get to there before you can judge for yourself whether or not some of the things that we're going to say respond to the comments that we heard then.

Also, I'll confess to you that we have everything we've done since then. And I guarantee you that grass has not been growing on our feet. We've been very, very busy.

You're trying to say, don't ignore us. We're trying to say, we're trying to do just the opposite.

Before we did the pilot program, before we even selected any volunteers, the Office of State Programs sent a

letter to each State and said if any State is interested -- before the March meeting -- is any State is interested in talking about this Rule, the Rule Routing Team will come and talk to you.

Now, I know that's what the letter says because I wrote that. And do you know how many letters we got? Very few.

Now, we had the meeting in March

MS. ALDRICH: You know, John, first of all, I never got a copy of that letter. Believe me, I would not have ignored something like that.

MR. TELFORD: Well, I wouldn't say it if it's not true.

MS. ALDRICH: Okay.

MR. TELFORD: Now, after the Reno meeting I personally faxed a letter to ten States. And Mr. Miller of State Programs sent a similar to all States saying we're going to have this meeting, any State that's interested please attend. You know, we even paid for two people to come, to represent the Conference and to represent the Subpart G Committee. So --

MR. WHATLEY: John, what was the date of your memo that you sent to the States? The Agreement States meeting was some time back. What was the date of your letter that you sent to those?

MR. TELFORD: Yes. Yeah, I've got to look it up. Let's go off the record just for a minute.

MR. WHATLEY: I would like for that to be on the record.

MR. TELFORD: I'm sorry, it will be.

[Discussion off the record.]

MR. TELFORD: Let's go back on the record. I have one letter here from Mr. Miller to all agreement and non-agreement states, dated December the 4th, and this is the same letter dated December the 5th. The faxes that I sent to the 10 states were in advance of this one by a couple of days, so we're talking the first of December, the first week of December.

MR. WHATLEY: Two weeks ago.

MR. TELFORD: Yes, sir. That was after the renal meeting and that was after several telephone conversations. I called Greta and Rita and Curt to determine if there was an interest in having another meeting and also to determine some of the issues.

Yes, Larry?

MR. COLLINS: I have two comments. Number one, it's very difficult for states to get out of state on that short notice. It was very difficult for me.

Secondly, I think the one point that you made earlier about whatever we accomplish here maybe being

reviewed and changed by upper management. I think upper management in NRC better start realizing that the states intend to be heard in these issues.

If they don't start recognizing that, it's going to get very tough on them politically. We discussed this in the agreement state meeting in Reno and I think the position of the agreement states is getting very firm.

MR. TELFORD: Please don't read too much into my remarks about what upper management will change or not. I merely through that out as a caution that, to be honest with you, there's some point in which others control what goes to upper management for review.

In truth, they don't change it really all that much. Sometimes our legal counsel and counsel from IGC makes us be very specific about time. You can't say a month, you can't say a week, you've got to say 7 days and things like that, but it's really not that bad.

MR. COLLINS: What division of compatibilities is the misadministration rule?

MR. TELFORD: Good question. How about Division 2.

MR. COLLINS: The only thing published by NRC, by NRC staff, was by Division III, the rule. Nothing else has ever been put in writing.

MR. TELFORD: Division III?

MR. CAMPER: I'd like to make another comment regarding Larry's comment. I want you to understand that upper management at NRC is aware of this meeting and fully endorses this meeting as yet another means of trying to advance the communication between our agency and the agreements states on this particular rule and perhaps on related issues in the medical area, so there is intense support and desire to do that by the management.

Also, too, I think it might be helpful, John, if you would put that in your statement a little while ago that some of the agreement states weren't aware that this was going to a final rule. I find that interesting.

MR. WHATLEY: No, let me correct that. That wasn't what I said.

MR. CAMPER: You said they didn't understand that a rule was being written.

MR. WHATLEY: That had been revised. They've had an opportunity to comment on the old one, but you just said it's going to be revised completely or it's going to be revised and my comment - that they have not had an opportunity to comment on the changes.

MR. CAMPER: It might be helpful, I think, if you could take a couple minutes to review the normal process associated with rulemaking as compared to the process that we're following with this particular rule.

MR. TELFORD: Lloyd, you had a point?

MR. BOLLING: Before we do that, let me talk a little bit about compatibility. Most of you know that the NRC state agreement program is revising its compatibility regulations, if you will, and it could be that the divisions of compatibility, Divisions I and II and III will be done away with. We'll come up with some kind of a statement which says, in effect, that any rule that is being contemplated has to be reviewed for its health and safety significance, and that will be the determining factor as to whether or not compatibility will be applied.

Let's not focus too much on Divisions I, II and III. I think we're going to probably see some more practical application of what the term, "compatibility," as it has to with regulations as well as the entire program --

MR. COLLINS: I apologize for bringing it up.

MR. BOLLING: If you didn't, I was.

MR. COLLINS: We've been working with the states anyway.

MR. BOLLING: If you didn't bring it up, I was going to.

MR. TELFORD: I think that's a good point, Steve, because I think that's something that is of keen interest to us. So, let me forget Division I, II and III. Let me say that we've been working on this rule since October of '87

and it had always been our intention that because the Commission says that it's a matter of compatibility, our intention is to say, yes, it will be a matter of compatibility, but this is the minimum that your licensees need to do.

If you want to be more strict, you can. Forget about Division I, II or III. That's really been our intention all along. There were some hands up.

MR. KULIKOWSKI: Getting back to Lloyd's comment, as I read it, this would be the Division II rule compatibility. Are state programs going to look at this when you make a determination and you say, it's going to be compatible?

You need to have something more than just compatible. It's going to be sort of a fly-by-the-seat-of-the-pants kind of determination on a case-by-case basis so there can be some definite criteria the Commission is going to put forth.

MR. BOLLING: The criteria for compatibility is going to be one of the things that's going to be looked as well as part of this study which will become a Commission paper. It will go up to the Commission. They will review it, vote on it and determine what this thing, compatibility, is; how it's applied, how it's defined and so it's really a pretty open question at this point.

MR. TELFORD: What Lloyd is talking about is the revision of the way that the Commission determines compatibility for all rules. For this rule, our Commission paper will suggest to the Commission that this rulemaking be the old Division II.

So, he's talking about a very general way of doing business, so his comments are very generally warning you that there's a change coming, but if we focus on this rulemaking, I wanted to tell you the way that we're going to propose it.

MR. KULIKOWSKI: Just one quick question for Lloyd, and I will phrase it in a positive way, I hope. How much input will the agreement states have in this study on compatibility, based on the assumption that the agreements states will have some input?

MR. BOLLING: I think you've already had some input via the questionnaire that was filled out back in Utah at the state meeting, the conference meeting. When the Commission paper goes up to be voted on, the Chairman and the other Commissioners obviously are going to want to know what are the state views on these things? At that time, somewhere between the time it leaves the EDO's office and by the time it gets to the Commission, you will be asked to comment on something you will have before you and you will have reviewed.

MR. KULIKOWSKI: What's the timeframe on that?

MR. BOLLING: I don't know.

MR. ANDERSON: Lloyd, there is a taskforce of the agreement states, people who are working on that. We'll have input into that decision.

MR. BOLLING: In addition, there will be a mass mailing to all agreement states, probably non-agreement states as well, because it does have some implications for them if they're concerned with becoming agreement states. There wi be requests for general review or comments.

MS. SALUS: Before we get to the substantive matters and issues in Part 35, I'd like to make what I think is a positive observation that on less than two weeks notice, representatives from about a dozen states are here. This obviously something that's very important to each of these states.

I think that good work is going to come cut of this. I also think that what the states' concerns are expressed today or in the near future or will be seen in the revised draft, needs to be considered very carefully and should be expected to be followed up on by NRC; that whatever concerns we raise at this meeting don't drop, regardless of how they're handled by the staff.

We're very concerned about the subject matter here because this affects more than half the licensees that are

going to be governed by this rulemaking effort, either as NRC licensees or agreement states licensees under compatible or complimentary rulemaking. I think that's a positive observation.

MR. TELFORD: Okay.

MR. BOLLING: I'd like to also say that the interest goes as far as Alaska. I got a call the other day from John Stewart up in Alaska, and he's expressed an interest in getting some information about what was discussed at this meeting. I've had letters and phone calls from the states of Maryland, California and a number of other states that expressed regret at not being able to attend, but obviously are quite interested in what's going on.

Just because they're not here, doesn't mean they're not interested.

MR. TELFORD: Do we have any more general business, agreement state business?

MR. CAMPER: Any additional state sovereignty questions?

MR. WHATLEY: I want to make a disclaimer. I'm serious about that. My comments here today do not reflect my state. I'm here as chairman of the Suggested Regulations Committee on Nuclear Medicine, and I just want it on the record that my comments here today are mine and they do not

represent my bosses or anyone else in my office.

MR. TELFORD: Okay. Are we ready now to talk about the QA rule? Folks, from my point of view, I think I have been trying pretty hard to get input from the states. What you're really telling me is it's not working.

Okay, we're going to spend two days together and we're going to give it a shot. If this is not enough, then we'll meet again in February. January is pretty booked up, but I'll let you know where we're at now, and if you guys have reservations, we'll do this again in February.

I think today is the December the 18th. I've been on the road for three days and I don't know what day it is. It's December 18th, and that's a couple of months notice. If you'd like to pick a date in February, that's fine with me.

KULIKOWSKI: We need a date and place.

MR. CAMPER: It's conceivable, at the end of this meeting that we can set a date at that time.

MR. TELFORD: How about Rockville?

MR. CAMPER: Come to Washington.

MR. TELFORD: The first week in February. Let's recap what's happened since then. Now, I realize that most of you sort of are observing this process from the sidelines. This is my attempt to bring you into the game. Mr. Camper suggested that I review for you the usual

rulemaking process and then this process. To the extent that that helps you understand what we're doing with this rulemaking, I'll do that.

The basic thing here is that we're doing a whole lot of work for this rulemaking that we don't do for other rulemakings. For example, if we're going to do an ordinary rulemaking, we develop a draft within the staff. We send it for what we call Division review.

Typically, at that time, we send it to the agreement states for interaction with the states. Then we file the comments, we make the changes and we go for what we call officer review. That's one level up in organization.

Then we make the changes that we need to make in order to get officer concurrence, then we send it to our Executive Director of Operations. He peruses it, it goes to the Commission. The Commission typically needs it for about a month.

They make a decision. We get a memo that what's we call the staff requirements memo that tells us what to do with the rule, what changes to make before we publish it. We publish it, minimally, 75 days in the Federal Register. We collect the comments and analyze those.

We group them into categories because we can -- on this rule, we had about 80 comments. On other rulemakings that we've worked on, we've had 400-500 comments. We

collect them into categories, maybe 10, 15, or 20 categories of like questions.

You respond to those and you give a response which will be in the Federal Register Notice. Then we repeat the process, going back to Division review and then that's where we would send it for comments to the states if they're involved, then for office review, back to the EEO and back to the Commission. They make a determination and publish a final rule.

Now, in contrast, this time around, we've been told by the Commission on several occasions, in writing, to work with the agreement states, to work with all medical associations and to conduct a pilot program. We have the pilot program and we have the manpower with all the clinical associations that have an interest in this rulemaking. I'll tell you about those meetings.

We are attempting to work with the agreement states so that's why I instigated this meeting and that's why we're here. I'd like to get back to Terry's earlier question and recap a little bit of history for you.

This did start back in 1987. The NRC published a proposed rule on what we call the basic quality assurance. We also gave advanced notice of rulemaking on comprehensive quality assurance. The staff briefed the Commission in March of '88 and said, here is the final rule.

This was a prescriptive rule. It says, you do the following 12 things, period. The medical community didn't quite like this because they didn't want to be told how to do it. If we just said to them, have a QA rule, it wouldn't have been nearly as bad. We told them exactly what to do.

They didn't like that, so we looked at options and the Commission chose to have a performance-based rulemaking. It's very important to keep in mind that what we have is a performance-based rulemaking. Following that in '88 we had one public meeting where we took the ACNUI and we said we're going to create a subcommittee and we're going to entertain public comments.

We held that meeting and then in January of '89, we had a two day meeting with selected medical use licensees, 9 licensees per day. On one day we had the therapy folks and the next day we had the radiopharmaceutical folks.

Then in March of '89, we met with the QA committee of the American College of Radiology in Philadelphia to discuss the regulatory guide and some ideas for the rule and obtained their advice. In June of '89, we did the draft proposed rule.

This was like on the 1st of June and on the 30th of June, the Commission said, make some changes. We made the changes and we gave it back to them. In August, the

Commission deliberated on this rule from August to December, a rather long period ot time. We got what we call a Staff Requirements Memorandum in December of '89. It said, make the following changes and publish it.

So, we published it in January of this year in the Federal Register. The Staff Requirements Memorandum said to do a pilot program, so we started our selection process for participants. Part of that process was the letter to each agreement state, saying, we want to be able to select volunteers from the agreement states.

If you would allow your licensees to be selected -- we can't guarantee you'll get somebody, but if you happen to select somebody, please agree to that. Secondly, send us a list of your licensees according to these programs. All states did; all agreement states did that.

In March and April we conducted what are called the pretrial period workshops which were a one-day meeting each in five locations around the NRC's five regions. In May, the 60-day trial of the rule was started.

What that means is, during the first workshop, we explained the rules to the volunteers and we told them what we wanted them to do. They were to develop a QA program which met the rule, but if there were any conflicts with our proposed rule and state requirements, Mr. Bolling was there at the meetings and he stood up and said, you follow the

state requirements during the 60-day trial period; right, Mr. Bolling?

MR. BOLLING: Right.

MR. TELFORD: So, the trial period was conducted and now we have a group of 60-odd licensees that had done more than just thought about this or talked about his rule. They actually tried it for 60 days.

We skip ahead to this item because actually it was August and September and then even into October that we have five more -- we had four workshops and -- scheduling of these folks was very difficult so we had a makeup session in October in Rockville in our attempt to go the last mile to get the input from these folks. We had two-day meetings and we went through the rule, the reporting requirements and the guide with these folks.

We said, now that you've tried this, we want to hear about your experiences and we want to here how you would want to apply this proposed rule. We conducted those meetings -- I only have one bullet up here on the meetings. I apologize that my viewgraphs are woefully out of date.

For instance, I don't have a bullet here for the March meeting with the representatives of the four agreement states. In August, we met with the ACNP and SNM, an all day session in Rockville. Now, let's see, let me think.

On November 19th, we had our first meeting with a

group of five societies. It was AA, PM, ACMP, ACR, AES and ASTRO. Does everybody know those societies?

We met on November the 19th. We didn't complete our discussions, so we held our second meeting with them on December the 15th which was last Saturday. We met yesterday in Chicago with the JCAHO because a lot of folks like our volunteers and others have told us, gee, you know, JCAHO was already doing part of this. You better go talk to them and find out how you interact with them or how you can minimize the impact to the licensees.

We did that. That covers our meetings.

MR. CAMPER: Did we mention the ACNP and SNM in July?

MR. TELFORD: Yes, and we've got ACNP and SNM. Does that answer your question?

MR. FRAZEE: No.

MR. TELFORD: Okay, what's your real question?

MR. FRAZEE: For the last few series of meetings, what has been their input? What did they object to? What has been your reaction? It's building on the same thing. You've got a January version and then there have been discussions that have come along and internally, you're digesting this and you're making decisions at a staff level and the -- you're taking all that stuff in and you're being real good about dealing with all these groups and

everything, but from our standpoint, it's all going into a black hole and we're not seeing anything come out.

I'm asking, what's going on in this black hole?

MR. TELFORD: This question does not bother me at all, because I've heard it 14 times. And the way I will address this is the way I've done before, is when we go through the rule, I'll tell you. This is a term people don't like. They don't like this objective. Here's what we've done. Okay? So I'll lay it out for you.

MR. WHATLEY: Was the draft -- what was discussed in your latest meetings?

MR. TELFORD: In all those meetings --

MR. WHATLEY: The proposed changes, or the --

MR. TELFORD: The proposed rule, as published?

MR. WHATLEY: In January?

MR. TELFORD: Yes, sir.

MR. WHATLEY: Do they know it is being revised?

MR. TELFORD: Well, as we met with the various societies, each one had a different point of view. And some things that they wanted to do, we could say yes to. It sounded good to us. Some things we had to say no to. We had a lot of discussion. What I'm really going to bring to you is the fruit of all this labor, and say, guys, this is the latest.

MR. WHATLEY: You weren't revising -- well, I

guess you've continually been revising, as you receive comments.

MR. TELFORD: Well --

MR. WHATLEY: To get down to it, I called you a week and a half or so ago and asked you did I have a current copy of what was going to be discussed here today. And the answer was yes.

MR. TELFORD: That's right.

MR. WHATLEY: And I get here this morning and find out that -- well, I don't want to quantify that.

MR. TELFORD: You found out that we've been working on the rule, we've made changes, and that the changes are in our head, and we're here to share those with you and discuss those with you. At this point, we want to be honest with you. I think they are tentative changes. I'd like this group to accept those changes, but you may not like them. So I don't want to call them final. Okay? I don't want to give it to you as a fait accompli, and lump it or like it. It's here's what I'm going to suggest. I'm here to discuss those things with you, to get your input. I want to know how you have changed this thing. I can tell you what we thought of it so far, and we're going to update it as we move along. But I think we have ample time to go through it piece by piece.

MS. ALDRICH: I guess, John, one of the things

that bothers me is that you've been going along with this in kind of an evolutionary process. And for us, it's like big gulps. You know, we had the original rule last January. We all lived with it for a little while. You had that meeting last March. I think we had all digested it by then and come to, it seemed to me, all the state people who were there agreed. It was really rather unnerving how well people agreed.

Now, it's nine months later. And obviously, there's a different animal that's going to be discussed. And again, for us, there's been nothing in between. It's like a time warp. And I think part of what I'm concerned about is that you're busy, we're busy, you know, everybody is more busy than they should be probably, and you get busier, because you have financial problems in the state. It's hard to carve out time to catch up with something that's very different and yet very important. Why couldn't we have been a part of the evolutionary process?

MR. TELFORD: This is it.

MS. ALDRICH: No, no. Why couldn't we have been invited to the meetings that you had with the professional societies as it went on?

MR. TELFORD: Excuse me. They were public meetings. They were announced in the Federal Register.

MS. SALUS: I'd like to make an observation, which

is, there was a meeting in Illinois yesterday that we probably would have sent a representative to, had we not found out about it around 3:00 O'clock yesterday when our Federal Register notice arrived.

Now, I know it was in the Federal Register. It also had the notice for today's meeting, which we had found out about directly. But Federal Register notices are great for information about following up on meetings that have occurred, but because of the time constraints of getting the things published and getting Federal Registers in the mail, which is nothing to do with you, the reality is that it doesn't usually work as a meeting announcement for people who aren't specifically invited.

MR. BOLLING: It usually takes about a good five days or so, from the time a notice gets to our office to the time it gets to your office. And I'm not sure how we can compress that time, except that when we recognize that there's a meeting like this one, we will fax it to you. And there's no faster way to do it than that.

MS. ALDRICH: Well, I mean, at the time the meeting was agreed upon, the states were notified. And there must be several weeks of lead time when you set up a meeting with major organizations.

MR. BOLLING: I think you're suffering under a slight misconception. We're telling you that there's been

changes to the rule. You're anticipating that there are great changes.

MS. ALDRICH: No, I'm not really anticipating anything. It's just that, oh, for example, even Part 35 when it was adopted, I think we all looked at it to some extent, the parts we were interested in. There wasn't an issue of compatibility. I don't know how close attention states really paid to it. But the whole criteria, for example, for the reportability of diagnostic misadministrations, I don't think anybody looked at very closely.

When I looked at the revised, or the QA rule, and saw those, to me they were new, because that's how little attention I had paid to what was in the original Part 35, because I disagreed with it. And it takes a while. You have to internalize these things, think about it, talk to your own licensees before you come to a reasonable conclusion on whether or not you think that that's a good, bad, or indifferent regulation.

And we're at a built-in disadvantage, having things sort of sprung on us new all the time, instead of being part of the process that led to it.

I mean, we've talked to the local, the state chapters of all of the organizations that you've talked to, or individuals in the state have belonged to them, if not

formally, the Astro for example. You have talked to the AAPM, the ACR people. In fact their lobbyists are in and out periodically.

That's not the same as being at a meeting and hearing at the same time as you are, so we're all hearing the same thing, the national society give you whatever input, say, the ACR has on this rule. If we could all hear it at the same time, it gives us the same kind of lead time to think about that and internalize it. And I think we're always coming in on things later than you. It's not really being kept up to speed. We're not really being treated as participants in the process.

MR. TELFORD: What do you call this meeting?

MS. ALDRICH: This meeting is nice, but it's nine months since the last meeting, and so much has gone on --

MR. TELFORD: Would you like to know what I've been doing in the nine months? I've been doing a pilot program. I don't have time to meet with you every three months.

MS. ALDRICH: Yes, but that's not really what I wanted, John. What I'm saying that I would, we would have wanted, was for everybody to know what kind of meetings were happening, when. Just so that all the states knew whether they could get there or not or cared or didn't care.

MR. BOLLING: I think we've pretty much kept the

states aware of what meetings were going on. We never anticipated that many, if any states would want to travel to the ACR meetings that NRC was holding. We had a standing offer for every agreement state to attend the four pre, or five pre and five post-pilot program meetings. Obviously, dollars are a concern, in your areas as well as ours. We had the standing offer to come out to your state or your region and put on a workshop like this. And we got, I don't think we got a single request to do that.

MS. ALDRICH: Well, first of all, Lloyd, the notice we got on the pre-workshop in New York State, if that's the one you're talking about, before the pilot program, it was two-days notice.

MR. BOLLING: Yes, but you could have attended any one of the five.

MS. ALDRICH: That was the one that was in New York State.

MR. BOLLING: Well, we had people attending from across regions. We had a physicist from New York, I think it was, or Massachusetts, attend one in California and another one in Georgia. And so it wasn't strictly divided according to region.

MS. ALDRICH: No. But New York is the one I would have gone to, and I got two days notice, which is not enough time for me programmatically to go anywhere, even if it's

within the state.

MR. TELFORD: How about the Philadelphia meeting?

MS. ALDRICH: The Philadelphia meeting I didn't know about until after it was over. The December 14 meeting in Bethesda --

MR. TELFORD: December 15.

MS. ALDRICH: -- December 15 meeting you told me about when I spoke to you on the phone about this meeting. and I had asked that this meeting if possible be scheduled for the Friday before that meeting so we could get to it.

MR. TELFORD: But I let the conference select the location and the date, the dates.

MS. ALDRICH: I understand that. I understand that. But I mean, I wouldn't even -- I couldn't get to that meeting. But I wouldn't even have known about it had you not said it to me on the phone. We didn't receive any notice that meeting was going to take place, John.

I'm sorry, I don't mean to be like endlessly complaining. I'm just trying to get you to understand --

MR. TELFORD: Why don't you write a letter to, Mr. Miller?

MS. ALDRICH: Yes.

MR. TELFORD: Because I'm here to talk about the rule, okay? I want to work with you folks. You seem to have complaints against the way that the NRC is interacting

with the agreement states. I'm sorry. That's not my job.

MS. ALDRICH: Okay.

MR. TELFORD: I work on this rule.

MS. ALDRICH: I understand that, John. I'm just trying to give you background on how we find it difficult to deal with something that has evolved to a certain point?

MR. TELFORD: Could we go forward?

MS. ALDRICH: Sure.

MR. TELFORD: Because as far as I'm concerned, I'm the driving force that brought about this meeting. It's through my efforts of sending faxes to ten states to say I want to have this meeting, because I want the input on this rulemaking. And I've already told you, if you're not satisfied after this meeting, we'll have another meeting in February.

MS. ALDRICH: I appreciate the effort. And I would also point out that I, my staff, faxed notices to all of the agreement states asking their availability on this meeting. And so I have tried to work with you on it. And I'm not, certainly not denigrating your having this. We appreciate the opportunity. I was just trying to give you some perspective of how we find it difficult to evaluate something that has grown during a period in which we haven't had really any knowledge of what's been going on.

MR. TELFORD: Well, may I suggest that we look at

it?

MS. ALDRICH: Okay.

MR. TELFORD: Because I don't see how you can even make those statements until you've seen it.

MR. WHATLEY: John, I think it sort of seems to me that there's a perception that the agreement states are opposed to what NRC is doing, and NRC doesn't want to ask the agreement states, because the expect the agreement states to say something negative.

I don't think that's the case at all. I think all the agreement states support quality assurance. I certainly do. And I've told you that before. And I understand where Rita is coming from.

You know, you put a long list of dates up there. We had one meeting in March, period, as far as the agreement states are concerned, until today.

I think we're all, I'm certainly committed to help you write a rule, the best rule possible. And I think all the other states would say the same thing. And that's all we're asking to do.

I don't think NRC has a monopoly on all good ideas. There are a lot of people, I think people in your regions, NRC regions. They write licenses. They are inspectors. They ought to have tremendous input to something like this. I think all agreement states should.

And I think when you do that, you come up with a document that is supported by everyone. It's this almost behind-the-scenes stuff, that we're going to talk with one group, and that kind -- it's a lack of communication, is what it boils down to. Nobody knows what's going on. We certainly don't. I don't. And I would have liked to have had more input to it.

I served as Chairman of this committee. My only input was to be invited to that meeting in Washington. The rest I found out by reading the Federal Register.

MR. KULIKOWSKI: Just to support what Kirk said, we're already got a QA program on the books.

MR. WHATLEY: I think the states support this.

MR. KULIKOWSKI: You've got to have support.

MR. CAMPER: I believe that statement that the states support it. And what I want to do is truthfully work with you guys and see if we can come up with a mutually-agreeable final rule.

MR. WHATLEY: I'll just share with you my gut feeling about this meeting. And I hope it's wrong. My feeling was that you know, here a meeting has been held with everybody else, and somebody said well, what groups have we left out, and somebody just said well, hey, the agreement states haven't been included, maybe we need to go on record of having a meeting with them. I hope that's not the case.

But that comes across. A lot of people have called me and shared that opinion with me.

MR. CAMPER: Let me tell you something. This meeting today is taking place because I came back to the agreement states, with the genuine concern and interest in getting as much input from the agreement states as possible.

I said in that meeting that the origin of this rule predates me and my current position. But I came away with the feeling that perhaps more needed to be done to get direct input from the agreement states. It was an oh, after the face, we forgot the agreement states. I came away with some very constructive discussions and some genuine concerns being expressed. And I thought we needed to look at these issues. I went back to John Telford. They agreed, totally And we said right then and there, let's get this thing together, because the agreement states don't want to find themselves in the position of having a rule on the street that either A, they haven't had a chance to comment on, or they get a chance to comment on it late in the game. They want constructive workshop, sleeves-rolled-up input. That's why this is taking place. It's not an oh, after the fact.

MR. WHATLEY: I'm glad to hear that.

MR. CAMPER: And also, with regards to time, one thing you need to try to appreciate is, since August we have been involved in 11 or 12 meetings. Unfortunately, whether

you like it or you don't like it, the agreement states, while they are very important to what goes on, are only a part of the process. We have tried very hard to meet with all the players, just like we're trying very hard to meet with you now. And I suggest that we spend the rest of our time trying to construct a rule. If you don't feel that you've gotten adequate communication from the NRC, or if you don't feel that you've been informed properly, I suggest you write a letter to Mr. Miller, telling him. Because it is our interest in the medical area and in John's shop to see that you guys get as much input as possible. We'll meet again. We'll get a draft to you, we'll talk by phone, we'll work with you. Okay? But if it's a communication problem or an administrative problem, write the agreement states. Give them a letter. Tell them. Okay? Let's spend our time constructively, that we have left.

MR. COLLINS: May I make one suggestion? Could we take a ten-minute break and then come back and let John start off with his prepared presentation and go through it, and pick up discussion after that?

[Brief recess.]

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

For the next item on the agenda, let's talk about the proposed rule. I'd like to go through this in the following fashion.

I'll put up some view-graphs that are cryptic descriptors of what part of the rule says. What I would like you to look at is a copy of the Federal Register with the proposed rule. Anybody who doesn't have a copy of that, raise your hand and we will get you one.

MR. DUNDULIS: If, as a result of discussions you've had with various groups, if there is going to be any differences in either style or substance between institution-based operations and private-practice operations, would you make a point of emphasizing those?

MR. TELFORD: Generally, I don't think so. I think there's going to be any difference.

MR. CAMPER: The only thing that might help you there would be the JCAHO possibility. When we get to that, we can share with you what JCAHO was proposing.

MR. DUNDULIS: Thank you.

MR. TELFORD: I'd like you to look at this two ways.

The first way is what you would do with each part of this proposed rule, how you would modify it, or delete parts or retain parts or modify parts.

Secondly, I will give you some additional information that we have come up with as a result of our meetings and our working sessions with the writing team.

So, I'd like you to sort of consider it

independently, as if you were looking at this and telling us what you do, because there are two people here that have told us their suggestions before. No, three, excuse me. Sorry, Terry. Three people. And the rest of you, we haven't gotten firsthand input from before.

So, let's do it in that fashion.

Let's start off with the name of this rulemaking. We currently call it a basic quality-assurance program.

First of all, the word "basic": It has been suggested to us that we drop that word. It may be a good idea to say this is just the program. This is the quality-assurance program.

Its objective is to ensure that the byproduct material is administered as prescribed. So, let's go for that intention.

Secondly, if we need to add a chapter, like on training, for instance, or on maintenance of machines or whatever, we don't call it basic. We just say this is the program. It's logically apparent that we can do that.

So, there's the first idea that I want to throw out.

Secondly, on the title, in our discussion with volunteers in the pilot program, they made the suggestion I am about to give you. The five societies that -- the ACR and four others that I told you about have made this

suggestion, and the JCAHO made it.

It is that don't call this quality assurance. The first reason is that organizations like JCAHO, the ACR, the ACNP, etcetera, etcetera, have been working on quality assurance, as they view it, for many years. The way they view it is this is the program for the entire hospital, in JCAHO's point of view.

Therefore, we're coming in, and we're looking one or two departments, very narrow focus. We're only focusing on the byproduct material. We only want to make sure that that stuff gets administered as prescribed.

So, it's really confusing to the licensees and to these societies. The best that we have come up with so far is "Quality Management Program," not quality control, not quality assurance but Quality Management Program.

Now, I want to take you along with me here, step by step. So, let me hear some comments, please, on the title.

MR. DUNLULIS: Instead of coming to quality management, why not the obvious, "Byproduct Material Quality Assurance Program"?

MR. TELFORD: Well, the first part of that is okay. But the second part has the same deficit that our original title had, namely that it causes confusion by connotation of the phrase "quality assurance."

When the physicians see it, they say, oh, I know what this is. I've been doing this for years for JCAHO. But then, we come in and say no, no, we don't mean all of that. We mean this little part here.

So, it has a very confusing connotation, and it's gotten us a lot of flak and a lot of heat from various people.

MS. ALDRICH: In our guide for teletherapy, we've been calling it quality assurance for over a year now, and it's one of the appendices, and we've been using the ACR quality-assurance program. No one has commented. That's what the ACR calls it. We haven't had any of those types of comments.

MR. SHARP: You're getting another term which you're going to have to define. You don't think that Bill is suggesting narrowing the focus of the QA is sufficient? In other words, this is not QA. This is not part of QA for nuclear studies.

MR. TELFORD: I think that's an improvement to what we had.

MR. SHARP: I'd hate to you use another terminology, at least around here, at this table, QA, we're getting used to.

MR. KULIKOWSKI: We have some QA rule on the books and for public comment, and we have a large number of

medical licensees, and we didn't have any negative comments about the use of that term.

MR. TELFORD: Well, it's a funny thing about public comments.

MR. KULIKOWSKI: I have talked to a lot of people in the local societies, and no one has ever come up to me and said this is confusing. They seem to know what it is and hone in on it, and most of our licensees haven't have a problem.

MR. KLINE: John, you might want to talk about yesterday's meeting with JCAHO, a parallel group, different in objective, slightly, but similar in their approach towards quality.

They're amending their current standards not to be called quality assurance or a quality assurance program. They are amending their standards to, as I interpreted what they expressed in the meeting, quality control and improvement, because assurance was causing quite a bit of controversy and concern as to what that meant.

They felt that the assurance process is not as descriptive as the improvement process, which is the intent of what they want to do during their evaluation of hospitals for accreditation. So, even within the groups which have been doing this since 1970, there is some concern as to what assurance is, a definition of quality assurance, quality

control, and similar terms.

MR. CAMPER: Let me add, if I may, that some of the things we've heard, also, about the term "assurance" and then you look at the objective, and we use the word "ensure," there seems to be a concern about "assurance" and "ensure" as being something that we're going to inspect, and there are those that said we cannot ensure this.

The purpose of a quality assurance program or the purpose that we're trying to get at here is to prevent some things. We can have that as a goal. We can attempt to do that.

MS. SALUS: When I hear "quality assurance" in the context of a medical rule, and it's in the title, it implies quality of medical care, which I don't think is really a target here. So, maybe something along the line of "patient safety program" or something like that, because we're not really concerned with whether or not the patient is getting a good medical treatment so much as whether the right person is getting what's been prescribed, I think.

MR. TELFORD: That's exactly it. We have heard that from physicians that were volunteers.

MS. SALUS: We've heard that, too.

MR. TELFORD: We've heard that from the ACR and other societies. We have heard that from the ACNP and the SNM. We have heard that from the JCAHO.

That's the connotation everybody has, is quality of care, when they hear the term "medical quality assurance." So, it certainly got our attention.

MR. SHARP: I am not sure your goals, your final goals are that far removed. Consider the diagnostic and therapy end points. You're trying to assure precision of treatment, correct treatment.

MR. TELFORD: Well, what do you mean "correct"?

MR. SHARP: Identity.

MR. TELFORD: Identity with what's prescribed.

MR. SHARP: Yes, the patient.

MR. TELFORD: If the authorized user prescribes anything, in that person's judgement, that involves proper material and that is delivered, then we're happy. It doesn't have to be necessarily correct for the patient. That's a medical decision. That's where we're trying to not infringe in that area.

MR. KULIKOWSKI: I just had a meeting with our attorneys at the New York State Radiological Society about that particular thing and the responsibilities of the authorized user. The consensus among the Society people -- and the attorneys were there just to make sure everything was legal -- and us, as regulators, was that we should not be infringing upon "the practice of medicine."

In other words, one, we want to make sure the

authorized user is included in the loop, which I'm sure we'll talk about in the next day or two, and the second thing is, you know, once that authorized user is involved in whatever way to make a medical judgement, the supervision and, by implication, the QA rule, which I still call it, is to ensure that what the medical decision of that practitioner is is carried out with a minimum number of mistakes or with the least possibility of making mistakes.

MR. DUNDULIS: Kind of as a followup to what John and Bob were saying, I think we're looking at two things.

The most obvious is, I think everybody agrees, is to use the lawyer term, "preventing adverse medical outcomes," but at the same time, I think we want, if for no other reason than consistency, that if, in his or her judgement, the authorized user of a facility has said unless I authorize otherwise, if I just put a referral for a patient as "brain scan," it shall consist of the following, or whole-body scan or gallium scan, cardiac workup, whatever.

So, I think it's not only preventing problems but, at the same time, for those bread-and-butter procedures that are done, to establish rules how those bread-and-butter procedures will be done, so that they're done consistently and, at least, hopefully, will minimize any artifacts which might affect the way in which a scan is interpreted.

So, I think that's an important part of any quality control, quality assurance, if you would, error prevention, that once a procedure is decided on, that it be done consistently on each and every patient, to minimize the number of error parameters.

MR. SHARP: Okay. We've got a problem, slightly, here.

You can make an analogy for driving the structure of a car. You've got a quality assurance program that could apply to driving a car down the highway safely that you might relate to medical efficacy of the practice of a physician, because you have -- the quality assurance program that we're interested in is in the delivery system, or in the car itself, which Lee Iacocca has now properly called, and I think we can understand what he is talking about when he uses those words.

We're talking about a technical delivery system and looking at the quality assurance program for a lot of cars. It's too bad that JCAHO and the medical element have used the same terminology to describe efficacy and delivery of the same final result.

I don't know that changing the terminology is going to help us sell QA for the technical delivery system any better. We'll just wind up with another term.

I think everybody in the medical community, in the

nuclear medicine community, pretty much knows what QA is. You know, now if we come in with a new term -- just for the sake of ridiculousness, call it "pink shirt" -- then everybody's learning curve is going to be that much steeper, until they get up with the new buzz words.

I think we should stick with quality assurance, quality control, because everybody uses it and knows that it means, and if we need to qualify it to keep JCAHO happy, then we need to rewrite the definition but not the term.

MR. TELFORD: It's not just JCAHO.

MR. SHARP: Well, I use that as an example.

MR. DUNDULIS: There is another term. You could use "quality commitment." It's the same thing.

MS. SALUS: What's wrong with not using a term at all and just call it a program for prevention of -- detection and correction of causes of errors, have a two-line header, and not refer to it as a program?

MR. CAMPER: Let me share a couple of things.

First of all, the use of the term "error" is something that we're moving away from. We're going to specifically state misadministration and event or reportable events and non-reportable events. Use of the term "error," we've been told, is too broad.

We keep getting back to what is the objective of this? The objective is to prevent so-called

misadministrations. Within this, there is going to be an attempt to, perhaps, redefine what a misadministration is.

But see, the focus is very narrow. Perhaps the title should contain some very narrow words that are specific to exactly what the objective is.

Now, for example, you can quality management programs prevent misadministrations. The problem is, of course, if you change the term and don't use "misadministration." It gets a bit cumbersome. Management program to prevent reportable events or something -- it gets cumbersome.

The problem with quality assurance is, it seems, at least, this term has come to be known as something throughout the medical community. It has a lot to do with the quality of medical. Whereas, this rule -- the purpose of this rule is very narrow and rather specific.

MR. TELFORD: Unfortunately, if you talk to somebody that has a quality assurance expert in an industrial setting, an automobile manufacturer or an electric parts manufacturer, and that person talked to a QA expert in the medical environment, it would be like one person from a different planet. They're totally different.

In the medical environment, when you talk to the medical societies, they're thinking quality of medical care. It's the entire department.

MR. SHARP: When you're talking to the medical societies for physicians. When you're talking to medical societies for technicians, you might find more acceptance of QA.

MR. TELFORD: I agree with you. I've talked to meetings, the technology section of the SNM, and they understand what I'm talking about. I think it's a minor translation problem. We're just confessing to you that -- these are suggestions that we have received.

Now, maybe we can just say either we need to change the title such that it doesn't use QA, so it's a prevention program or it's a quality management program, or we need to narrow the focus. If we end up using quality assurance, then we should narrow the focus.

MR. SHARP: I don't think that Larry's suggestion was that far off, and that's a tad cumbersome: "Misadministration Prevent Program."

MR. CAMPER: Well, the only reason I say it's cumbersome, as we'll share with you later, is the "M" word. We're looking at the "M" word. It becomes cumbersome in that example.

MR. SHARP: You're going to have to define the "M" word.

MR. CAMPER: Absolutely.

MR. COLLINS: Particularly if you break that word

down into three different words and have diagnostic events and therapeutic misadministrations, diagnostic misadministrations, all separately defined, instead of using one generic term.

MR. CAMPER: What we'll do, Steve, when we get to that point, John will step you through what our thinking has been thus far on that.

MR. SHARP: The word "error" is nicely broad. But you've been told it's too broad.

MR. CAMPER: The problem we're hearing is that, particularly folks in the AAPM and ASTRO and ACR -- you know, the term "error" means an awful lot of things. "Error," as we have used it in this rule, is particularly pertinent to misadministrations.

For example, one can make a mathematical error. One can label film wrong. That's an error. But it's not a misadministration.

MR. COLLINS: All of the discussion on what we're going to call it, are we talking about the substance of the rule?

MR. TELFORD: That's what I was just trying to say. I think we have two ideas on the table.

One is to call it something different; don't use the quality assurance term at all. The other idea is to narrow the focus but call it quality assurance.

So, let's leave it at that and move on, because are some things, some ideas, that might impact on that.

Let me direct your attention to the first paragraph of 35.35. Let's take the first sentence, which says that each licensee shall establish this program to prevent, detect, and correct the cause of errors in medical use.

Now, that phrase, "errors in medical use," has also gotten us a lot of discouraging remarks and criticisms, because the very phrase "medical use" brings up the connotation that we're stepping into the practice of medicine. It brings up the suspicion of what kind of errors are you talking about? Little errors, big errors, what errors?

So, our best suggestion for you, what we're now thinking, is not to use the term "medical use" anywhere; replace that with "administration of byproduct material."

Now, let's look at the word "errors." Our best suggestion for replacement for "errors," because it's not very specific -- it's too broad and causes too many people to be too nervous.

So, we said, all right, we want a program to prevent, detect, and correct the cause of what we will define for you as events and reportable events.

MS. ALDRICH: I guess my comment really kind of

takes us back to the QA, but one of the comments that I've made on the proposed rule all along is that even though it's called the quality assurance rule, there's nothing in it about quality -- about optimization, which in the evolution of quality assurance in New York State, as we've used it in the radiation program, it's related to optimization in diagnostics, say.

So, we extend that to therapy, which seems to be the way the ACR also uses it in their quality assurance program. There is that feeling or that intent that we're talking about optimization. And all along, your rule has been limited to this focusing on error, preventing, detecting, correcting error.

What about considering using, say, the AAPM's definition of quality assurance, which is a system of plans, actions, reviews, reports, records, whose purpose is to ensure a consistent and safe fulfillment to the dose prescription to the target volume, with minimal dose through normal tissues and normal exposure to personnel, and avoid the conceptive error?

I mean stick with the idea of insurance, of achieving the desired goal.

MR. TELFORD: The problem with that is only part of that's my job. As long as the byproduct material is administered as prescribed, even if the prescription is

wrong, but if it's administered as prescribed, I'm happy; I've done my job.

MR. SHARP: That's kind of new.

MR. TELFORD: That's kind of new?

MR. SHARP: There were dose ranges just a year or two ago.

MR. TELFORD: We will have to say dose not dose range, and I'll tell you why later. That's my thinking. That's our thinking so far.

MR. COLLINS: A suggestion: On 35.35(a), keep al of the first two lines except the last word, which is "basic." Delete all of the rest until you get to the next-to-the-last line, and pick it up with the word "meet."

So, it would then read, "Each applicant and licensee under this program shall establish a written program" -- keep the word "program" in the first line -- "a written program to meet the following specific objectives."

MR. TELFORD: You'd drop "prevent, detect, and correct the cause."

MS. SALUS: The program is to meet these objectives. That's what all those specifics are directed at doing.

MR. TELFORD: What's wrong with saying it twice?

MS. SALUS: Well, apparently, "correct, prevent, and detect the cause" are troubling words

"misadministrations or errors."

MR. TELFORD: Those words aren't troubling.

MS. SALUS: "Detect, correct, and prevent" you said weren't troubling. It's what you're detecting, preventing, and correcting.

MR. CAMPER: That's not the problem either.

That sentence, as we're thinking now, would say "detect and correct the cause of misadministrations or events in the administration of byproduct material."

"Detect, prevent" and what have you are key concepts that should not be lost.

MR. COLLINS: So, the "M" word is not a major problem, as long as you define it and restrict it. We were trying to help you get rid of the problem words.

MR. CAMPER: The only word that's a problem in that sentence is the term "medical use." It will be replaced, as John suggested, by the use of the term "administration of byproduct material." And the word "errors," where you see it, would specifically say "misadministration or events."

Is that correct, John?

MR. TELFORD: Yes. We could talk about either events and reportable events, where "reportable events" takes the place of the "misadministration" word, or we could talk about events and misadministrations.

The sentence would read, "Each applicant or licensee under this part shall establish a written," some sort of program, "to prevent, detect, and correct events and misadministrations in the administration of byproduct material."

Any other comments on that?

MS. ALDRICH: Well, what was it, John, in the AAPM definition that you said was outside your scope?

MR. TELFORD: The part about insuring anything other than delivery of the by-product material.

MS. ALDRICH: So, it consisted, in say, fulfillment of the dose prescription, is not what they're intending?

MR. TELFORD: The save fulfillment of the dose prescription is the idea that I'll attempt to capture in the second sense.

MS. ALDRICH: But it's not really outside the scope of what you're proposing, is it?

MR. TELFORD: That part is okay.

MS. ALDRICH: Yes.

MR. TELFORD: It's the rest of it that's outside our scope.

MS. ALDRICH: Minimum dose to normal tissue?

MR. TELFORD: Yes. I don't -- we don't -- that's outside our scope.

MS. ALDRICH: That -- doesn't that speak to some of what the errors have been, which have been not so much an error in the dose to the -- on the central access, but what we had in New York State. A number of the misadministrations involved a dose that was in -- within plus or minus 10 percent to the target volume, but off by a factor of perhaps a 100 percent where the dosimetrist had misunderstood how to combine.

MR. CAMPER: Well, this has more to do with the discussion of the threshold recording requirements, as related to teletherapy and brachytherapy. I think when we get to that, we'll share with you some of the findings that come up in the discussions. We've had some thought processes and efforts within our group to try to do something about those definitions.

What's been very interesting, Rita is to -- some of the most recent input, particularly from ACR about trying to get into expanding that definition to consider normal tissue or surrounding areas, non-target volume, things like that. When we come to that part, we can shed a little more light on why that doesn't seem to work very well.

That really is all about the definition threshold and what constitutes the trigger in which you work with.

MR. CAMPER: Larry?

MR. DUNDULIS: It would seem that one area of turf

that NRC has staked out prior to this is ALARA. It would seem to me that if a technique, be it external beam radiotherapy or administration of radiopharmaceuticals: if there is an established procedure, to localize that to the organ or organs of interest and you, through misuse of the technique, had irradiated non-target volume, then your procedure is not ALARA and, therefore, logically, should be part of the quality control program.

MR. CAMPER: The same question.

MR. TELFORD: Same question. Why don't you state it, because --

MR. CAMPER: Sure. Do, I understand that in a teletherapy administration you wouldn't be concerned wit the size of the field if a mistake was made and produced twice the tissue volume, even though your central dose target was irradiated properly. The irradiated ancillary material is not a concern. It seems like it would be.

MR. TELFORD: No, no. This -- the definition that Rita read said something like minimizing the dose to normal tissue.

MR. SHARP: Proper columnation, that's one interpretation. Don't abandon your idea yet, but we need to put a few more bricks in place on our wall before we can get up to that point.

MS. ALDRICH: I think your tying, with the

definition we're proposing, more closely to the reporting requirements than we are. The definition to us means that this is supposed to be what the goal of the program is. The trigger levels for reporting an event, we don't think needs to be -- to address every aspect of the definition.

MR. TELFORD: I'm not sure I'm following.

MS. ALDRICH: In other words, the definition, itself, doesn't drive what the trigger levels for reporting should be. The definition drives what you would expect the quality assurance program to consist of.

Again, I guess, we're really -- we're going off in slightly different angles. We're going after quality assurance and you're going after misadministrations, detections of errors. That's not the direction that we're heading in.

MR. KLINE: See, I think, if I could interject? It appears that your program is more in line with patient care. Okay, you're aligning more, I believe, in the concept, with that of JCHO. We're not into patient care; we're not into the quality. We're into whether or not the physician prescribed the method and whether or not it was followed out based on this prescription.

If we go a little further and get into teletherapy treatments and get into brachytherapy, it becomes very difficult, from a regulatory stance, to come in and decide

whether or not we organ dose at point A, though different from point B, whether or not that was acceptable. That's a physician's call, that's his judgment. We cannot intervene in the medical decision process.

It can be carried through your health department to the state boards, they can review the case and decide whether or not you practice accordingly, and then that goes on to malpractice and litigation.

We have to be very careful of that. This is a criticism we've received from a number of medical groups.

MS. ALDRICH: It's interesting that that's the way you interpret it, because that's not what is intended. We intend to stick to the physics aspects of this and not the practice of medicine aspect of it. But the physics aspect is there, because if their quality assurance program in, for example, their dosimetry or the computer dosimetry program their using is not QA'd to be assured that their dose distribution is going to be as intended, as well as his central access dose. That is a physics consideration, that's not patient care.

MR. CAMPER: Would you agree, though, that the case that you're making would call for broadening of the definition of misadministration?

MS. ALDRICH: No, I don't think that it needs to. I don't think --

MR. CAMPER: How can you get into discussions about multiple tissue, target volumes and what have you and not expand the definition of misadministration?

MS. ALDRICH: I -- as I said, I don't think the one drives the other. The whole idea of what is an error and what's an error of significance enough to report, has been NRC's concept and you're the guys who first decided their should be such a thing and that they should be reported. I don't know what the rationale was in the beginning, but, apparently, that reporting requirement was put into place, it seems, without a rationale that would be -- that could be supported, for example, some sort of radiation biology strong basis.

MR. KULIKOWSKI: I'd like a clarification from the NRC. It's my understanding that NRC considers the use of 2 different concepts as mutually exclusive and those concepts are ALARA. No way it would apply to patient. Well, the individual member the public is a patient and the current rule that we're working on are those mutually exclusive to the NRC and that ALARA applies to workers and releases to environment and that's all that applies to?

MR. TELFORD: Let me attempt to address that question by looking at the next sentence in here, because -- the first sentence -- let me attempt to clarify here.

We're trying to express to the licensee exactly

what we're going to go after here. So, we're saying to the licensee, in the first sentence, establish a program to prevent and correct the cause of, let's say events and misadministration, and we've got to understand those terms, in the administration of by-product material.

Now, we will -- in a minute, I'll define for you what we're -- what we might call events and what we might call misadministrations.

The second sentence addresses the [illegible] that Steve brought up. What's the purpose -- what's [illegible] what's the objective of this program? We had writte[illegible] the objective of the program was to provide high confidence [illegible] events and misadministrations in the administr[illegible] by-product material, would be prevented.

People didn't understand and don't feel comfortable with saying the objective is to prevent these 2 types of mistakes, even though we said high confidence, they have -- they're reading into this that we intend to prevent all errors; that zero is what we're going to try and drive to. We get long, detailed arguments about why that's impossible. Well, gee, that's fine -- we said high confidence. We meant, close to the zero-error rate.

So, we would like to change that second sentence. See, the reason that, Steve, your comment is appropriate to this is, during these various discussions, people have said,

oh, the purpose is minimization of errors or minimization of mistakes, or the goal should be to drive the errors down as low as reasonable achievable.

We said, no, no, no. Our goal, however, unachievable it is, our goal is no mistakes. That's not to be the goal of the program. You don't set out to build any widgets with .1 mistakes in it, or 2 mistakes in it; you set out to build it with none. So, we kind of fussed around with this sentence and we've come up with something like the following, that the goal of the program is to ensure that by-product material is administered as prescribed. In other words, the goal is to make no mistakes.

MR. KULIKOWSKI: Getting back to what we just said and admittedly, in our QA, we bar that phraseology from APM, what's wrong with just stopping and saying the program should be designed to ensure consistent and safe dose prescription?

MR. TELFORD: That's the same sentence that I just said, I guess, with different words.

MR. KULIKOWSKI: Minimum dose and minimum tissue -- minimum exposure.

MR. TELFORD: Yes, that's outside our charter. If the states want to bring that in individually, you're welcome, but that's certainly -- that's not out job.

MR. KULIKOWSKI: I have a question about what was

said earlier, just a clarification. The purpose of the QA doesn't really impact on patient care. Quality issue and patient care -- don't see how you can say that?

MR. KLINE: Well, the focus, by JCHO, is patient care, clinical activities, is contributory to the admission are the goal in that treatment process. Certainly the rule making process here does impact patient care, but not in the clinical sense. We're looking more toward following by the physician.

If the physician, for example, erroneously practices medicine, that's outside our privy.

MR. KULIKOWSKI: I agree with that. I think it's just a different phase of the patient care. Obviously what we're doing is saying to the authorized user physician, you've made a medical decision. What we need to do is to from that point to the administration and make sure that's done correctly, regardless of what your decision is.

MR. DUNDULIS: John, I think there are 2 very important words, and I like Bob's definition better than yours. You said "consistent fulfillment of the prescription."

MR. TELFORD: No, I didn't say that. No, no. That was somebody else's words.

MR. DUNDULIS: All right. All right. But I think the important words that are there: "Consistent and Safe."

I think the "and safe" is very important.

MR. TELFORD: What does "safe" mean?

MR. DUNDULIS: Well, I'm saying, it puts a qualifier because you can consistently be doing it wrong.

MR. TELFORD: If I -- we say safe, we're going to have to explain what we mean.

MR. DUNDULIS: I mean, I want to get to a point that, you know, not only consistency, but consistently right. So, safe to us is, if it's administered as prescribed. That's not only right, but we have to accept that.

MR. TELFORD: Okay.

MR. DUNDULIS: That is safe by, you know, by the bounds of our charter, that is safe. I mean, I thought I heard you say "consistently" --

MR. TELFORD: No, no. I didn't say that. Let me try this again. There's 2 ways to say this sentence; one is in the negative and one is in the positive, okay. In the negative we can say, the goal of the program is to prevent events and misadministrations. The positive way to say it is, the goal of the program is to ensure that the by-product material is administered as prescribed.

Got a comment?

Now, that's the best I can do, up to now.

Yes, Jon?

MR. SHARP: Let me ask a question about what's outside or inside your purview, as you see it at this meeting. Strict interpretation of what you've said would indicate that you wouldn't care what a physician prescribed in the way of a pharmaceutical, that there would be no restriction on what he will be able to do under license, and yet, most states limit that. You, the NRC, has limited it until recently and has only engaged recently in a pilot program to broaden what a physician can do somewhat from previous restrictions, using package inserts.

Is it fair to say -- say as a basic working principal for that meeting, that you don't care what a physician does?

MR. TELFORD: No, that's a little -- I don't like the connotation or that phraseology. But, if we have a licensee, an NRC licensee, there's an authorized user named on the license, there are certain by-product materials that can be used by that licensee. As long as the licensee is writing what's commonly called a prescription for a therapy use of those by-product materials; whatever that authorized user/physician prescribes, I don't have any legal authority to challenge that. I may not be happy with what is being prescribed, but I am limited by my ability to interact.

MR. SHARP: That's not really true, in the sense that the way we've all been licensed, P-32 was for certain

therapies, not for certain other therapies. But your statement would say P-32 could be used for anything.

So, what I'm saying is --

MR. CAMPER: What we're doing here is we're jumping over -- we've moved now into a discussion that deals with what authorized users can prescribe, what they can put into the procedures manual, what they do in response to what a physician requests or what have you. That's a little bit -- that's considerably broader than what we're focusing on here.

Again, the purpose of this rule, thus far, has been to prevent misadministrations. A physician may incorrectly order something and the department fulfills that physician's request properly, it is not a misadministration.

MR. SHARP: I disagree.

MR. CAMPER: That's fine, you can disagree.

MR. SHARP: Now, if he orders 10 millicuries of iodine, for a diagnostic study, that's an error that you want to catch in the system.

MR. TELFORD: We could agree with that.

MR. CAMPER: I don't disagree with that.

MR. SHARP: That's a physician order, it's written out, it's perfect.

MR. TELFORD: Now wait a minute. You're saying you've got an authorized user, we've got a -- NRC has an

authorized user. The physician makes the mistake. The physician intends to do a thyroid scan, b . mistakenly writes a directive that says use 10 millicuries of I-131 and the technologist delivers that --

MR. SHARP: There's no error according to the face rule you've established?

MR. TELFORD: Maybe so. In our opinion, that's probably a physician mistake, but not, you know, not according to the definition.

MR. KLINE: There is a provision in the quality assurance rule, by which we propose that once a prescription is received by the -- compared with the department procedures manual to make sure --

MR. SHARP: In fact, you are intruding, a touch.

MR. KLINE: No, no, that's not true, that's not even close. There must be the compatibility error, not broadly interpreted, as clinically the technologist is determining whether or not that application is appropriate. The procedures manual say what procedures are appropriate. If that procedures just doesn't match up, something is wrong, the feedback comes to the physician, it is prevented.

MR. SHARP: Do you have a procedures manual?

MR. KLINE: Yes.

MR. TELFORD: Let me try it this way. Let me give you case A and case B as an example.

The way we've envisioned trying to incorporate the way most people do business and to ensure some interaction and some control by the authorized users, is for -- case A would be a referral comes in to the nuclear medicine department, it's for a thyroid scan. Now, we get the authorized user involved by saying, there will be a clinical procedures manual. That really functions as standing orders from the authorized user. The authorized user will approve the clinical procedures manual.

Now, we all know that we don't need 10 millicuries to do a thyroid scan. You would use 123 or a small amount of I-131. So, we would expect that the clinical procedures manual that would be approved by an authorized user physician, would say, you know, use 100 millicuries, no 100 microcuries of 123 or 10 or 15 microcuries of I-131 for a thyroid scan, so that -- if the director of the department said, do a thyroid scan on Mr. Jones, the technologist could follow the standing order from the authorized user.

MR. SHARP: I understand where you're heading.

MR. TELFORD: Yes.

MR. SHARP: But, it seems to me, once you've asked that standing orders or a procedural manual be established, then you've paved the way for the use of pap --

MR. CAMPER: I need to try to get this back on the narrow. We're getting into a very broad area here and we're

not gaining a lot. But I wanted to point out that right now, as you know and we all know, there's a practice of nuclear medicine, and it involves a number of things: what your authorized user does; it involves getting orders from the outside; it involves the use of the procedures manual; it involves the use of checks and doublechecks, interfacing with the technologist and the authorized use and what have you and on and on.

Again, coming back to this rule, it's designed to prevent misadministrations, okay. Misadministration. What is misadministration? We all know what the definitions are of misadministrations as they currently exist in Part 35. Wrong patient, wrong round administration, radiopharmaceutical, and certain triggering thresholds. It's designed to prevent those. That's what we need to focus on.

MR. KULIKOWSKI: For purposes of discussion here, can we make the assumption that the prescription that's written is correct by the authorized use and then carry it on, look at the process from that point on and save the other discussion for some other time?

MR. CAMPER: That's certainly the underlying principle -- it goes on all the time, sure. But again, I'm trying to focus back to what this is all about.

MR. KULIKOWSKI: I'm just trying to get a clear

idea of where we're going.

MR. WHATLEY: Some of you may not be aware -- from 1981 through 1989, there were 3,571 reported diagnostic misadministrations. That was out of a total of 35 million. That's an error rate of 1 per 10,000. But there, for teletherapy, there were 73 reported misadministrations from 360,000 patients for an error rate of 3 per 10,000. That's patients; but if you're assuming 20 treatments per patient, that's 1 in 240,000. 1 error in 240,000 cases. That's what we're trying to reduce.

My comment, and my concern, from the very beginning with this -- it goes back to the issue of compatibility, which we've talked about before. But, in my opinion, had -- had the states been forced to adopt this, it would not have improved quality assurance, it would have done right the opposite.

By our definition of authorized user, is not the same as NRC's. I think -- I think, in my personal opinion, it would have reduced quality assurance, instead or improve it.

MR. TELFORD: Well, let's pick up authorized user in a minute, because --

MR. WHATLEY: Okay, I'll wait.

MR. TELFORD: I think that --

MR. WHATLEY: There's a place for it. I'm sure

we'll get back to that.

MR. TELFORD: [illegible] we can fix that.

MR. CAMPER: [illegible]op in, if I may quickly. I surmise, Kirk, from your [illegible] that you're pointing out that there's a low frequency of occurrence of so-called misadministrations?

MR. WHATLEY: That's true.

MR. CAMPER: And I can only reiterate to you what we've reiterated to a number of groups over the last several months. This rationale, for this rule, at this point in time, is not applied.

We have acknowledged that for the record. The Commission recognizes the frequency of occurrence of misadministration is small. We acknowledge that. But that is not the driving force for original rule.

MR. WHATLEY: What I started to say, is that there's a pretty good quality assurance program already out there; 1 instance is 240,000. That's a pretty good record.

MR. SHARP: Would you let us in on the driving force?

MR. CAMPER: The driving force is to prevent misadministrations.

MR. WHATLEY: I don't mean to imply that I'm opposed to quality assurance. I already stated that I was for.

MR. CAMPER: We understand that. But, again, that is the objective of this rule is to prevent misadministrations. The goal of it.

MR. TELFORD: Let's stop one thought process and let's -- let's focus on the need for a rule. Let's put that on the table. Do we want to talk about that? Because, with almost every group that I've met with, every workshop there's alwa·s, in somebody's mind, there's this question -- the need for a rule. It's kind of like a hidden agenda that just keeps popping up and coming to the surface and kind of, I don't know, fuzzing up our focus or something.

So, if we need a discussion on the need for a rule, then let's do it. I mean, let's stop this thought process, because this thought -- this thought process assumes that there will be a rule, there is a need for the rule; so if we're not all on board on that, then let's go back to the need for a rule.

MR. SHARP: I think we're going to get questions from our licensees. That would be helpful to know what you've come up with in the way of answers.

MR. WHATLEY: John, can you tell us, perhaps back in 1986 or '87, what was the driving force behind somebody's idea that there needed to be a QA rule? Whose idea -- I mean, just where did it come from?

MR. CAMPER: Let me make a -- make one cautionary

comment though about -- I think what John's about to do is worthwhile and good and I think discussing the need for a rule is something that we have a lot of interest in. But I would caution you though, the time you spend doing that is time not spent addressing specifics and rules the process. Just a cautionary comment about that. So, please recognize that all the time we spend discussing why we're doing this is time we're not spending discussing how we're doing it.

MR. WHATLEY: The horse is out of the barn.

MR. CAMPER: With regard to why, in '87, that occurred, because, again, it comes back to what I said a moment ago, the objection throughout this whole process, as far as I understand it, has been to prevent misadministrations. There is a concern in the commission about misadministrations.

John is going to show you, I believe, some examples of these misadministrations, that will hopefully enlighten you as to the concern that the Commission has. Again, the objective and the rationale and the reason for it, the cause, if you will, has been to prevent misadministration.

MR. WHATLEY: When you say Commission, you're specifically talking about a commission or several commissions?

MR. TELFORD: The 5 commissioners.

MR. DUNDULIS: Larry, just following up on what Kirk said. I think all of us agree, you know, that like ALARA, that we would be negligent if we didn't make some sort of rule or policy statement on, you know, patient safety and proper administration of radiopharmaceuticals. So, I think, in that respect, we all agree that some sort of rule or policy statement is necessary. I think, where the philosophic differences are, is to what extend does it go and, you know, what is the A, B, and C that we actually implement in the rule.

I think everybody agrees that there is a need for a rule or policy statement; but I think where we may disagree, is what elements are in that.

MR. CAMPER: Well, I suspect that, when it's all said and done, if we assume we need the rule, that there are going to be variances among some states as to what the quality assurance rule or whatever it is to be called consisted of. I suspect that some states would have more stringent requirements than NRC rule.

That's certainly up to the state, as we discussed before. This will not be an issue of so-called divisional compatibility.

MR. ANDERSON: That's what concerns us is what compatibility it's going to be, because some of us --

MR. TELFORD: Let me say again, I've been working

on this since October 1987. It has been our intent all along and it is our intent today that it will be a matter of compatibility because that's what the Commission told us. However, we will propose to the Commission in March of '91 that the states be allowed to have a more stringent program if they want it.

We all envision this as being --

MR. ANDERSON: Some of us even believe that doctors are deified and maybe somebody ought to be kicking them a little bit.

MS. ALDRICH: Even if it's division 2, if there are parts in the rule that we don't think should be adopted, that doesn't solve our problem.

MR. TELFORD: That's why we're talking.

MS. ALDRICH: Yes. Okay. John, if what you intend to do is go back over the -- the --

MR. TELFORD: Misadministrations?

MS. ALDRICH: The misadministrations that cause the Commission to, you know, focus on this -- I think we're probably all familiar with that, you know, I don't think you have to do it; but maybe, Kirk, you know, Kirk just wants a brief answer I think, as to you know exactly --

MR. TELFORD: I hear 2 questions. One question is: What was the motivating force back in 1986? The second question I hear is: What are we going to tell our

licensees? What are we really trying to fix here? Right?

MR. SHARP: At what cost? It was just a comment.

MR. TELFORD: Let's go back to 1986 to the comprehensive rule. I think what was happening in 1986 was that quarterly the NRC reports to Congress on abnormal occurrences. The Commission looked at that and said we had one well logger, we had one overexposure that exceeded five rem for an annual basis or one and a quarter rem on a quarterly basis for one worker at one nuclear power plant and we've got these five misadministrations here or three next time -- an annual rate of about eleven per year from 1980 to 1988.

I think the Commission looked at that and said to the staff, what are you doing? What are not doing?

Our job is the adequate protection of the public.

We told them we are making them report.

They said, the Commission said, we want a rule that addresses those problems. They are the obvious problems. We want a very definite rule. We want it enforceable and we want it now.

This rule was published in October. A few months later, March of '88, we're presenting to the Commission. Now this time period is usually ten to twelve months so we had November, December, January, February, March -- five months later we are before the Commission. That is twice

the speed that most other rules go by so the Commission definitely wanted a rule to fix the basic kind of problems.

Then they said, oh, by the way, if this doesn't do it, we'll come back later with a comprehensive rule and we'll include everything you don't have here.

We looked at the misadministrations 1980 to 1988 and what we discovered was that there were three deficiencies, if you will.

One was inattention to detail. Technologists are not looking at the charts. Patient comes in, he's supposed to get a teletherapy dose to the lung. Technologist said, oh, yeah, I know what to do with this patient -- dose to the brain! Just gross neglect of detail.

Second, it was no procedures at all or very inadequate procedures for how to do things, like a teletherapy treatment is supposed to be stopped but the procedure was to write an open chart. Oh, gee, I looked at the chart but I didn't see it -- you know, it wasn't an obvious kind of sign so just kind of a nonexistence of a procedure to do a simple thing like stop a treatment at the direction of an authorized user.

The third thing was no supervision or grossly inadequate supervision. For instance, x-ray technologist, two weeks of training last February -- this is now the fall of the year, October-November, on weekend duty. Supervisor

at home. Difficult case comes in. Technologist says I know what to do, I've treated two patients, I've gone through two procedures since last February. Calls the supervisor, supervisor talks to the technologist over the phone. Misadministration of a diagnostic case.

I could go through all of these. Two of these are from 1988, one of which, Kirk, is the Maryland case in which it was a single teletherapy case in which it was a single teletherapy misadministration report but in involved 33 patients so I am always a little nervous about numbers.

My personal opinion is those numbers, those rate numbers are very, very fuzzy. People count misadministrations. They don't count patients, so I think the numerator is fuzzy.

Secondly I think the numerator is fuzzy because as one practicing oncologist observed in the public comment letter was that if you look at the patterns of care study, you look at the cure rate of institutions that are very well equipped and very well staffed, the cure rate is quite high. It's higher than anybody else's. If you look at the facilities that are not quite so well-staffed or well-equipped their cure rate is quite a bit lower, significantly lower.

The writer said let's look at the folks that are reporting misadministrations. Are those the rural hospitals

out in the middle of the boondocks that are not very well staffed and not very well equipped? No. No, it's not.

The names I could show you in here are not those kind of hospitals at all. They are the good ones.

Thus the writer said what of the detection of misadministrations or the non-reporting of misadministrations from those hospitals in the boondocks? Okay, they are not there!

Why are they not there? For those folks, are they just blessed? Do they not make mistakes? Do you and I believe that? No, we don't.

So the numerator is highly suspect, denominator -- eh! Doesn't make a lot of difference. It's not very precise. We said seven million diagnostic cases a year. I don't really know, you know, what that number is but I'm not terribly worried.

The problem is that I can't make an argument on rate. Rate is almost irrelevant. What is driving this is first of all the Commission said fix it. We looked at the mistakes that have been made and we said three basic categories -- inattention to detail, inadequate supervision/ no supervision, inadequate procedures/no procedures.

Now these cases, most of them come from 1989 and 1990. We had twelve in therapy, misadministrations in the therapy range in 1989. So far we have had 20 in 1990.

When I look at these, that's the same story as I found when I looked at '80 to '88. It's just there are a lot of people out there that are still committing these same kind of mistakes so when we say our goal is to make sure that events and misadministrations are prevented we do that by focusing on those three types of mistakes that are made that can range all the way from just no procedures or just rather gross mismanagement of a whole department so that is what I would tell the licensees.

When I conducted the workshops with the volunteer participants, I didn't want to beat them up with this collection of horror stories but when they asked I did, I gave it to them. I showed it to them.

What they said was almost universally, my goodness, that's a lot of bad stuff -- we don't like that. We wouldn't endorse any of that. We certainly would like to have procedures to prevent all that, so that's what I would tell the licensees.

MR. KULIKOWSKI: I'd like to play the devil's advocate for a moment and just share our experience in New York City within the past couple of months.

Our QA rule went into effect August 15th of this year and heretofore we'd been getting maybe two or three reports of diagnostic misadministrations per year in the past three or four years, one therapy misadministration in

that period of time that was reported to us, one which was uncovered during the inspection which involved treating a patient with teletherapy to the wrong side of the brain for the entire course of treatment.

Since August and given say roughly a month, month and a half lead time before people realized that they had to start reporting certain things, we have had as of when I left the office yesterday three diagnostic misadministrations and one therapy misadministration. Two of the diagnostic misadministrations were what I would term insignificant. One however I don't think was insignificant. At least it was a misadministration -- white blood cells -- in which two patients were mixed up and reversed and unfortunately one of the patients was HIV positive so that someone who was HIV negative got injected with HIV positive white cells, a serious misadministration. Even though it was a perfectly normal diagnostic range it probably would not be -- well, it would be reported because it was to the wrong patient.

The therapy misadministration which we are still investigating because it only happened a couple of weeks ago was a beam modification device in the teletherapy unit which was replaced with a new device and the computer program was not updated properly. There was one definite misadministration which luckily was able to be corrected

during the course of treatment to provide the correct final dose and the radiology staff has gone back and looked at the records. There were eight patients in the time period from when the new device was put into use and in the current time. However their records were inadequate to show which device, which beam modification device was used so that is being investigated right now through various committees.

I guess the bottom line is, and this was really important to us philosophically because New York City does a very large share of nuclear medicine and therapy procedures it does about five percent.

To answer Kirk's question about reading statistics from the NRC I think those probably, we're the low end of the estimates and just from our experience we're seeing a lot more reports now. People are saying, is this reportable? Even if it is not reportable there have been mistakes out there.

So you know I think we just deal with such a volume in absolute numbers that for us, you know, I would feel much better having something on the books.

MS. ALDRICH. The therapy report you got though, Bob, those you have been getting anyway because of the HSM reporting requirement, right, so that shouldn't be impacted. The diagnostic is the same thing, it's an increase?

MR. KULIKOWSKI: Yes. I feel more comfortable

with therapy reports than I do with diagnostics because I know from what people tell me that because we do have such a large of authorized users in the medical field. We have 400-500 licenses, most of them multiple authorized users that very frequently the authorized user is left out of the loop.

You know, John Jones comes in for a walk-in bone scan and his GP in fact does it without any involvement with the authorized user whatsoever.

MR. TELFORD: We see about 400 diagnostic misadministrations per year. Sixty percent of them are due to the wrong radiopharmaceutical. Twelve percent are wrong patient. Seventy-two percent, two causes.

MR. KULIKOWSKI: John, to make a comment on another, if you would, philosophical reason for a rule and even though you said you can't get into medical practice I think that it should go as close to it as you legally can for reasons I'll explain.

Many of the state medical licensure boards are realizing if only for their own protection they are going to have to start cracking down on some of these people and if there is, if you would, an established federal standard of quality of care -- you see where I am headed -- then they can take that as due notice in their deliberations if we start having problems and refer people or if they have

people that they are looking at for other reasons, then this will give them one additional parameter to review and hopefully maybe put some of the bad actors into retirement.

MR. WHATLEY: John, you answered my question. I am all for going on with the discussion of the rules.

MR. TELFORD: Let me give you a reference. It's the Reports to Congress on Abnormal Occurrences.

Some of you have seen some of these. I am about half-tempted to go through them.

MS. ALDRICH: John, we have had 38 of them in the last few years, therapy so I think you can leave that out.

MR. SHARP: I think we are making arguments of reasonableness that these causes seem simple to address and I think that is one way to settle this.

I think the rate is problematic at the moment --

MR. TELFORD: Okay. Here is what we are after. This is what we see. We see inattention to detail. We see no procedures, inaccurate procedures. We see inadequate supervision, no supervision.

We have had comments to add another one, which is training, which we have by design left out of this rulemaking but is logically there. It could have an impact here and we are pursuing that separately.

MR. SHARP: We find ourselves living in the real world where rate is important and I think your arguments

about rate are important.

MR. TELFORD: Okay -- so if we could have this, we could have each licensee to have a program to ensure that the byproduct material is administered as proscribed designed to go after those three types of mistakes I described for you, that is where we are really headed.

We would like this to have a minimum sufficient program across the country because we think this is -- we need a national solution is what we are really saying. We are coming around behind and closing the door to the barn after the horse is gone because we find one problem in teletherapy in one hospital and we say to the licensee, what are you going to do? So these reports are all full of that, what the licensee suggested as a solution and, sure enough, they suggest on their own things like the procedures, better supervision, more training.

We see that time and time again. Brachytherapy, you find that other hospitals. Nuclear medicine, you find that in other hospitals so we are going about it in a very inefficient manner. We should be coming in on the front end and saying, all right, just have a minimal sufficient program instead of fixing the problem after the fact.

MR. CAMPER: Let me add this if I may. There is a related issue that we will discuss more when we talk about thresholds to be associated with misadministrations or

whatever.

That is, there is a group of individuals right now who received exposure through medical procedures because of mistakes that are not currently addressed by the misadministration requirements. By that I am referring to, for example, the situation that occurred in the hospital in Hawaii. That is, embryo fetus in nursing infants. There is a concern amongst the Commission that this is an area that should be addressed via misadministration requirements as well as an area that we are exploring as we look at redefining misadministrations as part of this process and determining whether or not we should include some consideration for that group of individuals.

Again, I think that point, are you -- that it is not only a question of rate of occurrence because the situation in Hawaii I think all would agree, when you have an embryo -- a nursing infant that receives 30,000 rads to his thyroid gland, you know, that's not going to happen very often and that's good. You don't want it to happen very often, so it's not only a rate driven phenomenon. If one looks at other areas we might consider adding to the concept of misadministration.

MR. SHARP: You know, fill our procedures manual.

MR. CAMPER: In this case there was a procedures manual. In this case there was a questionnaire that

specifically required asking of that question. In this case that question was not asked.

MS. ALDRICH: So how would any proposed rule change that? That is I guess what some of us are wondering. You reach a point at which you can't make people do something.

MR. CAMPER: We're not sure we're at that point yet.

MS. ALDRICH: Yes --

MR. CAMPER: We are not certain we are at that point yet. We have heard that and I would submit to you that the judgment on whether or not this will reduce any misadministrations is still out.

MS. ALDRICH: It would be interesting to see what happens a few years after the rule is introduced, whether the rates go down.

MR. CAMPER: I would agree totally and I suspect that part of the ongoing process will be to do some followup analyses to determine if we had any impact.

We hope that we do but I would not sit here at this moment and say that we won't.

MS. ALDRICH: See, one of the things that I'm concerned about is that the rule seems to be in large part addressing things that have happened, lessons that have been learned when you try to, you know, make sure you put

something in there, you know, to cover that.

But for example, I see your last report on 1989 misadministrations. There were four teletherapy that all seemed to be one root cause -- that the wrong part was being treated by the technologist and, John, you mentioned something about techs treating the wrong part as being sort of neglect of detail.

One of the concerns that we have had is we see so many incidents like -- well, of the proportion, of the number a large proportion where the wrong part is being treated it starts on the first treatment and continues. That hospital seems to have no requirement or even private offices that the physician who worked the patient up and staged the tumor theoretically knows the part to be treated isn't there for at least that first treatment, that there is not particular attention paid to the quality assurance at that critical time. Nothing in your rule addresses that.

What I am getting at --

MR. TELFORD: I disagree. That is a very debatable statement.

MS. ALDRICH: Yes.

MR. TELFORD: No, wait a minute -- what is your purpose here? What is your bottom line, because -- because, Rita, you are going off and you're firing shots at the proposed rule and I am wondering what are you going to gain?

What are you trying to gain?

MR. ALDRICH: John, I am not firing shots, trying to fire shots!

MR. TELFORD: You just fired one! You just said, you just said that there is nothing in the rule to address that problem and I strongly disagree.

MR. ALDRICH: What I was trying to get at was I don't think that you can in the rule address every single problem that's going to be a concern, you know, that has caused problems in the past. You can't legislate everything.

MR. TELFORD: Well, so what!

MS. ALDRICH: I thought --

MR. TELFORD: What's your point? What is your bottom line?

MS. ALDRICH: I think that that is a consideration that we should keep in mind as we address this, that we should not try to be too specific about what we are going to be requiring people to do.

MR. CAMPER: Well, I think it is recognized that we are never going to catch every contingency. We are never going to totally prevent human error. Everyone recognizes that.

By the same token there's a number of things going on right now as the Commission looks at its mission to

protect public health and safety and says we don't think we have done enough in this area. That's is what we are trying to attempt to do now.

As I said before I mean we don't know whether in the final analysis this is going to prevent these events from occurring or is going to reduce them but we do think it is a constructive step and the right way and we hope that it will achieve that goal but time will tell.

MR. ALDRICH: And I'm still on record, John, I am not against the rule. I am in favor of a rule. I have some problems with what is in it in the way of specifics.

The reason I mention something like that is I think it is important for us to conscious of the fact that you cannot always identify exactly what it is in a process that is going to result in mistakes down the line.

MR. TELFORD: We are not attempting to.

MR. CAMPER: Let us try to deal with specifics.

MR. DUNDULIS: Larry, you or John made a point earlier about the rate and Bob and I came to the same conclusion. We suspect based on his experience in New York and what you said earlier about perhaps some under-reporting out in the boonies that what you may see is once this rule goes in and a lot of these places that aren't the big time operations where they now have to train their staff in the QA procedures they are more aware of it. I think initially

you may actually see an upshot and then it will start to decay off but it wouldn't surprise me in the least to see an initial increase in reports just if you would because of the heightened awareness of facilities that have been under-reporting.

MR. KULIKOWSKI: And actually just the reporting requirement itself.

MR. CAMPER: That could certainly be the case but again -- that could be the case. You're probably correct. I think the point I would make though again is the point I made a couple times earlier today.

We have spent a long time discussing the rationale and the efficacy. That's important to a point. That's time we are not spending on the specifics of the language and the rule.

MR. DUNDULIS: The only reason I made that point -- was that in your briefing to the Commission because their objective has been to get the rate down and I think in the paper -- not the rate -- all right, I'll drop it.

MR. CAMPER: It's not just to get the rate down. It's to prevent --

MR. DUNDULIS: No, but the point that I am making is that in the briefing to them there should at least be the possibility that at least until this rule gets cycled in there may be an initial spurt that appears as though the

rule's not working and that shouldn't be justification to go in and try to make a quick fix. That's the point I was trying to make.

MR. CAMPER: That's a good point. All I was trying to point out, that there is an area of other incidents that go on that is of concern to us that perhaps should be considered as part of the misadministration. I used the example of Tripler because of the severity of the case.

MR. WHATLEY: Just one quick comment.

I asked a question about the history because when this becomes an item of compatibility we take it back and we are going to have to dump these rules and we have public hearings and meetings and everyone there and I want something to tell my people more than what is an item of compatibility with NRC.

That is why I asked the question. I thank you for the help you gave me.

MR. COLLINS: Are we ready to go back to 3535?

[Pause.]

MR. TELFORD: Before we were talking about really what's the goal so I was trying to get on the table that our goal is prevention. It's not minimization. It's not ALARA. It's to ensure that byproduct material is administered as prescribed, to state it in the positive.

To be stated in the negative, we'll say the goal is to prevent misadministrations to the greatest extent possible, or something like that -- but the goal is to prevent.

Are we all on board with that?

MR. FRAZEE: Which way are you going to go?

MR. TELFORD: I would like to go the positive way.

MR. FRAZEE: I would too because prevention gets back to the preceding argument. It is an impossible goal because it is human error. As long as there's humans involved, you'll never obtain zero -- so it's a great goal to go with but state it in the positive, in the positive sense because that will help us sell it to licensees because we are not trying to do the impossible.

MR. TELFORD: So the second sentence is really this, and I would modify that to state it in the positive, to ensure byproduct material is administered as prescribed.

Yes?

MR. DUNDULIS: Just to maybe, even though it is obvious from the context, prescribed by an authorized user, the reason being you asked about possibly conflicting state requirements.

MR. COLLINS: Every state is different on that -- leave that alone.

MR. DUNDULIS: In other words I don't want it to

get to the point where if you say prescribe and at least by context because in some states you say any MD can write a prescription.

MR. TELFORD: Let us define what we mean.

MR. CAMPER: Also, too, Bill, could you, with regards to that sentence, what are you --

MR. DUNDULIS: I said by an authorized user.

MR. CAMPER: Where in the sentence?

MR. DUNDULIS: At the end where we say byproduct material is administered as prescribed by an authorized user.

MR. CAMPER: It can't be administered by anybody else but.

MS. SALUS: It's referring to a prescription being from an authorized user.

MR. DUNDULIS: Technically though the actual administration can be done by a technician under supervision.

MR. CAMPER: That's a delegated responsibility.

MR. DUNDULIS: Right, but I wanted to make it clear that because of the various state medical boards on prescription, particularly like on a staff, one of the concerns that a lot of us in the agreement states have is that some MD prescribes something and that person may just be an internist with no nuclear medicine and yet it --

MR. TELFORD: We can handle that. Get better definitions, hang on.

MR. CAMPER: Is there someplace in that sentence or that first paragraph that you are getting at?

MR. DUNDULIS: No, just the context that we want it clear that there's authorized user involvement in the prescription and the screening of patients.

That is the point I want to make, how you do it.

MR. CAMPER: Right. I think what we need to do at some point but not here I think is to talk a little bit about this term "prescribed," "authorized" user -- who does what? That does a prescription in the context of ordering nuclear medicine scans is an interesting concept and we have to talk about it some where and I think probably definitions.

MR. DUNDULIS: That is the point I was trying to make, Larry. That's why I added definitions into this item on the agenda to discuss the proposed QA rules, 3535 and associated definitions.

MR. CAMPER: We'll do that last to keep you all here.

MR. TELFORD: Okay. That's the opening paragraph. And I think we really should go to definition next, because without that, we're going to have a much harder time to look at the objectives.

So there's a couple of key definitions. And one is prescription.

This is on Page 1447 of the handout.

But we've had several suggestions not to use that term, "prescription." That brings up problems to various groups. So our latest thinking is to say we'll talk about a written directive that is signed by an authorized user.

So, rather than defining a prescription, we will define a written directive, and it will mean essentially the same thing. The one principal difference ni this definition that you're looking at is that it will say signed by an authorized user, and not the following clause. It will not say "or a physician under supervision of an authorized user." The reason being that in 10 CFR we have 35.25, which allows supervision of other physicians or staff by the authorized user.

So the NRC licensees can delegate that authority if they want these other physicians to sign a written directive.

However, in each state, you can determine those folks that you want to sign this.

MR. COLLINS: Could it also say, or a visiting authorized user?

MR. CAMPER: No. Because it's clear elsewhere in the regulation.

MR. TELFORD: A visiting authorized user is an authorized user.

Now, comments?

MR. WHATLEY: Prescription applies to radiopharmaceuticals which are, iodine-131 and iodine-123, brachytherapy, and teletherapy. Prescription, the word prescription does not apply to diagnostic uses, other than iodine-131 or iodine-125.

MR. CAMPER: I have a question for clarification.

MR. WHATLEY: That's important, now. You need to realize that now. When you're talking about diagnostic, the term is used, unless that's been changed, as a written request, as opposed to a prescription. That's important.

MR. CAMPER: The term "prescription," our plan thus far is to not use the term "prescription," but to use written directive, because of the confusion that associates with the technical concept of prescription, which raises a question I'd like to ask.

I've heard some dialogue off and on with various members of the agreement states about this concept of a prescribed dose by the authorized user. And I'd like to get a feeling from perhaps Bill on what you view as a prescription by an authorized user.

For example, a physician orders a study, a nuclear medicine lung scan, for example. The patient shows up at

the department with that request. And the patient undergoes a lung scan. What in that process or where in that process do you view the authorized user as creating a prescription?

MR. DUNDULIS: Larry?

MR. CAMPER: Yes.

MR. DUNDULIS: I think what Kirk and I are concerned about is John Smith, M.D., Internal Medicine, no training in nuclear medicine, decides he wants his patient worked up for some nuclear medicine procedure and the patient just walks in, a lot of times his secretary talks to the technologist. In comes the patient. They get that procedure. And the first time the authorized user is involved is when the scan is already developed and the authorized user reads it.

And I think what we're saying is that at some point that before a dose can be administered, if a request comes in from a non-authorized user to perform whatever, that the physician review it, and, even if it says okay, his name and the date. But I think what we're saying is that the authorized user be involved to make sure that for some reason that may not be apparent to the non-nuclear medicine physician, that the scan is contraindicated.

MR. TELFORD: You're talking about a referral.

MR. DUNDULIS: Yes. So we're less concerned about the prescription than the authorized user involvement, at

least for me. I'm not sure if that's Kirk's feeling.

MR. TELFORD: Hang on a minute.

Number two, we're going to use the prescription, or we're going to call it a written referral.

Number three, this is a referral.

So, let's first focus on a written directive; next we'll focus on a referral.

Kirk's statement, I believe I'm hearing it correctly, I agree with it. We'll get to it. We have to take this one at a time.

Now, Larry had a question about use of a written referral.

MR. CAMPER: What I'm getting at is, I clearly understand that -- and I don't oppose anything that you said or that Kirk said -- I personally, and our department, clearly endorses the idea of an active involvement by authorized users. I think authorized users should determine that a study is indicated and should okay the patient procedure.

What I think is so confusing though is saying the authorized user creates a prescription. The authorized user sees the patient. The authorized user interacts with that patient. The authorized user says okay, Mary Jones get this scan; Mary Jones gets her scan in accordance with the procedures manual.

What I think breaks down there is, at what point did the authorized user prescribe.

Now, part of the confusion may be the definition of a prescription. And I think all of us know in the classical sense what a prescription consists of. We think of it in terms of drugs, tentatively.

So there's been, at least in my mind, I think, some confusion as to what a prescription by an authorized user means.

I would submit to you, for example, that in the context you're referring to it, it's really a review of the patient's history and a review of the patient, and a use of a procedures manual, as opposed to a prescription by definition.

MR. DUNDULIS: In other words, what it is to me is, unless state law says otherwise, it's a written concurrence by the authorized user, either that it is his patient or her patient, and he is saying Mrs. Jones to get bone scan per procedures manual.

MR. TELFORD: You're talking about a referral.

MR. DUNDULIS: Well, no.

MR. TELFORD: There's a distinct difference between diagnostic referral and how the authorized user in the department reacts to a diagnostic referral, as opposed to a prescription.

Remember now, that prescription had to do with therapy and things of that nature. We've heard, throughout this process that, look, you can't take away diagnostic referral from us, because that's how nuclear medicine gets done. We've got to have the flexibility of having phone requests, electronic transmissions, as well as requests. And you can't take away that flexibility.

So I do draw a distinction between diagnostic referral and written directive, if you will, rather than prescription. See what I'm saying?

MR. DUNDULIS: I think a prescription, if you want to narrow the focus to prescription, I think there's two things. Because then you're limiting it to therapy, and then it should be spelled out specifically, if it's a standard procedure that is done in the facility for which a procedure exists, then it could be. Hyper-thyroid is in treatment per Procedure 1.5, and sign it --

MR. TELFORD: You're talking about therapy procedures?

MR. DUNDULIS: You're saying that --

MR. TELFORD: People, our volunteers have told us time and time again, don't talk about a procedures manual for therapy procedures; only talk about a diagnostic procedures manual. But it set up a therapy procedures manual. It's not universally done. Let's put it that way.

MR. CAMPER: Let me make a suggestion if I may, John, that we go back and do what you were just suggesting a moment ago.

Let's talk about diagnostic referral, first.

MR. TELFORD: Okay. Let's do referral first.

MR. COLLINS: Could we do this in the context of your stated goal of making sure this is the right patient, and the right treatment, and the right radiopharmaceutical, since the rule is narrowed to that, and we're getting off into quality of professional care again.

MR. TELFORD: Okay. Let's do referral. Let's do diagnostic cases in general.

We have a definition here for a clinical procedures manual on 1447. Now, by that we mean a collection of all the procedures that will be used for diagnostic studies. Everybody is familiar with that, what we're saying we need to have in each nuclear medicine department. So that when a referral comes in for a bone scan or a thyroid scan or a gall bladder scan, the technologist can follow the clinical procedures manual, because that is in essence a standing order from the authorized user because the authorized user approved of all this. Whether they're right or they're wrong, the authorized user approved of it. Hopefully, they're right.

Now, the question is, how do you get a referral

into the department; and the second question is what's the interaction of the authorized user?

So far, the only interaction that I've defined for you is the approval of the clinical procedures manual by the authorized user.

MR. FRAZEE: Does that have indications, contra-indications?

MR. TELFORD: Clinical histories, yes. But the procedures manual will say clinical history. I think it does not say now, but will have.

MR. FRAZEE: But the technologist is going to be the one who asks those questions?

MR. TELFORD: Wait a minute. Don't jump to any conclusions. Okay. That's a good question. Let's hang on to it for a minute.

MR. KULIKOWSKI: I'm going to read something which is in part of our law in New York State. Nuclear medicine services shall be ordered only by a physician with Federal or state licensure and staff privileges allows him to do referrals.

MR. TELFORD: What kind of procedure is that?

MR. KULIKOWSKI: Nuclear medicine services.

MR. TELFORD: Meaning diagnostic studies?

MR. KULIKOWSKI: Diagnostic and therapeutic.

I just had a discussion with some of our

radiological society, including the nuclear medicine department, and it is our feeling, and I think it was a consensus that came out of that meeting -- they met the day before we did -- that there definitely needs to be involvement of the authorized user in determining on an issue by issue basis delegation of authority and supervision of patient-by-patient basis. There needs to be involvement of that authorized user even if there is a clinical procedures manual which spells out in exact detail. It medically is a generic procedure, but they do routinely, and the clinicians that I spoke to agreed to this in principal, that there may be mitigating circumstances on a patient-by-patient basis that a procedure is not to be performed according to procedures manual and therefore is the responsibility of the licensed authorized users to ensure that one, in the prescription, written directive, or whatever you want to call it, at some point, and I emphasize the word "written," has to be there at some point in time, that either yes, that procedure as published in the procedures manual is fine, or do it this way because of this particular patient's needs.

You know, there needs to be some involvement of the authorized user.

MR. TELFORD: I got it. Let's look at referral.

What we wrote in the proposed rule was a referral

means a written request signed by a physician, meaning it could be a GP, that includes the patient's name, diagnostic clinical procedure, and clinical indication, medical history.

Now, that did not go over very well. The primary objection was that it was written and had to come with the patient. The way that most folks do business we are told by a lot of folks is that it's a telephone order. The referring physician, the primary care physician says I'm going to send Mr. Jones in for a thyroid scan or a liver scan. So there's a telephone call from the referring physician's office to the nuclear medicine department. And Mr. Jones shows up and says here I am, and there is recorded certain information in a log in the nuclear medicine department.

Now, let me give you our suggestion for the best we've done to date, and you tell me how you want it modified.

We've been saying now that a referral means prior to administration of byproduct material that you have three choices.

You can have a written request, initiated by a physician, that includes the date, the physician's name, the patient's name, the requested procedure, the diagnostic clinical procedure, clinical indications.

Or you can do that verbally, over the phone, provided that those five or six pieces of information that I gave to you are recorded by the nuclear medicine department upon receipt.

Thirdly, you can send that electronically.

Now, we've omitted the need for the signature of the referring physician. We are still using the idea of the diagnostic clinical procedures manual. So far, all we're asking for is that the right information get to the department, it gets recorded, so that it's written down, and the technologist can understand what it is, to use the standing orders contained in that diagnostic clinical procedures manual.

So far, we do not have the review and approval by the authorized user.

MR. KULIKOWSKI: That's why I find the problem. You've cut the authorized user out. Why write a license at all, then.

MR. CAMPER: Wait a minute. Why have you cut the authorized user out? Let me ask you a question and make a statement.

I am a physician, and if I see a patient and I want to send that patient to your department to be imaged, is that not a diagnostic referral?

MR. KULIKOWSKI: Of course it is. It is.

MR. CAMPER: All right. We get the request for the study to the department. We use the term diagnostic referral. What in that definition thus far cuts out the authorized user?

MR. KULIKOWSKI: Because if you just follow that patient in, say you're the oncologist and I'm the nuclear med. guy, you have John Jones as your patient. And this is the case we talked about. The patient has been treated, and it's an ongoing thing.

Your secretary calls the nuclear medicine department and says John Jones is coming in for a bone scan. The patient walks in, is scheduled, the tech. runs up the dose, administers it, does the image, processes it, and I find it the next day in the scans that I have to review.

I am then left out of the process for that particular patient.

In other words --

MR. CAMPER: I don't disagree, Bob. This is a diagnostic referral.

MR. SHARP: What he's saying is that is no status.

MR. CAMPER: I'm saying this a diagnostic referral, my definition of a diagnostic referral, we're talking about a mechanism whereby a physician, any licensed physician practicing medicine, requests a study to go to your nuclear medicine department. That is a diagnostic

referral.

MR. FRAZEE: Take it the next step, and have the authorized user approve it orally.

MR. CAMPER: Well, would you do that in the concept of a referral?

MR. FRAZEE: Yes. It doesn't distinguish whether the scan is done via referral or whether it's done in-house. The scan is going to get done, and there needs to be involvement of the authorized user at some point.

MR. WHATLEY: I think the term diagnostic referral ought to be thrown out the window, period. What it does, the physician that's authorized, the authorized user, the only physician that's qualified by training and experience, does not even have to read the film. He doesn't have to select the patient. He doesn't have to prescribe the dose to be administered. He sets up his little book. So be it. He doesn't look for things such as pregnancy or possibility of pregnancy, medications taken for clinical conditions that influence transport, or capillary blockage, and so on, or previous nuclear medicine procedures that might be involved. He' snot involved there at all.

A patient comes to a nuclear medicine department; a technician takes that diagnostic referral, does the study, gives the film back to the patient who takes that to the office. The authorized user is completed eliminated from

that process, with the exception of setting up the procedures to start with.

Now, I question, if that's the case, why don't you just have a radiation safety officer in the institution and let one doctor run the procedures for diagnostics, for many hospitals? If he's not involved in the procedures whatsoever, what's he there for?

Let me finish.

Why, if a physician is interested in practicing diagnostic radiology, nuclear cardiology, which we all have problems with, why are we asking him to have 200 hours of radioisotope training, experience, and 500 hours clinical experience, if any doctor can send a patient in there and have a study done?

Let me finish.

I just think what you've done with this diagnostic referral eliminates, in the name of quality assurance, or whatever we're going to call it, the only person who by training and experience is qualified to make those decisions.

I've got some letters from the NRC, if you ask why. And let me --

MR. CAMPER: Let me ask you a question, just to understand your point.

MR. WHATLEY: Let me finish. Let me finish.

MR. CAMPER: Okay.

MR. WHATLEY: This is a letter from the U.S. Nuclear Regulatory Commission. Subject: Explanation of Authorized User on Medical Licenses. Licenses issued for individual medical practice contain a condition which requires that byproduct material is to be quote, "used by" unquote, a specifically-trained physician. This condition is intended to require that the physician, and only that physician, may, (a), select patients for radioisotope administration; (b), prescribe the type of radioisotope and doses to be administered; and (c), interpret the results of the diagnosis and treatment.

Now, that has been the practice in many agreement states. It was taught in NRC's nuclear medicine licensing courses through the mid-'80s. I don't know, I'm not aware when that was ever rescinded.

And I'm just, I have no problem. If you throw diagnostic referral in, I think every patient, if my wife went to a hospital, or my child needed a scan, or whatever, I would want her to be seen by somebody that's qualified to make a decision is this the best isotope to be administered to her; is it necessary; is she on some medication that may interfere with the study, or whatever.

What this does, it eliminates the only person by training and experience who has done that.

If I were a physician in diagnostic nuclear medicine right now today, and I was aware of what this does, where it authorizes any physician in this country to practice nuclear medicine -- and that's what it does -- I would be very upset as to why I had to go take 200 hours training plus go through a six-month training program in a hospital.

MR. CAMPER: Are you finished?

MR. WHATLEY: For the time being.

MR. CAMPER: There is nothing in this definition that prevents authorized users from practicing nuclear medicine.

Let me finish.

MR. WHATLEY: All right.

MR. CAMPER: There is nothing in this definition. What we are talking about here in this definition is the vehicle, and what that vehicle contains, by which a nuclear medicine study gets requested.

Now, nuclear medicine physicians don't self-refer. They are requested to have studies performed by other practicing physicians. Those doctors there in that nuclear medicine department, they perform the procedures, they interpret the images. But those patients don't get to that department by virtue of the authorized user. They get there by virtue of other physicians requesting a study in

the course of the treatment of their patients.

And what we're saying in this definition is, that vehicle that comes to the nuclear medicine department, that the authorized user reacts to, should contain, minimally, certain things.

That's what this definition does.

MR. WHATLEY: Can I respond to that, please?

MR. TELFORD: Let me make a point first.

What I'm trying to do is modify the proposed definition of referral.

Now, we're trying to modify it so that the licensee has various ways, three ways, to receive a referral.

Now, we're trying to qualify the information content that comes in. Now, I think where we are departing is that we have not said referral must be reviewed and approved by an authorized user prior to administration.

MR. WHATLEY: That's the bottom line.

MR. TELFORD: So first of all, I wanted to ask you, hey guys, how about the information content here? Is this a sufficient information content to get the patient? Because, as Steve is reminding us, look, the errors occur and the mistakes occur because you get the wrong patient. So we have to have sufficient information to identify the patient, like name, date of birth, Social Security Number,

address, so that the patient can be redundantly identified.

The wrong radiopharmaceutical, so that if I-123 is what the clinical procedures manual says, but the technologist doesn't have sufficient guidance and uses I-131, the wrong radiopharmaceutical.

So let's, could we step through this? I mean, first of all, information content of -- these patients have to come in some way.

MR. KULIKOWSKI: I'm in full agreement with that.

MR. CAMPER: I'm just reacting to the concept of doing away with the diagnostic referral totally.

MR. KULIKOWSKI: In principal, you're not going to be able to do that, because of the way nuclear medicine works. I wouldn't call it an order, prescription, or written directive of the referring physician. That's something that's reserved for the authorized user. I think the referral slip should say the type of study he wants done, not necessarily the isotope that he wants to be used, because he doesn't have the training and experience.

MR. TELFORD: Definitely not.

MR. KULIKOWSKI: Then it is incumbent upon the authorized user, or should be incumbent upon the authorized user, to take that information, knowing that it's Sally Jones, her bone scan, you know, to do X, Y and Z, that these are the pertinent clinical history things, for that

authorized user to look at Sally Jones -- or maybe he's seen her three times in the past six months and doesn't have to do that, because that's a medical decision -- that he can be comfortable in writing what we call a classical prescription for Sally Jones to have a bone scan. And that prescription should say, the patient is Sally Jones, signed by the authorized user, and it contains the other pertinent information that it is a bone scan to be done according to the clinical and diagnostic procedures manual, Procedure A, B, C, or D, or that procedure with the following modification, or do it this way. Depending on her clinical condition, he has to make a judgment as to whether that procedures manual is the best procedure to use for that particular patient or whether he wants to write some custom-tailored prescription. And in that respect, the clinical and diagnostic procedures manual is not a substitute for the authorized user. It is just a work-saving device for him instead of writing out the same procedure over and over again for the commonly-used procedures.

MR. TELFORD: Okay. So if I can interpret your message, it's that we have set up the vehicle of using the clinical procedures manual as a handy work-saving device for the authorized user, and you're basically saying that it's not sufficient. The authorized user needs to okay, approve each procedure before it's done.

MR. DUNDULIS: Absolutely.

MR. KULIKOWSKI: That's a patient-by-patient decision. Maybe the standard procedure is not correct for that patient, and the tech. is not going to know that.

MS. ALDRICH: I have to disagree. I think we need a variety of mechanisms.

Some procedures, the classic thing that physicians will bring up are emergency room admissions. The authorized user isn't going to be around, and of course they'll do the procedure.

So I think to answer Larry's question about the mechanics of the mechanism, I think we would be flexible on the mechanism.

Initials by an authorized user on a referral, for example, to us would be acceptable evidence that that person has made the judgment, even if it's after the fact.

In other words, the authorized user takes responsibility for which patients get on. We don't necessarily require a prescription. And I wouldn't go so far even as to include specifics on what should be on a referral. I think that is medical judgment.

MR. CAMPER: Well, I don't think it's medical judgment when you're asking for a patient's name and procedure requested, date. That's not medical judgment.

What we're trying to do here is make sure the

patient's diagnostic referral document contains minimally a certain level of information, hopefully to ensure that we're doing the right procedure on the right patient.

MR. KULIKOWSKI: Let me just clarify something.

A computer transfer, that falls in the generic category of prescription. We do recognize that there are medical emergencies. Somebody throws an embolism has got to have a lung scan right away. This is not meant to preclude medical care or quick medical care as practiced by the physician. It may be that after the physician looks at the scan, he says, yes, -- he signs off on the interpretation of the scan and that's good enough for us, too.

The principle is what I'm trying to get at. The authorized user has to be in the loop somewhere.

MR. CAMPER: There is a medical problem here.

MR. KULIKOWSKI: When I spoke to some people in New York City, there was one representative I spoke with, admittedly in one of the larger nuclear medicine departments in the city, he didn't seem to have any problems with our concept.

MR. TELFORD: For clarification: do you mean prior to administration? When is the authorized user in the loop?

MS. ALDRICH: That's really what I was speaking to. If Larry says that this information has to be there,

I'm not going to disagree with that, but it's the prior to administration that preceded all of this. I don't think all of that information needs to be written down anyplace to it. I think that there we're interfering, because there are circumstances where that isn't going to happen.

MR. TELFORD: I want to come back to that question, but Curt has had his hand up and wants to make a point.

MR. WHATLEY: As far as our regulations are concerned, it's our patient rules that they select patients that they prescribe radiopharmaceuticals and interpret the results. That's part of our rules. They define how a physician could do that many years ago.

They said a physician can select patients three ways: number one, referring - talking with the referring physician on the phone or whatever, by telefax of whatever mechanism he wants to, by examining the patient himself or viewing the patient's chart, one of those three ways must be used in determining that radiopharmaceuticals will be administered to that particular patient. That was NRC's criteria that we've all used for years.

MR. TELFORD: What's the overt step that the authorized user takes that we require, like; is there an overt step like they have to initial each one before it's done? Do they have to sign it?

MR. WHATLEY: It basically comes down to; an authorized user tells this technician, administer this radiopharmaceutical to the patient.

MR. TELFORD: That's verbal.

MR. WHATLEY: It may be a verbal prescription. I have no problem with a verbal prescription. It is a prescription as long as it -- it may be documented on the patient's chart later on.

MR. CAMPER: What happens in those cases when the physician is not on the premises at the time?

MR. WHATLEY: Give me an example. Emergency room?

MR. TELFORD: No, standard, not emergency. We can fix emergency conditions easily.

MR. CAMPER: I would submit that there are many cases in this country every day, routinely, where diagnostic nuclear medicine procedures are performed at a time when the authorized user is absent from the department for any number of reasons.

MR. WHATLEY: In my opinion, it's malpractice. Let me share a letter with you from the Director and Professor of Nuclear Medicine, Division of Nuclear Medicine of the University of Alabama Medical Center. I'll just read part of it.

"If there's an in vivo test then the nuclear medicine physician should see the patient." This was an

answer to a question we raised. "We have nuclear physicians see every patient before the examination and after, to see whether the procedure answered the clinical question or whether some other steps should be made."

MR. CAMPER: I would agree that that's good nuclear medicine practice.

MR. WHATLEY: In our efforts over the last 25 years, we've certainly made a tremendous effort to enforce that. That's one of the primary concerns on our inspections.

MR. CAMPER: I would agree that that's good practice. Let me make a point though. What we've heard is that in the practice of nuclear medicine, if you get down to the point that it's a regulatory requirement, you impose regulatorily, language about an authorized user seeing a patient prior to or specifically approving prior to the administration of, that you're posing a problem in the normal course of the practice of nuclear medicine in busy departments.

We have procedures in place. We have clinical procedures manuals. We have interview sheets to be used by technologists. We have a way of dealing with this problem which includes not only the authorized users specifically interviewing and reacting to each and every patient -- there is a concern that --

MR. TELFORD: Let me be constructive here. I have a two part proposition for you here. The first part is the information that's contained in the request or whatever it is that we're going to call it. The second part is who is going to approve it and how. Let's be constructive.

Let's go back to the referral itself. Now, what I'm telling you is that I have gone through a lot of meetings and a whole lot of water under the bridge to get to this point.

This is the best I can do after several or many, many months here. So, I've got a referral, a diagnostic referral. I want to propose that we include certain information. Now, today's date; is that any problem? Is that interfering in the practice of medicine?

MR. WHATLEY: No.

MS. ALDRICH: Are we still presuming that the wording, "prior to administration," that this has to be -- that this information has to be there?

MR. TELFORD: We need to know what we're going to do before we do it, so this is prior to the administration.

MR. WHATLEY: Can I interrupt you a second?

MR. TELFORD: Yes.

MR. WHATLEY: I think we're not to that point, and let me tell you why.

MR. TELFORD: All right.

MR. WHATLEY: I think NRC's criteria is different than our's. The NRC doesn't require -- apparently, they don't require a physician to do this anymore.

MR. CAMPER: Why do you say that? I was going to make some comments about that later.

MR. WHATLEY: I'm asking.

MR. CAMPER: Why do you say that?

MR. WHATLEY: I said, apparently. Help me out; do they? Help me. What does the term, "radioactive materials shall be used by," on the NRC medical license mean? I'm asking; what does that mean to NRC, NRC inspectors.

MR. CAMPER: It means that the materials that are authorized in a particular license have got to be used by or under the supervision of the designated authorized physician users. Those materials -- the responsibility for utilizing those materials is often delegated to technologists.

That responsibility is conducted through the use of procedures manual for performing studies, through patient questionnaires, through departmental protocols, but that means that those radioactive materials cannot be utilized unless they're utilized under the supervision of an authorized user who has demonstrated to the NRC or the agreement state that he or she has adequate training as it relates to radiation safety to protect public health and safety.

Now, that hasn't changed. I don't know whether there's confusion there. The greatest confusion that we see is the question of interpretation of image only. That poses a significant problem to us. Our position on that is really no different than it has been for some years now and that it's a twofold problem.

On the one hand, if you look at Regulatory Guide 10.8 on page 8 of that document under Item 7, we identify those things which authorized use involved in medical use involve the following special responsibilities: we list them.

MR. TELFORD: Read the first one, Larry.

MR. CAMPER: Examination of patient's medical records to determine if the procedure is appropriate, prescription of the radiation dose and how it is to be administered, actual use and direction of technologists or other paramedical personnel and finally, interpretation of results, diagnostic procedures and evaluation of results and so forth.

Our position has not changed on that. It's still very clear and I don't think there's anything in the concept or definition of the diagnostic referral that changes that. These are the things we believe an authorized user should do.

A tough question comes in there, though,

sometimes, and that's the interpretation of the image only. There we have a problem. On the one hand, we believe that it is incumbent on the licensee, the institution, to see to it that a procedure is carried out properly, that it's controlled at all times by an authorized user and that a proper interpretation is made by an authorized user.

On the other hand, there's nothing in our regulations that prevents any doctor in the practice of medicine from interpreting an image. So, there's two sides to that problem. Nothing in that implies that we see any lessening of responsibility of the authorized user.

MR. SHARP: Also interpreting?

MR. CAMPER: There are cases -- we believe that it is the responsibility of the licensee to see to it that the proper interpretation takes place. That proper interpretation involves an authorized user. In those cases where an authorized user decides to delegate that responsibility to someone, it's clear that the licensee is exercising the proper responsibility.

That happens in many cases with pre -- physicians, for example, residents and the like. Where it gets tough, where it gets very tough -- pardon me?

MR. SHARP: He's not really delegated interpretation.

MR. CAMPER: The authorized user has the

responsibility to make the interpretation. If he or she chooses to delegate that responsibility to a resident or to a preceptor, as far as we're concerned, that's okay. I'm just saying that it's okay as far as we're concerned.

The licensee, the institution, has the responsibility to see to it that adequate and proper interpretation is made as part of the process; that it's done by an authorized user. An authorized user, if he or she chooses to delegate that responsibility to someone, we have no problem with that.

MR. SHARP: Our medical practice, for example, will allow the task of, say, supervising the technician to be delegated, but not the responsibility. The responsibility stays with the authorized user. The task can be performed by someone else.

MR. CAMPER: Any time I delegate; anytime anyone delegates the authority to someone to do something, the delegator never relinquishes responsibility. The thing that gets tough sometimes though is in those cases where a physician who is not an authorized user wants to interpret an image.

There's nothing in Part 35 that prevents a physician practicing medicine from interpreting an image only.

MR. SHARP: What you're saying is, also, that

image exists is properly ordered and properly interpreted. The image sits around and can be interpreted by anyone else. If that's the only interpretation that happens on that image, then no.

MR. CAMPER: What you're getting at is this scenario: an image is created as a result of authorized materials being used under the supervision of an authorized user; that image is produced. What you have to have happen is you have to have a scenario where the authorized user says, I don't want that image to be produced so that Dr. X can interpret that.

That would have to happen, otherwise the image does not get created in the first place. Where you can envision a problem is where --

MR. TELFORD: Why are we focusing on interpretation of the image.

MR. KLINE: Let me make one comment. We've got to get back on track on what we're originally here for. The goal of this proposed rule is prevention.

Now, in writing the rule, you have to look at where we are finding the misadministrations. Where are they occurring? You can't write a rule unless you know where the problems are and why they're there.

Our data that we collect -- and again, this is the misadministration database we're collecting -- the data we

collect is voluntarily sent to us -- appears to indicate that a majority of misadministrations, the wrong pharmaceutical differing from the prescribed dose by 50 percent -- this is based on current NRC definitions of misadministration -- wrong patient or undefined reason -- the major precipitator is at the technologist level.

The referring physician is a small percentage of the problems that we document. Let me give you some numbers. There were 387 misadministrations diagnostically in 1989 reported to the NRC. Out of those 387, 244 were via the imaging technologist -- these are approximate numbers -- hot rad technologists. Twenty three were attributed to the referring physician.

Again, if we focus on the problem areas, is this a big problem, the referring physicians? It appears not, based on our information. Again, we don't know how many are reported, but we're assuming, based on our database to date, the problem is misinformation, miscommunication, knowledge and knowing what you're doing.

The second thing is, talking with the medical people in the field, discussing these sort of concerns with professional societies, you get into cost and benefit analysis. You get into what return medically will the community get from this misadministration rule. What the concern is that with escalating medical costs, can we afford

to have an authorized user review each individual case? That's an argument.

The third one is the current practice of medicine. Are we going to change the current practice of medicine? This is an argument. So, you see, you have a lot of people in the medical field who are saying, why do we have an authorized user review each diagnostic radiopharmaceutical study? It sounds good; I'd love to see it, but logistically, costwise and problemwise, why are we requiring this.

You might want to consider that in your arguments. These are good arguments by the medical profession.

MR. TELFORD: Steve, you had your hand up.

MR. COLLINS: I think that's exactly what Kirk was trying to consider when he was saying that if you're not careful when you write the qualified individual out of all of your requirements, that if you don't have -- or if you don't specifically write them into the requirements, then you haven't addressed the problem at the technologist level or below where most of the problems are occurring, and that's because the training and the school and the qualified individual is not forced to be involved at the level to have that --

MR. KULIKOWSKI: Steve's point should be well taken. If you go back and read on page 8, the first

responsibility of the authorized user is to make sure the procedure is appropriate for that patient, whether it's examination of the patient or -- in the discussion that I had a week and a half ago with our nuclear medicine people, the concept of having the authorized user make sure that the determination is made that that procedure is appropriate for that particular person, without specifying it's got to be examination of the patient or examination of the records or what have you, you know, that we agreed upon was the medical decision. How he made that determination was the medical decision.

What was in our purview was that he made that decision as an authorized user.

MR. CAMPER: Well, I think unfortunately what's happened to us here is that we've gotten into some discussion here because comments have been made, rather generally, about NRC's position on the authorized user. All I tried to do here is to say that our position on the responsibility of authorized users has not changed.

The point of confusion is, I think, that there's nothing, as far as we are concerned, that has changed the requirements of Part 35 or the guidelines set forth in Reg Guide 10.8 as it relates to the definition of diagnostic referral. Now, what I hear is some discomfort or some concern that -- from some of you -- that the definition of

diagnostic referral is either, A, not good at all, or it should include some statement which further endorses, further emphasizes, beyond the scope of already existing regulations and regulatory guides, the emphasis or the part of the authorized user in this process.

MR. TELFORD: If I can see if I understand this, you're saying you want either written or verbal approval of this procedure prior to administration.

MR. KULIKOWSKI: Let's not even say written or verbal. Let's just say approval by the authorized user as your guidelines specify.

MR. TELFORD: We'll have to specify somewhere or in some way, what we mean by approval. For our understanding, we would accept verbal or written approval prior to administration.

MR. FRAZEE: Could you add that as one more diagnostic event? If the authorized user doesn't approve, then that would be another way of getting the concept into this particular bit of rule which would maybe take care of --

MR. TELFORD: That's worth considering. Let's pick that up when we get back there. I note that it's about ten minutes of 1:00. Please engage me here for a few minutes and let's see if we can get the information content there and then let me suggest that the NRC propose something

and then let's see if that interferes with your ability to add on that where you can advise us to how you would do that, this approval stuff, for example.

Okay, diagnostic referral, information content; our best shot at this so far is to ask for a date, today's date. Does that interfere with anybody?

[No response.]

MR. TELFORD: A physician's name? Does that interfere with anybody?

[No response.]

MR. TELFORD: Referring physician's name, the patient's name and other information that will assist in identifying the patient; for example, date of birth, social security number and address, stop.

Requested diagnostic clinical procedure or requested diagnostic clinical s ıy, if you prefer; does that interfere with anybody?

[No response.]

MR. TELFORD: Clinical indications, clinical history --

MR. SHARP: As to those two, I want to find out about this which is the clinical indication.

MR. TELFORD: For example --

MR. SHARP: Clinical history is --

MR. TELFORD: Clinical history is a better term?

MR. KULIKOWSKI: Put something like -- will be accepted, or --

MR. SHARP: It doesn't tell what the patient has had before.

MR. TELFORD: You're trying to figure out if the patient should get a thyroid scan or a whole body scan?

MR. WOOD: Appropriate clinical history?

MR. SHARP: A clinical history would be closer.

MS. ALDRICH: I was going to suggest just simply, Reason for the Request. We're all assuming that the authorized user is going to have a very active role in this, and that therefore, this is not all there's going to be.

MR. CAMPER: It is interesting to note though that physicians have indicated to us that the idea of putting in clinical history, by definition, is not a bad idea. They'd live getting a more comprehensive history.

MR. SHARP: But they're presuming that the authorized user --

MR. TELFORD: What if we said appropriate clinical history or reason for the test or study?

MS. ALDRICH: Reason for the request.

MR. TELFORD: Reason for the study or procedure.

MS. ALDRICH: I guess that brings me back to something I was going to say before. The use of the word, "request," is kind of intriguing here.

MR. TELFORD: Referral is what we're talking about.

MS. ALDRICH: Right, but request to whom? Request is like asking for, which is another way of --

MR. TELFORD: They're requesting the nuclear medicine department.

MS. ALDRICH: Okay, let's say we're at a private office and you have a secretary who takes this and how should that word be viewed? I mean, how is it intended that you wan that word understood?

MR. TELFORD: Reason for referral. In other words, why is this patient being referred?

MR. KLINE: Well, if you left off the definition, and said, diagnostic referral instead of request, period, it just seems like it's redundant.

MS. ALDRICH: Yes, but that's where the request, in that definition of diagnostic referral -- how do you mean that to be understood.

MR. TELFORD: Diagnostic referral.

MS. ALDRICH: Yes, you say diagnostic referrals are written requests. Requests to whom? Somebody is asking for the study. I am presuming that someone else would make the decision on whether the study is done.

MR. CAMPER: It's the request to the authorized user to --

MS. ALDRICH: Okay, if that's the way it's understood. The way I'm thinking is that that ties the authorized user into this process. This referral --

MR. TELFORD: You want to say a written request to the authorized user?

MS. ALDRICH: No, I'll let it go at that. I was really just asking for how you intend that word to be interpreted. We will be asked that; what do you mean, request? Request to whom?

That automatically assumes that the authorized user is going to make a decision.

MR. COLLINS: Reason for the request to licensee; reason for the request to authorized user or licensee, reason for the request to this department.

MR. CAMPER: Technically, it's a request to the licensee.

MR. TELFORD: She's saying, diagnostic referral means, prior to the administration of material, either, A, a written request -- it's that request that she's asking about. She means request to whom? We mean to the licensee or to the authorized user.

MS. SALUS: That's not necessarily the case. Would the necessarily be the same, the licensee or the --

MR. TELFORD: They're not the same.

MR. CAMPER: That's her point.

MS. SALUS: That's the question. We need to specify.

MR. BOLLING: Request to the department.

MS. ALDRICH: I'm just asking what you meant when you used the word, that's all.

MR. CAMPER: Request for imaging procedure is made to the licensee who is authorized to possess nuclear materials for medical purposes. That could either be an institution or an individual physician.

MR. TELFORD: That's the licensee. Do you want us to say a written request to the licensee?

MS. ALDRICH: No. I'm not really asking for a change of wording. That was for clarification, because it colors how you think about what should be on it.

MR. TELFORD: The question is; to whom? To the licensee.

MR. SHARP: Depending on whether or not you get one of the authorized users to see the patient beforehand or only after.

MR. TELFORD: That's next.

MR. SHARP: How about clinical history? We're still on that part.

MR. TELFORD: Appropriate clinical history or reason for the test or reason for the study.

MR. SHARP: If you're not going to see the

authorized user, then clinical history may be more important.

MR. TELFORD: Agreed.

MR. SHARP: It depends on which scheme, I guess, we're talking about as to what we want to say there.

MR. TELFORD: Right.

MR. SHARP: Even if you're going to see the authorized user before you give the test, when do you transmit such information to him that will enable him to make the decision? When are you going to give him the clinical history?

MR. TELFORD: This is prior to the administration.

MR. SHARP: When is the clinical history going to come to that authorized user.

MR. TELFORD: You're jumping ahead to the next subject. I haven't gotten the authorized user into this yet. I haven't gotten anybody into it.

I've just gotten the information to the department.

MR. SHARP: Should it be accompanied by a full clinical history or just --

MR. TELFORD: It may not even be there yet, because it could come over the phone. So, so far, all I'm claiming is that we're going to have appropriate clinical history or reason for the study, to be there, period.

Now, let's go to the next step. So far, we're saying our best suggestion is to say let the technologist get this information and if the authorized user or if the licensee so choose to allow the technologist to perform these studies using the clinical procedures manual which we would view as a standing order from the authorized user, to date, that's my best shot.

What I'm hearing from you is that you would prefer that we say, approved -- that the study is approved by the authorized user prior to the administration of the material, but you would allow either verbal or written approval of that action. You just want the authorized user on the hook, whether or not they really -- you realize, when we say verbal approval, they could say, okay, I do it, and never look at anything.

MR. DUNDULIS: It's a conscious effort on their part to say, do it, and then if the chickens come home to roost, the tech is noting, you know, verbal approval from Dr. so and so to perform standard procedure.

MS. WOOD: What the authorized user has to do with that referral is sort of a different issue as to what is the referral. For purposes of defining diagnostic referral, this information is probably fine, but there seems to be a lot of concern about what happens in the nuclear medicine department once the referral is received.

That's sort of the next issue. It's a slightly separate issue than what is a referral. The role of the authorized user doesn't have to be included in the definition of diagnostic referral.

MR. TELFORD: We can either say no approval step required -- and you ought to look at that two ways: what if we said that, realizing that the state is free to add that approval, because we're not negating that.

The second way to go is --

MR. COLLINS: We can add it if it's in the definition. We can add it but we can't put a definition.

MR. TELFORD: You can add the requirement that the authorized user go through an overt approval step, regardless. I haven't said anything that would negate that or even go against that in any fashion.

We could omit that, or we could add the approval step, either written or verbal. My gut feeling is that if it's verbal, we're going to get a little heat over it, but we might sell that.

MR. DUNDULIS: I think it's important, at least from my perspective in Rhode Island where we're surrounded by two NRC states and one of the things that I get from the Director of Health is, well, what is NRC doing in Massachusetts and Connecticut? It would be very difficult for us, without making a very strong case, to go beyond what

NRC has required.

My personal suggestion would be for NRC to bring the authorized user into the loop as part of the requirement and, you know, that it's up to the authorized user -- you know, I'm less concerned about the verbal or written, but I think that the authorized user should be in the loop as part of the rulemaking.

MR. TELFORD: Okay, now, just a minute.

Larry, if we say the verbal approval, by the authorized user, if we say in accordance with that reg guide 10.8 particular step; don't we already have that -- that approval step?

MR. CAMPER: The only thing I would say is this. If you look at the definition of a diagnostic referral; in other words, nothing in what we have said thus far alters or changes the requirements for an authorized user to participate in accordance with the terms or conditions of their license, according to the terms and conditions of the regulations, or according to the guidelines in the regulatory guide.

MR. TELFORD: No, no. We've got the referral covered.

The question on the table is, should we take the next step? Should we say the authorized user, this out outside the definition of a referral, we've got that.

Everybody is happy with that, I think.

Now, the question is, do we require or do we suggest very strongly that the authorized user give approval prior to the administration. So this would be --

MR. CAMPER: In what --

MR. TELFORD: In what vehicle?

MR. CAMPER: In what vehicle?

MR. TELFORD: I don't know yet.

MR. COLLINS: Instead of a written directive signed by an authorized user, we'll have an approval by an authorized user. That's what's on the table so far, right?

MR. TELFORD: No. We could put -- we could put it here. Here, this says that objective 3, when you have a referral made, and we could say approved by the authorized user.

MR. CAMPER: Yes, it would seem to fit as objective, yes.

MR. TELFORD: We have a couple of choices that come to my mind as to where we could put it. We could put it in the objective that says, you have the referral and it is approved by the authorized user; or we could say, we have it here, then say, in the reg guide, we think it's a good idea if it's approved by the authorized user, as we have said in the previous reg guide.

So, there are 2 vehicles for you.

David?

MR. WOOD: Could a pre-approved procedure be allowed by a licensed user, writing into a procedure manual, certain clinical diagnoses as being pre-approved. For example, a diagnostic bone scan could be performed on the basis of these 5 clinical situations, osteomyelitis, bone fracture, metastases, blah, blah, blah -- covers the average 98 percent of the circumstances, when the technologist says this diagnosis doesn't fit my clinical approved/pre-approved clinical diagnosis, then I must take it to my authorized user for verification of what he wants done.

MR. TELFORD: That's more or less what we had in mind, is the way the diagnostic clinical procedures manual is used.

MR. WOOD: A lung scan being performed for pulmonary embolus or whatever. You know, you may have a select list of pre-approved, they're straight-forward.

MR. COLLINS: That's the way it's done now, I believe, and that's exactly what we've been trying to address, as far as getting that with 200-hour or 500-hour man or woman back into the circuit of making that judgment, as opposed to a general practice and then the tech.

MR. KULIKOWSKI: One of the things that that doesn't address is the -- any patient-specific condition which is not related to the diagnosis. Yes, maybe the

patient weighs 600 pounds, your standard procedures manual may not fit that. It might give you some crappy image that this is what you want to avoid.

MR. CAMPER: Bear in mind, again, that this performance-based rule of how the licensees would go about accomplishing the objectives, are entirely up to them. If they want to use a procedures manual or a departmental protocol, which most of them do already. But the technologist asks a series of questions and indicators come up that don't fit, maybe certain things that involve the authorized user, that's fine. That's up to the licensee. It's a performance-based program.

MR. KULIKOWSKI: Larry, that seems to be slightly inconsistent with what the following responsibilities are reserved to the authorized user, physicians under his supervision. One is examination of the patient to ensure that the procedures are appropriate.

MR. CAMPER: I certainly hear you, Bob, and I certainly agree. But the problem is a practical problem, and that is that the departments have one physician are averaging 35 -- more than 35 or 50 patients a day. While he may deal with thyroid therapy and what have you.

In many cases, the authorized user has made a decision that he or she is comfortable with having their technologist ask a series of questions on routine

departmental questionnaires. All questions come up in the usual answers or variances that aren't acceptable they will perform a procedure.

MR. KULIKOWSKI: Maybe the answer to that is have the commission be making some policy that's published in reg guide 10.8 to modify that.

MR. TELFORD: Well, can we be specific to this rulemaking here? Bob, are you saying that you would like to see this approved, either verbally or in writing by some means --

MR. KULIKOWSKI: Right.

MR. TELFORD: -- by the authorized use or by the licensee here?

MR. KULIKOWSKI: Exactly. We'd like to see that.

MR. TELFORD: All right. Bill, you're saying that too?

MR. DUNDULIS: Yes.

MR. TELFORD: Jon?

MR. SHARP: I'd love it.

MR. TELFORD: You'd love it? Steve?

Okay. Number 3. Our purpose in number 3 is to get the information, in writing, to the department so they know what to do. Now, this is an additional step that -- that you're recommending to us, and that is approval by the licensee, prior to it?

MS. SALUS: It's not really new at all, from what I've been hearing.

MR. TELFORD: No, no, well -- it's a new thought here.

MR. COLLINS: We're with you so far.

MR. ANDERSON: I think it's fine. With approval. Pre-approval, prior to --

MR. TELFORD: Rita?

MS. ALDRICH: I still just have a problem with the prior to.

MR. TELFORD: Such as?

MS. ALDRICH: Such as the cases where the physician -- well, maybe we're talking about the same thing to some extent -- that the physician will take responsibility and the physician will sign off on -- on the order afterwards. I -- just as long as it wasn't interpreted as requiring some physical evidence that the physician, you now, signed off on this procedure before the fact.

MR. WOOD: You mean --

MR. SHARP: Technician documents are --

MR. KULIKOWSKI: If they do a procedure based on someone who comes in and they can't get a hold of the authorized user -- well, can he do it anyway?

MR. TELFORD: We call that an emergency

conditions. We have an escape clause -- you go ahead and do the emergency condition period.

MR. SHARP: Hundreds of miles a way, we'll ask verbally?

MS. ALDRICH: Thinking in terms of what's happened in the past, after a while, the rule, the way it's written becomes something immutable and what went into the thinking if it gets lost, and that that will be seen as somebody insisting that you've got to have the physician sign off on this before it's done, that's all.

MR. TELFORD: I want to get a clear yes or a clear no from you.

MS. ALDRICH: Ha-ha, yes.

MR. TELFORD: Wait, let me clarify.

MS. ALDRICH: As long as we're not understanding that we need something in writing from the authorized use ahead of time. Yes.

MR. TELFORD: This set of objectives would say, oh, please look at your page 1449. The lead-in sentence to this would say "this program must include written policies and procedures to meet the following specific objectives." Because it's a performance-based rule, we want to word it that way. They don't even say, objective number 3, that, start right here, that diagnostic referral is made and approved by the licensee where I have this and prior to the

administration of by-product material or any radiopharmaceutical for any diagnostic radiopharmaceutical procedure. I think I have those in not a very good order, but the thoughts are there.

So, what this says -- this approval would be either verbal or written.

MS. ALDRICH: Okay, got it, yes. No problem.

MS. SALUS: And the footnote about emergent condition stays?

MS. ALDRICH: Yes, that will come later.

MR. TELFORD: Just take my word for it.

MS. SALUS: Okay.

MR. TELFORD: Emergent conditions are covered, okay, don't sweat that emergent conditions here.

Okay, so, what's your answer, yes or no?

MS. ALDRICH: My answer's yes.

MR. WHATLEY: That's been my major problem with it all along. I certainly support that, as far as I'm concerned, I'm ready to go home.

[Laughter.]

MR. FRAZEE: Yes.

MR. TELFORD: Larry?

MR. CAMPER: A clarification. Would you please read then how it would -- what would be the wording, because we've been using -- substitute, if you will, instead of

medical use prior to administration of by-product material, so we'll understand exactly the wording.

MR. TELFORD: Maybe that, prior to the administration of by-product material, the diagnostic referral is made or is received, one or the other and approved by the licensee for any diagnostic radiopharmaceutical procedure. Take off the second sentence.

Now, we will have to define this approval as being either written or verbal.

MR. CAMPER: Right, that's true, but I don't think you're going to be able to limit it to that. I think you're going to have go give the authorized use flexibility in exercising his or her responsibility and use of established clinical protocols, operating parameters, clinical procedures manuals and what have you. Because there are going to be many cases.

What you don't want to create is a scenario where an authorized use, because he or she didn't specifically authorize, either verbally or in writing, an individual patient procedure, that they can be cited for that. I think that would be something to avoid.

MR. TELFORD: Now, wait a minute, we still have the clinical procedures manual.

MR. CAMPER: I understand that.

MR. COLLINS: Would you read it again, carefully; read the statement again?

MR. TELFORD: That, prior to the administration of by-product material, the diagnostic referral is made and, is received sounds better to me -- is received and approved by the licensee for any diagnostic radiopharmaceutical procedure and we'll have to define "approved" somewhere as being either verbally or in writing.

MR. WOOD: Since the licensee could be a facility, shouldn't it say "authorized," in lieu of licensing because it could be a facility or hospital?

MS. SALUS: You don't to beat RSO, for example.

MR. TELFORD: We've been saying user --

MR. CAMPER: It shall be pre-approved by the licensee, if the licensee is the hospital and the hospital or its authorized agent, the administrator, is he going to be doing the pre-approving or should it be, instead of licensee, authorized user for his authorization?

MR. TELFORD: Okay. Okay. Replace licensee with authorized user.

I don't know, Tony. Go ahead.

MR. TSE: I listened to this conversation and found it very interesting.

But first question I have is which state currently, already requires the authorized user approval in

each of the diagnostic --

MR. WHATLEY: That question was asked at the Agreement States meeting specifically -- in the Agreement States meeting. Most states held their hands up. By far, the large majority of the states did. There were a few that did not. Of the persons who held their hands up to answer that, I'm not sure they knew. But most states did.

MR. ANDERSON: There only 3 of them that said that, Kirk.

MR. TSE: Anderson said that they don't require pre-authorization.

MR. WHATLEY: That's been as we've been taught. On inspections, our annual reviews or whatever, it was taught in the medical licensing course for years. I know it was taught because I taught the course.

MR. DUNDULIS: Could I respond?

MR. TELFORD: Please.

MR. DUNDULIS: I think there are 2 ways of answering them. In Kirk's case, it's specifically written into the Alabama regulations exactly the way Kirk has answered. I think, the way most of us responded, at the Agreement States meeting, I know, in Rhode Island, it's not specifically in the regulations, but it's as a matter of policy, that's how we interpret it.

So, if your question is, do we implement it? I

think the answer is yes. I think Alabama and a few others are the only ones that actually have it written into their regulations.

MR. TSE: Second point is that, from our pilot program, the volunteers generally do not say that they are required to have this procedure -- have the authorized user approval.

MR. TELFORD: Let's -- yes, let's take the State of Texas.

MR. SHARP: That's a good example.

MR. TELFORD: Do your -- are your licensees required to -- and your authorized users required to approve these prior to?

MR. SHARP: We have not got anything in the rules to indicate that.

MR. TELFORD: All right.

MR. SHARP: We make a specific point of requiring that for mobile scanning, so-called mobile scanning operations and that is a physician, though he may be a 100 miles away, calls in. For a major institutions, in general, when they've asked us the details of what an authorized use means, we have accepted, in the procedures manual, that without documentation by a technician, without a written documentation, that they've got prior approval and we have not made it a point to enforce things as Alabama has.

We have been overwhelmed by the arguments of the larger institutions, I think, since we're included here as one of the objectives, in the QA program, we would have an easier time of trying to encourage our licensees to start doing that, but, in some cases, we've got smaller hospitals that are doing it now that have been particularly and carefully reared along those lines, if that's fair to say, and the larger institutions that have given us arguments that Dr. Tse and, in fact, in the pilot program, I'm sure, a few Texas licensees have been involved in that have said that.

It's one of the problems of the pilot program. They were telling you how they did things and nobody was asking us how we -- what we thought. If that's not compliant with our regulations, we thought that was. That part of it was.

MR. TELFORD: Today, you're saying it's a better idea to take that approval step?

MR. SHARP: We have, in the smaller institutions. They have never had the freedom, let us say, to not have the verbal approval in mobile scanning situation. I think there are a lot of good reasons for getting our medium-sized institutions back to that. I don't know how successful we'll be. I think that's very problematic with our major institutions.

If we're ng to be able to do it, especially with the verbal or hat requires no documentation. I think we can encourage them, as part of the QA program, and we should. So, I certainly would support its completion and the QA objective. But, whether or not we make this an item of compliance, is anothe- story.

MR. TELFORD: You mean, within the state?

MR. KLINE: Let me, for the record, clarify.

MR. TSE: I have a couple of more points very quickly, and I'll finish.

One more point is that, what is the problem in trying to correct right now to say you require authorized to approve each and every diagnostic referral because Ed's suggestion about the misadministrations were reported to NRC.

MR. SHARP: It is not to further the aims of your program, but it is to prevent the undoing of wholesale of other state programs that already exist.

MR. TSE: Okay, but -- but, the last point is that if the practice -- current practice, most people practice the current way of doing business without the authorized user approval or accept standing orders.

MR. SHARP: That's true in some states, not all.

MR. TSE: I mean, over, nationwide. What would be the justification to increasing to require everybody to do

that? Is it justifiable with whatever kind of problem we see? Thank you. I'm finished.

MR. KLINE: I wanted to clarify the comments earlier on the reg guide 10.8, revision to August '87. We talk about the individual responsible for training experience, and, in particular, they talk about RSO physicist and authorized users. In that section, item 7, it does not say that the authorized user has to review every medical use of by-product material prior to adminstration. It does not say that.

It, in essence, says that the authorized user involved in medical use must have the following responsibilities and it talks about examination of patient, prescription of dosages, but it doesn't say you have to review that patient administration project. You need to clarify that first of all.

MR. KULIKOWSKI: Could you just read that first objective -- that first responsibility, examination of patient?

MR. KLINE: Okay. It says "examination of patients and medical records to determine if radiation procedure is appropriate."

MR. KULIKOWSKI: I mean, you can't determine if the procedure is appropriate after the fact.

MR. KLINE: But verbatim, it talks about

prescription of radiation dosage and how it is to be administered and things of this nature.

MR. CAMPER: What it does do -- the wording, the way it currently is, is flexible to allow authorized user discretion in how they carry out their responsibilities. Again, I reiterate that in some cases, in many cases, a nuclear physician's authorized users have chosen to use departmental protocol or protocols, patient and clinical questionnaires, procedures manuals, which are primarily carried out by technologists on behalf of the authorized user and NRC is reluctant to go to its authorized users and demand that they practice or carry out their responsibilities in a certain fashion.

I mean, we feel that there's a need to allow that authorized user certain flexibility.

MR. KULIKOWSKI: As much as I hate to do this, I will drag our attorneys into this. The interpretation that they gave us of the very explicit language in reg guide 10.8 was that the authorized use has to determine whether the procedure is appropriate by examination of records and patients. That's what it says.

MS. ALDRICH: Could I say one thing.

We've had this same kind of discussions. The way we interpret that is that those are functions that are reserved to the authorized user; not that the authorized use

must do this for each and every patient, but these functions are reserved to the authorized user. I have to -- you know, I keep talking about the time sequence here -- approving in advance kind of thing. We accept after the fact approval. I mean, realistically, we know how departments are run. The point that -- that we're trying to get across to all licensees what we want from them, as the authorized user, is responsible for each and every study. Therefore, he can't sign off after the fact.

I get back to the fact that this is diagnostic QA. I don't regard misadministrations with diagnostic radiopharmaceuticals the same way as therapeutic. So, even if there is an error made -- if -- if what I'm saying is that the authorized use has to approve, at some point. It may be after the fact, if it was a mistake, that that's one of the functions of the quality assurance program, is to detect errors that might have been made and correct them.

So, I don't regard it as life-threatening that a mistake could get by because the authorized user could not do that approval ahead of time. I mean, realistically, that's going to happen, and not just in emergency situations.

MR. CAMPER: Well, just to, and please understand that what we're emphasizing here is that the NRC believes that the authorized use has certain responsibilities. I

think the question or the controversy, if you will, revolves around to what degree does our regulatory agency or yours, for that matter, get involved in assuring that that responsibility is carried out. This comes down to a timing problem almost. But, the responsibilities are still there for the authorized user, as far as we're concerned.

MR. KULIKOWSKI: I just wanted to take one slight exception to what you just said about the -- the importance of diagnostic misadministrations. In New York City recently, they did not involve the authorized user directly diagnostic misadministrations in these states can have significant impact -- life threatening in this case.

MS. ALDRICH: Yes, but Bob, that had nothing to do with the radiation?

MR. KULIKOWSKI: Right, I know.

MS. ALDRICH: I know, I mean. That could be true to any injection in any medical setting anywhere. I'm talking about the risk of radiation. You know, relative to diagnostic versus therapeutic. I don't think --

MR. KULIKOWSKI: These 2 couldn't really be separated from that.

MR. TELFORD: Wait.

MR. CAMPER: There was a case recently, involving the VA Hospital in California. It was a diagnostic procedure in which radiation consequences were significant

in the diagnostic procedure.

MS. ALDRICH: What was it?

MR. CAMPER: 5 millicuries of -- antibody was to be administered; but in fact that 200 millicuries of titanium was administered mistakenly. The radiation dose to the authorized user because he chose he infused this as you would -- antibody, over a long period of time, dose to his hand was significant.

MS. ALDRICH: No, no, I accept that. There have been times. Yes.

MR. CAMPER: I'm just saying there are scenarios where diagnostic procedures can carry with it a significant radiation.

MS. ALDRICH: I don't argue with that. I was curious, I think that's happened before that an eluit was injected instead of a dose.

MR. CAMPER: Yes.

MS. ALDRICH: But what I'm saying is that, you know, on the -- and in the general case --

MR. CAMPER: Right.

MS. ALDRICH: -- I regard them as 2 separate levels of concern and I think they should be treated differently.

MR. TELFORD: Does that mean you're going to change your response on objective 3 as we reworded it or

not?

MS. ALDRICH: It's -- the way that I kept responding to you about the timeframe is driving, you know, whatever discomfort I have with this. But I can -- I can live with that wording. I still think we have room for interpretation with our licensees.

We recently had a meeting with all of our licensees in the Albany region because a recent inspection focused on something like this and the inspector, in sending the enforcement letter, was very specific about signing prescriptions, etcetera, etcetera, or actually even, you know, did not examine patients and make a determination that a procedure was indicated, really, quoting from the guide.

During the meeting, we asked, you know, how the individual physicians approve procedures. There really wasn't anybody in that room who wasn't doing something that was acceptable. A lot of it comes down to either the way that the inspector asks the question or the kind of document that we expect to see.

What I'm -- as I said, I'm in favor of quality assurance. We require it now. But I just would like to be sure that the wording, in the final rule, isn't such that we're going to be requiring people to jump through hoops that are unnecessary, that's all.

MR. KULIKOWSKI: We agree with that too.

MR. TELFORD: Give me a clear signal folks. It's not made of water, we're going to do it or we're not going to do it. If we're going to say that, prior to the administration of by-product material, diagnostic referral is received and approved by the authorized user for any diagnostic or radiopharmaceutical procedure. Is that or is that not your best advise?

MS. ALDRICH: I can live with it.

[Chorus of ayes.]

MR. TELFORD: Now, understand that approval means verbal or written, but if we say up here, prior to the administration, it will mean prior to administration. We haven't said anything about how to document that approval. But that -- I want to know, is that your best advice for me?

MR. KULIKOWSKI: Right, and we've left an escape clause for --

MR. TELFORD: Emergent conditions escape, definitely.

Now, we've now looked at referral. Before we look at prescription, could we go to lunch?

MR. CAMPER: I assume now because we're changing the wording objective, that's a suggestion that the wording diagnostic referral or addressing this issue as part of the definition diagnostic referral, that's taken care of; is that correct?

MR. KLINE: That stays as is.

MR. CAMPER: Your concern is captured in the objectives; are we together on that?

MR. TELFORD: In other words, the definition of referral that I gave you is acceptable?

[Chorus of ayes.]

MR. TELFORD: Nobody objects to that?

[No response.]

MR. TELFORD: Okay. Let's -- it's almost 1:30. We'll come back in an hour.

[Whereupon, the meeting recessed for lunch to reconvene later this same day.]

AFTERNOON SESSION

[2:40 p.m.]

MR. TELFORD: Let's go back on the record. Welcome back. Let's pick up where we left off.

We have discussed so far the definition of a referral, and we have so far modified, or so far we have modified Objective number 3.

The other part of this, we started out talking about what formally call the prescription. So, this relates to Objective number 2.

So, the definition that we need to focus on is what we called a prescription here. I think, my best shot right now is to call it a written referral. That's, if I take all the advice that I've been given, they all would call that a written referral.

Now, I would say it's an order, it's a written order. It's signed by an authorized user. It contains certain information for teletherapy, certain other information for brachytherapy, certain other information for radiopharmaceutical therapy.

MR. KULIKOWSKY: You said written referral. Do you mean written directive?

MR. TELFORD: Written directive, did I say? I stand corrected. Yes.

So, for prior to administration of byproduct

material, we have a written directive.

The information that we would say is the minimum information content would be essentially what we have here on page 14-47 in the upper right hand corner. For teletherapy, brachytherapy and radiopharmaceutical therapy.

I think, very slight modification of that in some cases. That's basically the idea.

Now, first of all, does anybody have any heartburn over using the term written directive in place of prescription?

[No Response.]

MR. TELFORD: Some people are shaking their head no.

MR. FRAZEE: No heartburn.

MR. TELFORD: Okay. Then, let's see if we can look at Objective 2, and we would say that, prior to the administration of byproduct material -- take out this phrase "medical use" everywhere -- that, prior to the administration of byproduct material, a written directive is made for (a) any teletherapy procedure, (b) brachytherapy procedure, (c) any radiopharmaceutical therapy procedure, or (d) any radiopharmaceutical procedure, any, involving more than 30 microcuries of I-125 or I-131.

[Pause.]

MR. TELFORD: Any comments?

[Pause.]

MR. SHARP: What have you found in the way of objections? I mean the Iodine question.

MR. TELFORD: Relative to 30 microcuries?

MR. SHARP: How is your pilot study?

MR. TELFORD: Okay, let's see. From the volunteers in the pilot program, I believe that most of them would accept this, would accept the 30 microcuries.

The medical societies that we met with, like the AAPM, the ACMP, ACR, ES and ASTRO, I believe in the end, on the second day they were willing to leave that.

MS. ALDRICH: John, that 30 microcuries is sodium iodine?

MR. TELFORD: Yes.

MS. ALDRICH: Okay. I just want to make sure.

MR. TELFORD: As sodium iodine.

MS. ALDRICH: Okay.

MR. TELFORD: Yes?

MR. WHATLEY: Was there a reason for putting 30 microcuries as opposed to just saying any iodine-125 or iodine-131?

MR. TELFORD: Yes, there was a reason. Many diagnostic procedures, as you know, happen or take place using amounts of I-131 less than 30 microcuries. So, we would like to catch the big mistakes, but the uses of I-131

with small quantities, you know, we wanted to have minimum impact on them. So we look at those as diagnostic procedures, which would be down here in Objective 3.

MR. KLINE: John, you might want to comment that the 30 microcuries, if a mistake were made, it's in the millicuries. Thirty millicuries then gets the reasonable range of any real significant biological damage, not exceeding the significant affect.

Also, the 30 millicuries -- 30 microcuries -- was, I believe, a recommen[illegible] one of the medical societies?

MR. TELFORD: Yes. There were several considerations. One consideration argues in favor of a lower number. That is, if you make the micro- to millicurie switch, you might want to be minimum 5.

But if you look at the argument in the other direction of most of the procedures are conducted down at 5, 10 or 15 microcuries, so people say there's no need to bother this. So, that argues with driving it up.

I mean, we did hear comments from some of our volunteers to make this 15 or make it 100. But, you know, there were sort of no overwhelming arguments in favor of moving it one way or the other.

Then there's a third argument that says, what if you give something of this level or slightly more than that,

what are the stocastic effects over the next five years? Or, either hypothyroidism or cancer of the thyroid.

You consider those and that argues for in favor of something around 30, and that was the recommendation from a member of the ACMUI.

MR. SHARP: Just to make sure that I understand what you're saying, you got around the question by saying this was as iodine. So, we should see as iodine there.

MR. TELFORD: Yes. We should say as sodium iodine. I meant to say that but I didn't.

[Pause.]

MR. SHARP: Talents 2 and 3 both?

MR. TELFORD: Take this sentence out of 3. Okay, is everybody willing to let Objective 2 and Objective 3 rest for now? Let's back up to Objective 1, for 35.20.35.

Let me give you some feedback on what we heard from some of the members of the pilot program, the physicians in particular.

A couple of the physicians said you shouldn't say that in your objectives. You ought to make a footnote that says we assume that this is required and it will be carried out in accordance with your license as a physician along with the requirements that you need for JCHO or somebody else.

On the other hand, other volunteers that are not

physicians, or medical physicists, or technologists thought that it was a pretty good idea, they liked that. When we met with the ACR and the four other societies, we had three physicians. Of eight people in the room, three of them were physicians.

I was surprised to hear, "Objective 1 is great." Okay. When we met with ACNP and SNM, they said take it out. First of all, they don't really want to discuss the objective of the Rule because they want to go on record as being totally opposed. But if you ask them they'll say get rid of that.

Now, JCHO would say, no we do that. We want that. We wouldn't necessarily advise you to get rid of that. So, we have sort of mixed signals, if you will, on what to do with this.

Here is my best recommendation to date. I would take it out because I don't need it. What I want to do is make sure that the byproduct material is administered as prescribed, and I would hope to demonstrate to you that if I get a written directive, a referral, and then I have some other objectives that says make sure it is administered as prescribed, etcetera, then I can live without Rule 1.

So, I recommend to you to take it out.

MR. SHARP: It seems to be consistent with what you said earlier about not intruding in the practice.

Because that certainly is contained in there.

MR. WOOD: I would also add to it that it would be difficult, if not impossible, to quantify that value, or measure it or inspect it, or regulate it.

MR. TELFORD: If I were an inspector, I would look at the record here, you know. If it's therapy and you're looking at the written directives, that's pretty good evidence that that happened. I'm just speaking personally.

So, do I have any objections to taking it out? Rita?

MS. ALDRICH: I was going to say that before you put in approval of the referral by the authorized user it might have made more sense. But I think once you add the approval of the diagnostic referral, then you don't need that anymore.

MR. TELFORD: Yes.

MS. ALDRICH: You already had it covered for therapy because you said prescription. I think, while diagnostic referral stood alone there, that first objective made sense. But now I think you have it all covered and you don't need it.

MR. TELFORD: Okay.

MR. WHATLEY: I'll agree with that. I ought to note that on my paper that said the only person who could do that was a person who was trained properly.

MR. TELFORD: Okay. Then I hear no objection to taking it out?

[Response.]

MR. COLLINS: We don't want anybody from NRC to ever assume that lack of comment means agreement. So I'll answer.

MR. TELFORD: Don't we speak in double negatives, here?

[Laughter.]

MR. COLLINS: As far as I'm concerned, I would say go the rest of the way around the table.

MR. TELFORD: Okay, I'll start over here, then. Bill, what do you say about number 1?

MR. DUNDULIS: I would agree that, if we get the language changes in the other ones that we've talked about, it becomes redundant.

MR. TELFORD: Okay, thank you.

MR. KULIKOWSKI: I agree.

MR. SHARP: I think removing it is consistent with the established practice.

MR. TELFORD: Steve says out.

MR. ANDERSON: Out.

MR. TELFORD: Larry says out. David says out. And David says out. Rita says --

MS. ALDRICH: Out.

MR. KELLEY: Out.

MR. TELFORD: Rick says out. Kirk has already said out.

Okay. Now, let me re-visit number 2, here. Because before when I was speaking to you before cluded the brachytherapy procedure as a written directive.

We've got some feedback from almost everybody, like the volunteers of the pilot program, the medical societies, that you really cannot have a written directive for the brachytherapy procedure prior to going to the O.R. It's got to be after implant.

So, we have come up with the idea of having what we're calling a pre-plan so that, prior to the brachytherapy procedure you have pre-plan.

MR. WHATLEY: Could you just explain, help me understand why you can't have one before you go?

MR. TELFORD: Yeah, sure. In the event you have a written directive prior to the completion of the treatment, this is the way it goes.

If you are going to do an implant procedure, what we say in a written directive is that you have to talk about the administration of the byproduct material in terms of the dose. Now, for brachytherapy you can talk about total dose. In parenthesis you can talk, either the source strength or the number of sources, the radioisotope and the treatment

site. But what you can't get to, I'm told, is to quantify the does.

The physician hasn't put in the seeds yet. Now, the physician wants to put 27 seeds into the tumor site. But in the O.R. the physician discovers that they can only get 22 in there. Or ultimately they can get 32 in there.

So, to try to specify the dose prior to implant is sketchy guesswork at best. What we're saying to you is the pre-plan would specify the number of seeds and the sources, the activity of each and the isotope.

Now this is a plan that's written that the people can follow, they know what to do. They go to the O.R. The physician plants these seeds. Now the physician knows absolutely how many seeds he's put in. Then they are either using a template or they're using radiographs or other methods to determine the exact location of these seeds. That way the isodose curves can be calculated or it can be determined how long to leave the seeds in. In other words, that's the definition of the dose to be delivered. And it is done after implant.

So, then we say you have a written directive which would call for the dose. And we say a written directive is made prior to completion of the treatment. By that we mean that after you come out of the O.R. the clock starts ticking.

Now the seeds come out at some point, and you have to go away and calculate what you've put in there and what you are delivering. And if you are going to treat to the 80 or 90 percent isodose curve, exactly how long, exactly how long you want to leave the seeds in, which is the definition of dose to be delivered.

So, what we want, we think, is prior to the clock st- ing that the written directive is signed by the ..orized user. It is specified before hand, if you will.

Now, we didn't word it such that three hours after the implant, or 24 hours after the implant, or 72 hours after the implant, because we tried that and we found out that that was froth with a lot of difficulties as to exactly when you specify that.

So upon further thinking we said, well, gee, what we really want is just prior to completion of the treatment. And this phraseology was accepted by the ACR and the other four societies represented as being sufficient.

We had the benefit of talking to some physicians who were practicing oncologists, and they're pretty tough on their colleagues. They're looking for some procedures that would be sufficient.

Anyway, that's my best recommendation, so let's get some discussion of this. Jon is first.

MR. SHARP: Is your suggestion to change the

objective or to change the definition under written directive?

MR. TELFORD: We would change the objective. We would throw out, delete, number 1. Number 2, with a draft. Three things. It would address teletherapy, radiopharmaceutical therapy and amounts of I-131 greater than 30 microcuries. Then we would add another objective here that would say for brachytherapy procedures.

MR. SHARP: I see what you're saying. Let me then suggest instead that you take a look at the definitions of prescription which would be written directive, 1447 in the upper right, under (D). You have for brachytherapy the elements that you don't want under written directive.

What you have suggested are difficulties only with one kind of brachytherapy, interstitial implants with removable sources.

MR. TELFORD: How about high dose radioactive orders?

MR. SHARP: There's not a problem about where that catheter goes. Before you initiate treatment they know. They've been able to put the catheter --

MR. TELFORD: How about if we talked about non-permanent?

MR. SHARP: What I'm suggesting is that you have (E) under these four things, for brachytherapy with

removable sources. Interstitial brachytherapy with removable sources.

A pre-plan which includes your elements there, assuming it's tied under definition and you haven't cluttered your objective with one special case. And you've got it where it belongs, as a subset of all brachytherapy. And you can put your special pre-plan ideas right there.

MR. TELFORD: We have an (A) which allows for pre-plan.

MR. SHARP: But for this one kind of brachytherapy, we need this, permanent source implants, you can't control once you've got the seeds in, you're going to leave them there, you're stuck with whatever the dose is. There's no control to exercise.

I don't think this is really going to come up, but if you want I'd put it in dose because there might be median thing.

In general, you don't have a high dose rate. But if you do, that could be included as a removal interstitial brachytherapy application and could be included.

MR. TELFORD: Bill?

MR. DUNDULIS: Two points. One of them was the point John made about the after loaders. I wasn't sure if some of the protocols you were talking about would be appropriate for the remote after loaders.

And the other thing which is just something I've seen in at least a couple of instances where the placement has not been interstitial at all. In a couple of instances they've used gold foil, a gold needle, just superficially affixed to a skin lesion.

Again, the pre-plan escape clause, if you would, might not be appropriate and you'd want to plan out exactly in advance what you were going to do.

MR. TELFORD: Well, for the high dose after loaders, I think you'll need a written directive prior to.

MR. TELFORD: Right, prior to administration.

MR. SHARP: To the extent it imitates iridium, and it can be covered by you're saying, similar to the pre-plan for the micro selection. To the extent that it imitates intercavitary.

MR. TELFORD: The only problem that I'm momentarily having with your suggestion is we would be saying that you have to have a written directive for brachytherapy, then you start to give definition of a written directive, and it says, oh, by the way for sudden and non-permanent.

The brachytherapy procedure is that we don't really mean that you have a pre-plan prior to going to the O.R., and then you sign the written directive.

MR. SHARP: But only for one kind of

brachytherapy. The rest can be as before, as teletherapy. The kind of brachytherapy where the morphology of the treatment situation has to be decided in the operating room. That can be covered by a relaxed set of standards in the definition.

MR. TELFORD: David?

MR. WOOD: The example you gave in the scenario of a surgeon not knowing how many seeds he was going to put in during the O.R., so the post plan is more important, was more on the lines of a permanent implant, not the temporary removable kind.

MR. SHARP: Right. But if the clock starts after the O.R., the clock makes sense only for removable sources. You're not going to remove palladium seeds. So you're stuck with whatever treatment you get. There's no point in revisiting something you can't change.

MS. ALDRICH: Isn't there already in here -- I can't find it at the moment -- but, a provision that if a change is made to the prescription it be documented later? Isn't that really what this would be? In other words --

MR. TELFORD: That's in the Reg Guide.

MS. ALDRICH: Oh, okay, it's in the Reg Guide. I'd favor putting it in the regulations to make it clear that anyone can change a prescription at any time. I mean, even in the middle of fractionated therapy, they might

decide to change the dose. As long as it's documented, who cares?

MR. TELFORD: That's true. But that's not a thing you put in the Objectives.

MS. ALDRICH: And the Objectives, okay. I just think it's a non-issue and I wonder if the clinician can change his mind.

MR. TELFORD: David?

MR. ZALOUDEK: In the definition you use for prescribed dose you've got reference to revise resources after implantation.

MR. TELFORD: So, do you think we've covered part of it in the definition?

MS. ALDRICH: Yes.

MR. WHATLEY: If it's a prescribed dose.

MR. ZALOUDEK: The prescribed dose column already takes care it.

MR. SHARP: Yes.

MS. ALDRICH: In either sense they should know. If you change it later you'd just be modifying your prescription which is okay.

MR. FRAZEE: Why does it really matter? Unless I'm terribly confused here, they know what dose they want to give.

MR. SHARP: But they may not be able to give it

within 20 percent because the tumor just doesn't allow that packing.

MR. TELFORD: If I'm hearing John correctly, he is agreeing with the definition of the pre-plan. He's just saying how do you implement it.

What he's really saying is not a big enough deal to put it in the objective.

MR. KULIKOWSKI: I agree with that.

MR. TELFORD: You can do it some other way that took in the definitions.

MR. KULIKOWSKI: Or just semantically, the pre-plan can be called the written directive, and prescribed dose, definition (b) just allows that written directive to be modified after the fact. We're arguing what we're going to call it.

MR. SHARP: He could make reference under (d) to the definition under (b).

MR. TELFORD: John, you're saying address it both in the definition of the written directive and under prescribed dose.

MR. SHARP: It seems to be developed under prescribed dose. You can just put an arrow under (d), as written directive, pointing to (b), prescribed dose, and say use this definition for brachytherapy, which would allow a pre-plan, or the quantity of radiation as stated in the

prescription as documented and revised to reflect the actual dose.

MR. COLLINS: And out of those we would use something called an agency note. All you're wanting to do is clarify or refer back to somewhere else that provides a clarification, which is the recommendation we got.

It's not clear enough to us if you are just stuck in one place with the definition. So here in this other place, you just put note, or agency note, and refer to the definition --

MR. SHARP: Total dose as revised.

MR. COLLINS: But it doesn't have to be a rule itself. It's just explanatory material.

MR. DUNDULIS: I kind of agree with what John said. I have a comment on teletherapy, which is based on something Terry said.

MR. TELFORD: Let's keep one issue on the table at once. Let me ask, okay, pre-plan is the way I prescribed it and maybe the way that John has suggested using it, is that something you could all agree with, not disagree with?

[A chorus of yeses.]

MR. DUNDULIS: Yes.

MR. KULIKOWSKI: I'd be happy with it the way it is now, with an explanatory note.

MR. TELFORD: Would you not object to the way that

John said?

MR. KULIKOWSKI: I agree with what John said. I mean, based on the way the definitions are written here, the least amount of change occurring, leave it the way it is and just put some sort of explanatory note in (d) up here referring back to this definition.

And I think that would cover it, without introducing a new set of terminology.

MR. SHARP: It doesn't look like you need anything more than a note to cover it and you could avoid the use of the word "pre-plan" altogether.

MR. DUNDULIS: That's what I was agreeing with. I was agreeing with John's concept.

MR. COLLINS: We don't need "pre-plan" at all, just a little note in there saying "prescribed dose."

MR. SHARP: Dose means dose as revised?

MS. SALUS: And then under section (d) for prescription, written directive rather, you would say brachytherapy, with a footnote that says, if due to the true execution of this thing you can't achieve the original dose as contained in the written directive, you changed the prescribed dose as allowed under the definition of prescribed dose?

MR. TELFORD: Well, the physicians would tell us that they don't even know the dose.

MR. SHARP: Then they don't need to put --

MS. SALUS: What's the plan?

MR. TELFORD: Their plan is to go to the OR with a certain number of seeds and see what they can do. They would have a range in mind, if you're really going to put them in a corner, they might say oh, three thousand to five thousand rads. But that's not a dose.

MR. SHARP: Then perhaps let's say the total, since they've talked to you about pre-plans, they had in mind a dose for the pre-plan.

MR. TELFORD: Not necessarily. Maybe a dose range. Maybe a large dose range.

MR. SHARP: So maybe instead of saying total dose under (d) we should say dose range. Or do you want to be that specific for the other forms of brachytherapy?

MR. TELFORD: I think then you create a loophole. I thought your first suggestion may be workable to say under (d) you acknowledge that or you create pre-plan and then after the OR you require a written directive.

MR. SHARP: I hate to see the use of the word pre-plan if it's not needed.

MS. SALUS: To me the term written directive is broad enough that if you want to say your pre-plan is your written directive initially, but it subject to revision later, that could be fine, but pre-plan doesn't seem hard

enough.

Before you start injecting the sources or implanting sources, you should have a pretty good idea of what it is you are trying to accomplish.

MR. TELFORD: Well, maybe under -- excuse me. Go ahead.

MS. SALUS: That just seems to be bothering me, that the pre-plan should be pretty specific. And if you want to, instead of saying "total dose" say number of seeds or implants. So you have your written directive saying what it is you're going to try and do, and if for some reason that's not possible, then afterwards you go ahead and revise, that's one thing. But to say that we don't need something as concrete as a written directive, which is a pretty loose term anyway, that makes me nervous.

MR. TELFORD: Let me try it this way, if I'm hearing what you're saying.

Under written directive in (b) we say, we say what a written directive is prior to implant and then we say what it is after implant.

So, prior to implant, we say that the information content contains or includes number of seeds, activity, isotope. After implant, we say dose, or we say time and source string. Treatment site can be common to both, either before or after.

So there we have it. You don't have to have a pre-plan term. We just have said what the written directive means prior to implant and after implant, and you recognize that a difference needs to be stated.

MS. SALUS: And in lots of cases maybe there won't be a difference, maybe the pre-plan will be so good it will be able to be followed. That will be exactly what you were hoping to accomplish to begin with, hopefully that will be the case. That doesn't always happen.

MR. TELFORD: In some cases, yes. Probably for the high dose rate afterloaders, you're really going to need a written directive that talks about dose prior to administering. But in other cases, you're only going to know things like the isotope, number of seeds you're going to try to put in, and their differences.

MR. KULIKOWSKI: John, that's already covered in the prescription (d). It says the total dose, and then you've got, parentheses, or treatment time, number of sources, and activity. You know, that gives you the leeway. And another advantage of addressing it the way we've described is that it becomes more generic. If they're doing a teletherapy treatment plan, they can make --

MR. TELFORD: Teletherapy is included elsewhere.

MR. KULIKOWSKI: By approaching it in this generic way, if they find halfway through the teletherapy treatment,

they find that the tumor is progressing faster than anticipated, and they want to modify things that way, this allows them to do that as well. It's just the same general concept.

MR. TELFORD: I don't understand the necessity of what you're saying.

MR. SHARP: Revisability.

MR. TELFORD: It would give them revisability.

MR. KULIKOWSKI: That's all you need.

MR. SHARP: That's all you need.

MR. TELFORD: But what the physicians are saying is that for several types of brachytherapy implants, they cannot specify a dose going in.

MR. SHARP: It's giving them the option of treatment time, number of sources.

MR. KULIKOWSKI: Under the definition of brachytherapy.

MR. TELFORD: They don't know brachytherapy time.

MR. KULIKOWSKI: They know the number of sources that they want to come in.

MR. TELFORD: They don't know all of it.

MR. KULIKOWSKI: It says, or you can change it to hard --

MR. TELFORD: Be careful. After implant, we definitely want dose. If you're not going to talk about

dose, you can only talk about the source string that you put there and how long you're going to leave it. That's okay, too. That's what we're saying inside the parentheses, Larry.

MR. ANDERSON: I think we're arguing over things I think this is not germane to what we're trying to do.

MR. TELFORD: Okay.

MR. ANDERSON: When we have that written directive, that's what you do. Now, we're saying that they've got to have something else that tells you what's in the written directive.

MR. TELFORD: No, we're saying --

MR. ANDERSON: That's what we're saying, if we've got the written directive, that's got to happen before any of this happens. Why do we need something in addition to that? I don't understand that.

MR. TELFORD: Let me try it again.

The folks that we've talked to, the consensus of opinion that we've got is that what we're calling a written directive, what we would really like to have in a written directive, which talks about dose, cannot be done prior to implant.

MR. ANDERSON: I understand all that. I'm just saying they got a written directive, and they can say what they think they want to do in it. Are you going to keep

them from changing it?

If they get in there and they find out something is different, or they can't put this many sources here, or they find that the tumor is not what they expected it to be and they make this decision, are we going to say hey, you can't do that, because you've already done this? No, hell no. We're going to say, change your written directive.

MR. KULIKOWSKI: That's what it says now.

MR. ANDERSON: I think it 's adequate the way it is.

MR. SHARP: They shouldn't be quite so afraid of a nominal written directive in brachytherapy, that's what really we're talking about, in two of the three kinds of brachytherapy, the nominal one is gong to be quite accurate. The third type, the interstitial type, is removable sources; it won't be accurate. But still, you have built in the nominality of this by allowing the prescribed dose to change.

I think, except for the fear of calling that an estimated dose, we'd be all ready to go home on this one.

MR. TELFORD: Well, perhaps you're right. We certainly got a lot of negative feedback on that particular one. We were trying to accommodate --

MR. SHARP: And deleted a footnote.

MS. SALUS: It's subject to revision. If we're

not going to specify total dose or in the alternative specify treatment times, sources, and activity, why require a written directive?

Unless you want to say this is what we anticipate we're going to do subject to revision if things aren't the way we thought they were going to be. Otherwise, I don't even know what the plan would be.

MR. SHARP: I think the word "pre-plan" is just for their comfort level, and it kind of messes things up.

MR. KULIKOWSKI: It's just confusing things by adding another term.

MS. ALDRICH: I've seen it used in brachytherapy orders in some of the incidents that we've had. They do call it a pre-plan and a post-plan.

MR. KULIKOWSKI: Does it matter what we call it?

MS. ALDRICH: I don't think they're going to care. They're going to go on using it. But that might be where they're coming from when they made those comments.

Do you think then, John, that there's wording in the guide that might be moved into the regulation about approval of changes that might help to solve the problem?

MR. TELFORD: No. We're pointing out that prescribed dose already has that.

MS. ALDRICH: Yes, the alternative is there. I just mean that in the guide you have the requirement, the

changes in the prescription document, and I'm not sure whether that's in the regulation or not. Right now I can't find it. Why not move that into the regulation, if it's not already there, because it could also apply to teletherapy, which often is changed.

MR. TELFORD: It is there.

MS. ALDRICH: Is it in teletherapy?

MR. TELFORD: In the form of prescribed dose.

MR. COLLINS: And at appropriate places in the text, for clarification, you can just say dose allowed and explain it.

MR. FRAZEE: See prescribed dose.

MS. ALDRICH: Oh, right. I didn't expect to find it in a definition.

MR. WOOD: The term "pre-plan," is it here?

MR. TELFORD: No.

MR. WOOD: Because, did I remember some physicians complained that there was a concept for the term "pre-plan" sometimes included isodose curves, that they were concerned might, they sometimes intervened with a concept? That's another thing that wouldn't apply.

MR. TELFORD: Treatment planning.

MR. WOOD: Treatment plan was the term.

MR. TELFORD: Treatment plan is the term they favored, rather than treatment planning. That comes in

another objective.

MR. KULIKOWSKI: I think we should move on. Maybe it would be useful just to expound on this just as an explanation of this, and just leave the regulations the way they are.

MR. SHARP: The interstitial situation --

MR. TELFORD: You're telling me we can cover it in the definition of directive and in the definition of prescribed dose.

MR. KULIKOWSKI: In fact, if they still have heartburn, it could be ameliorated by some guide.

MR. TELFORD: Any other thoughts on this^

Okay. Yes? Do you want to go to teletherapy? Okay.

MR. DUNDULIS: Under the prescription, soon to be written directive, telecherapy, I think there is one important word or words that's missing. Total dose, number of factions, and treatment site, I agree with. And I'm going to borrow something from diagnostic, and explain what I mean. Route of administration.

By route of administration, it is sometimes very important how the dose is to be delivered. Each fraction may consist of 280-degree portals, it may be rotational therapy, so many rads per arc, or if you can adjust the output rate, you know, so many degrees of arc per minute, or

what have you.

So I think it's important, even if route of administration is not the medically correct term, how each fraction is to be delivered should be an important part of the prescription.

I know most oncologists that I deal with that do it, that's an important part of the term "treatment plan," but the prescription that the technicians have to review is, and I think that should be part of the quality assurance directive. A part of the written directive.

MR. TELFORD: Does anybody have any comment on this point?

MR. KLINE: That could be captured in Objective Number 8 if we go ahead by the treatment planning in accordance with the written directive. That is a concern and that is something very important in a treatment planning process.

You might want to consider in the definitions what is considered to be prescriptive and what is considered minimum information to fit those generic needs. That might border on being quite prescriptive. Defining route of administration is very difficult.

MR. DUNDULIS: I'm saying, not in the regulations, but I'm saying that particularly if you've got more than one oncologist, either a hospital or a large group practice,

it's important. Again, the technician is the weak link in the chain, and the technician is the one that's going to be implementing this prescription, and I think it's important that a technician should always get a single dose straight, the single dose angle, and that should be part of the written prescription to the technologist that's going to be implementing.

MR. TELFORD: Yes. The question is, can that be covered under the treatment plan?

MR. COLLINS: My preference would be not to make any change in the rule we already have, even though I agree that there have been very few cases where there's been a problem, it really complicates the rule to put all that in. As far as I'm concerned, it's de minimis gain.

MR. TELFORD: I think it can be covered under treatment plan.

MR. DUNDULIS: Okay.

MR. TELFORD: Can we move to Objective Number 4?

We've gotten some negative comments about Objective Number 4, along the following lines.

That it is, number one, unnecessary; that you have the next objective, you don't need that one.

Next, what is it exactly that you have to do to make sure that you have this understanding? You usually come down to an answer which is training, testing,

counseling, et cetera. So my best advice today would be, take it out.

Now, what are your comments?

Yes, Bob.

MR. KULIKOWSKI: I agree with that. I think one, it's covered, it should be covered under training program, that any license applicant should submit, it should be in that. And yes, I think it, to a certain degree, overlaps with number 6, and 5.

MR. DUNDULIS: I think also the fact that we've put the authorized user back in the loop, I think it becomes redundant, because the authorized user is in the loop and it's not a case where the referral is coming in and the tech. is just going right to the procedures manual. So I think it becomes redundant, with that consideration.

MR. SHARP: You are asking in the first part of that sentence that the order is legible; is that what you're asking?

MR. TELFORD: Well, there's all parts of the --

MR. SHARP: What do you mean by "understand"?

MR. TELFORD: Well, that's the kind of complaints we've gotten.

MR. SHARP: If you want legibility, why don't you say legibility?

MR. TELFORD: We talk about legibility in the

guide, that you ought to be able to read the thing. You've got to go on from there. You can't just say okay, it can be read by an intelligent third party. You have to go on to say, does the technologist know what to do with this directive; and does the technologist know that they should not do anything that they don't thoroughly understand and if they have questions they should go ask? Those things are covered in the guide.

MR. KULIKOWSKI: That's more appropriate for the training program.

MR. ANDERSON: Okay. Take it out

MS. ALDRICH: Take it out. It also seems to be covered under the heading of "supervision."

MR. TELFORD: Okay.

MR. KELLEY: I agree.

MR. FRAZEE: Out.

MR. TELFORD: Kirk?

MR. WHATLEY: I concur. Take it out.

MR. CAMPER: Having gone through four objectives now, and four more to go, give some thought to or some feedback on the idea in each of these objectives of eliminating the word "ensure."

MR. TELFORD: Well, notice that when I say them for you, I have left out the word "ensure." I don't mean to be sliding that by you. I mean to call attention to the

fact that when I stood there and rewrite Objective 2 verbally, I did not start with the word "ensure," I started with the word "that." And I also call attention to the fact that the preamble, or the lead-in sentence under the first Paragraph (a) in 35.35 says, okay, here's the following objectives to include in your program.

So I have been leaving out that word.

MR. SHARP: You're not trying to ensure, you're trying to do it.

MS. SALUS: Keep in mind that this is a written program. Because it's a written program is the reason that I thought number four should go. I don't know how a written program would make someone understand what was in the procedures manual. It didn't make any sense to me.

MR. CAMPER: My sense of your comments is we're getting basically a good feedback, positive feedback on elimination of the term "ensure." Is that generally the consensus?

[Chorus of yeses.]

MR. CAMPER: Let's get a few comments. How about the word "ensure"?

MR. DUNDULIS: Even if it's not there, I think it's implicit when you say to meet the following specific objectives, and you say that, this, that, this, that, it's kind of implicit that because that's your objectives, you're

going to be taking whatever steps are necessary to ensure that those objectives are carried out.

MR. KULIKOWSKI: It's also from a practical point of view, from the client's perspective, it's real hard to enforce a regulation that says "ensure" because the licensee will say of course we ensure that, it's just that we haven't been able to do it.

MR. COLLINS: Throw it out.

MR. WOOD: Out.

MR. KELLEY: Out.

MR. WHATLEY: Out.

MR. FRAZEE: Out.

MR. TELFORD: Let's consider Objective Number 5 for what we've been calling 35.35.

The only change we need here that we would call your attention to is medical use, that is, the administration of byproduct material. We still have referral, we still have the diagnostic and clinical procedures manual. Now we have a written directive in place of prescription.

We have nearly universal agreement to keep that in. So my best shot today is to keep it in. Because this really seems to be the heart and the soul of this, is to make sure that the administration of the byproduct material is in accordance with the direction that's been given. So

let's get some comments on this. Let's start over here with Terry this time.

MR. FRAZEE: I think with the changes we're talking about, wording changes, that certainly would be very reasonable.

MR. TELFORD: Okay. Kirk?

MR. WHATLEY: Diagnostic referral still scares me a little bit. But I don't have any basic problems with that.

MR. TELFORD: Diagnostic referral, now we're talking about the approval step being there.

MR. FRAZEE: Add the word "approved," the "approved" --

MR. WHATLEY: I'm not suggesting a change.

MR. TELFORD: You're not suggesting a change in Objective Number 5?

MR. WHATLEY: It's fine with me.

MR. TELFORD: Rick?

MR. KELLEY: I'm okay with it.

MR. TELFORD: Rita?

MS. ALDRICH: I don't know. It seems almost as though it's implicit in several of the other things. But it doesn't hurt to have it there.

MR. TELFORD: Okay. Dave?

MR. WOOD: I think it's important. But I wonder,

is there somewhere further on that suggests any kind of, for example, annual review?

MR. TELFORD: Yes. We'll get there. Good idea. I like that.

[Laughter.]

MR. TELFORD: I like that idea. It's there.

MR. ZALOUDEK: I think it looks good.

MR. TELFORD: Okay.

MR. ANDERSON: I think it's fine.

MR. COLLINS: Steve says okay.

MR. SHARP: With two and three above, it seems completely redundant.

MR. TELFORD: Two and three just says you have to have a written directive and have to have a referral, not follow it.

MR. SHARP: Well, but in following two and three --

MR. TELFORD: Well, except that we'd have to put it in twice. Here, we're calling it, we want to call attention to it, because of literally, everything is okay if the byproduct material is administered as directed.

Betsy.

MS. SALUS: If we're changing the lead-in language in Paragraph eight to say the objective of the program is to ensure that the byproduct material is administered as

prescribed, then we come down to five to say we ensure that the byproduct is administered as prescribed in a written referral or written directive, I don't know that we're getting anything different, unless we're saying that's what a prescription is.

MR. TELFORD: Well, notice what we're doing is with these objectives we're chronologically stepping through the delivery process. As John observed this morning, what we're really after is making sure that the delivery process works. So here we start off in two and three, old two and three, Objectives two and three, and saying, first of all, you've got to have a written directive. What you're going to do has got to be documented in writing so people can read it and won't forget it.

To me, this one comes last, but I can play with the order later.

Chronologically, we're saying, first of all, let's get it written down what we're going to do, let's identify the patient, let's have our planning correct. Then let's deliver it correctly.

So what I'm going to do is I'm going to suggest to you later that this one be last, but overall, I just want you to have this picture that I'm sifting down chronologically through the steps of --

MR. SHARP: Wording to emphasize these steps, the

words you presented, to deliver, you know, definition or technical parameter, identification, deviations, delivery. And emphasize those words. Because everything else looks so much the same, that you don't see the differences, unless you look very close.

MR. TELFORD: Okay.

MR. WOOD: I think so far in the objectives we haven't really addressed clinical procedure manual, or we've only touched on the importance that it is to the technologist in the field, especially when there's not real good continuity in a multi-technologist department or less-than-optimal communications fields between the authorized user and the technologist.

I think they key for leaving that is the procedure manual, and its value to the good functioning of the department.

MR. TELFORD: You're saying that because we're creating a diagnostic manual.

MR. WOOD: That hasn't been addressed before on the objectives.

MR. TELFORD: This says pay attention to it and follow it.

MR. WOOD: Yes.

MR. TELFORD: That's a good point. Any other comments on this objective?

MR. SHARP: Do you want to discuss the creation of one of those as the first step?

MR. TELFORD: We attempted to cover it in the definition.

MR. SHARP: And the delivery process. That's the first step. Replace your abandoned one. The creation of a clinical procedures manual to prescriptions, delivery.

MR. TELFORD: We're trying to give these folks credit for what they already have. In the definition we say sort of we understand you already have one, we want it to contain this information and we want it to be approved by the authorized user.

MR. KULIKOWSKI: That's not really a step. They go through it with each patient.

MR. SHARP: That's a good point.

MR. COLLINS: How important is it to the health and safety to have it in one binder.

MR. TELFORD: I would say that you have put your finger on one of the requirements that our legal counsel has insisted on.

MR. COLLINS: I think counsel could find something wrong with counsel.

MR. KULIKOWSKI: Let me support NRC's position on that. In New York, we have a firm called Rent-A-Tech where we have techs that come in to a place from a service and I

think it's very important that it be in one place so that they always know where it is.

MR. COLLINS: I agree with that. My problem is back in the older days when I used to do some inspections, I saw some clinical procedures manuals that were about so thick. So whether it was in one binder or two to me made no difference as long as it was in one place in an organized fashion.

MR. KULIKOWSKI: Obviously we're not going cite them if it's in two binders, A and B, as opposed to one binder.

MR. COLLINS: I have some inspectors that will. I read every letter and whack them out.

MR. SHARP: We're being so carefully general in this and the all the rest of this is in unusual specificity.

MR. COLLINS: My real question is did nobody else bring this up in the comments? No?

MR. TELFORD: Very little comment about that, no.

MR. COLLINS: There must not be a problem.

MR. CAMPER: It did come up at one of the workshops.

MR. WHATLEY: We didn't really figure that was going to be a Category 1.

MR. TELFORD: Okay. Let's be ready to move to No. 6. The way we would change No. 6 is we would -- instead of

medical use, we would say administration of byproduct material. We would take out "ensure." We would say "The patient's identity is redundantly verified." And then put in "written referral" for prescription. Written directive. So my best advice today is keep that one.

MR. DUNDULIS: I would like to explore this concept of redundantly for a moment. Does redundant identification of the patient seem to pose much of a problem as far as many of you are concerned?

MR. KULIKOWSKI: What do you mean by redundant? Two people have to identify the patient.

MR. CAMPER: By more than one means. For example, you might call the patient and say --

MR. TELFORD: Excuse me. One at a time. The Court Reporter might have a little difficulty here.

MR. CAMPER: You might go out to the waiting room and call the patient's name. Betsy Salus in this case. You would get up and come up and say, Betsy, you were born the 22nd of October of whatever year, and you would say yes; or, Betsy, you do live at such-and-such a street; that type of thing. Some means of redundantly verifying the patient.

MS. SALUS: I think the concept is fine. I would ask that we don't use the word redundant for verifying. Let's say verify by more than one means, only because if you put redundant in regulations, someone is going to say this

is bureaucracy at its best. It's arbitrary and unnecessary rather than say verified by identifying the individual by more than one means; name, photograph, social security number.

MS. ALDRICH: I guess one of the problems that I'm having stepping through this is that in my mind I see that there are differences between what we want for diagnostic and what we want for therapeutic uses. Since we're using one animal -- in this instance, you would most definitely look for redundant identification before you do a therapy procedure. A diagnostic procedure? No, I can't see that.

Most departments I know of do that. Hospitals will do that. They'll always ask the patient your name or something else. You want to be sure, because often you're dealing with patients who are maybe a little of out of it, inpatients, for example.

MR. TELFORD: I have all kinds of cases I can show you of the wrong patient stepped up, was supposed to get technetium and got socked with ten millicuries of I-131. You're not worried about redundantly identifying that patient?

MS. ALDRICH: I realize that that can happen. I'm not saying it can't. But I'm saying that in general I do make a distinction between what you want in the way of identifying the patient for diagnostic procedures and what

you definitely want for therapeutic procedures. I would definitely -- in this instance, it comes down to what Betsy is saying, that I would -- if we're talking about therapy, I definitely want that in there clearly stated, that you want to use two different means to identify the patient.

I think that if you're going to put that in for diagnostic, it sounds like bureaucratic overkill.

MR. KULIKOWSKI: We had this diagnostic misadministration in the past year where two inpatients that were in the hospital had the same last name and the wrong person got taken down. They were both named Jones or whatever and they were both approximately the same age, females, and there was no -- had they been using a redundant system, it probably would not have happened.

But they just said Ms. Jones, and they said yes.

MS. ALDRICH: I'm not saying that couldn't happen. I realize it could happen.

MR. KULIKOWSKI: It's more than thinking whether it's a diagnostic procedures or a therapy procedure, that the right patient get the dose that's meant for them.

MS. ALDRICH: I agree. I'm just saying as far as the regulations are concerned, I think I would feel very differently about ensuring that that wording is in the therapy procedures than I would for diagnostic. That applies to a few of the things we've looked at so far. I'm

just saying that for what it's worth.

MR. TELFORD: Let's be clear here. We have a general statement like this. This applies to both diagnostic and therapy procedures. So let's put it out on the table. Do you want to have identity of patient by two means for both diagnostic and therapy?

MR. ANDERSON: I had this happen to me personally about three months ago at the hospital. The only reason I knew they had the wrong person was because they said they were going to do X-2 and I said you haven't got enough people in this room to do that to me. I knew what I was in there for. But I bet you nine out of ten of them --

[Laughter.]

MR. SHARP: I think at this stage, patient identification, you have not made a separation between diagnostic and therapy. You can misidentify a patient and run them in for therapy. So at this stage, I think patient identification is going to occur before your downstream branching.

MS. ALDRICH: That's true. Yes.

MR. SHARP: I think it's appropriate for the patient ID.

MR. DUNDULIS: One thing. This came up at a couple hospitals in Rhode Island. Particularly inpatient, where you have to be careful what the redundant means are

because if you're dealing with some geriatric patients, particularly alzheimer patients; are you Mary Smith, uh-huh, you were born in New York, uh-huh. I mean, they're just going to say yes no matter what.

What a lot of the hospitals have done in Rhode Island, both inpatient -- they already have the wrist band and the schedule that comes down to Nuclear Medicine actually identifies patient by number and those that are coming in as an out-patient, they have out-patient processing. You come in, all of the information from the doctor is there, you're given a number, and it's verified -- the redundancy is done there.

It goes down to Nuclear Medicine and all the tech does is just check your wrist band. Now, I don't know if you want to get that prescriptive in here, but a lot of -- but, I mean, I think you have -- you don't want to put the total burden on the tech for redundancy if they've already done it at another point.

I agree that you need to double-check, but I don't think you want to focus it so narrowly that if it's already been done, the tech has to ask for a driver license and social security card.

MR. TELFORD: Well, this is a performance-based rule. This is the objective to be done. So that the licensee can decide at what step. We didn't say here the

technologist must do this.

MR. DUNDULIS: I thought that was implicit in it. That's the only reason I brought that point up. I would agree it can be performance-based. It's just the way the conversation was going, I got the impression this was being put on the technologist.

MR. WOOD: I agree with Larry. Did you phrase that to say more than one or did you say two?

MR. TELFORD: We can say redundantly verified or verified by more than one method.

MR. COLLINS: The same way that one enters it. If they want to use ten, I don't care.

MR. SHARP: Sounds fine.

MR. ZALOUDEK: That's fine.

MR. WOOD: Yes.

MR. TELFORD: Yes, you want to keep it?

MR. WOOD: More than one means is appropriate. Absolutely.

MS. ALDRICH: I go along with the group consensus.

MR. KELLY: More than one.

MR. WHATLEY: More than one.

MR. FRAZEE: More than one.

MR. SHARP: Before we leave the subject altogether, we do not, for instance, want to consider any further definition on the means, such as, in most of the

examples you've given, you've indicated the physical means. Do you want to say by more than one means, one which shall be physical means?

MR. TELFORD: What we have in mind is to say in the reg guide -- I'll give some examples -- ask the person their name; ask them to sign their name; ask their date of birth; ask their social security number; ask their address.

Are we ready to go -- no. Let's take a break.

[Brief recess.]

MR. TELFORD: Let's go back on the record. I think we're on Objective No. 7 of 35.35. This one always brings out a little question about what do we mean "unintended deviation." But when we explain that we mean that's a deviation you didn't intend to make, that if you wanted to make it, then you don't count that. You modified your written directive or you modified the referral or the authorized user signs off on, say, a different radiopharmaceutical or different dose, that deviation is not one of these.

Then it's pretty well accepted by the people we've talked to. So my best recommendation today would be to keep it.

MR. ANDERSON: Keep it.

MR. TELFORD: Okay. Any comments? Let's get some discussion on this. Terry, do you have a thought here?

MR. FRAZEE: No, not at the moment.

MR. TELFORD: Okay. Kirk?

MR. WHATLEY: I think it should say.

MR. TELFORD: Rick?

MR. KELLEY: Stay.

MR. TELFORD: Stay.

MS. ALDRICH: Stay.

MR. ZALOUDEK: Stay.

MR. WOOD: Stay.

MR. COLLINS: As long as I have a list of what unintended deviation is. I would like it -- we can't get a vague word like "unintended" through our administrators, rulemaking review body, or the committee on administrative rules.

MS. SALUS: If it wasn't defined? If it wasn't any deviation that's not incorporated in a prescription or something like that, that's what it means, no problem.

MR. COLLINS: I'm in favor of the concept is what I'm saying. I'll just have to slightly change the word to get it through our rulemaking procedure.

MR. WHATLEY: You don't really want any deviation to be identified and evaluated.

MS. SALUS: For purpose of your objective.

MR. TELFORD: How about if you --

MR. SHARP: Question. How much after the fact

retrofitting or rationalization would you allow? That's the only thing left up in the air. Let's make that intentional. Let me rewrite that.

MR. TELFORD: You don't allow changes in the written directive after the fact.

MR. SHARP: It sounds good. Now that that's nailed down --

MR. KULIKOWSKI: You said you don't allow changes in the written directive after the fact.

MR. TELFORD: Right. That's called coverup.

MR. SHARP: We call it a pre-plan.

MR. TELFORD: No.

MR. SHARP: I was being facetious.

MR. TELFORD: I understand. Bob?

MR. KULIKOWSKI: I guess no comment at the present.

MR. TELFORD: Bill?

MR. DUNDULIS: I'm not sure the word "unintended" is necessary because it says either the referral of a manual or the prescription and if the doctor has authorized it in advance, then that deviation is part of the prescription, so I agree with the point that was made that we want any deviation because any, if you would, intended deviation would be addressed by the prescription. I don't see any problem leaving it in, but I don't think unintended -- it

opens a possible Pandora's box w'' the word "unintended."

MR. TELFORD: Okay.

MS. SALUS: As a enforcement or a practical matter, you might get into arguments with the regulative community about whether a deviation was intended or unintended.

MR. DUNDULIS: We don't intend to make that mistake.

MS. SALUS: We intended to substitute, but we didn't get it written down.

MR. DUNDULIS: If they say they intended to do it and it's not written down, I don't care what they say, it was unintended.

MS. SALUS: If you leave the word "unintended," it's covered by the reactions.

MR. SHARP: The subtler rationale is that this is within the treatment parameters of that kind of therapy or this will cause no consequence to the patient, it might be less prone to be raised if you said any deviation instead of unintended. You may be raising a red flag that we don't need to.

MR. TELFORD: Okay. Any other comments on No. 7?

[No response.]

MR. TELFORD: Are you willing to move to No. 8?

MR. FRAZEE: In or out?

MR. TELFORD: What I'm hearing is say any deviation. Objective No. 8. The only advice we've gotten on this is to change treatment planning to treatment plan. We've heard that from several sources. My best effort today would be to say that brachytherapy and teletherapy final treatment plans and related calculations are in accordance with written directives.

I put in a new phrase there for you. Final treatment plan and related calculations. Related calculations would be, for example, for teletherapy, where you're calculating the time. You set the machine to run for a certain amount of time. That's a related calculation.

MR. SHARP: Repeat your wording.

MR. TELFORD: That brachytherapy and teletherapy final treatment plans and related calculations are in accordance with the written directives. What we're really after here is to make sure that the whole process of formulating a plan for treatment or a treatment plan, whatever you want to call it, including things like set calculations; in teletherapy, the use of anything; all of that process to be in accordance with the written directive.

Often in brachytherapy or teletherapy, that's a fairly elaborate process.

MR. WHATLEY: Do you want the plan or the treatment to be in accordance with the prescription?

MR. TELFORD: No. 5 here, which I would make the last one, the last objective, which says that you want the administration of the byproduct material to be in accordance with the written directive. I'm looking at what is now No. 8 as an intermediate process of planning the delivery, planning the administration of the byproduct material.

Can we get some comments here? Bill?

MR. DUNDULIS: Just a comment that I raised before. I think as long as we're linking the two with the treatment plan, it definitely talks about degrees of arc and portals and so forth, identifies where it should be put in.

MR. TELFORD: Bob?

MR. KULIKOWSKI: Do you have any feel for a temporal relationship between these two, the written directive and the plan?

MR. TELFORD: Definitely.

MR. KULIKOWSKI: Which is supposed to come first?

MR. TELFORD: We created a written directive back in what was the old No. 2. That will become No. 1 now. So it's first definitely.

MR. KULIKOWSKI: The feel that I get from No. 8, then, what is currently No. 8, is that the treatment plan must follow the written -- must adhere to what the written directive says.

MR. TELFORD: The written directive is the driver

for your plan of treatment.

MR. KULIKOWSKI: Fine.

MR. SHARP: Sounds good.

MR. TELFORD: Steve?

MR. COLLINS: I'm still trying to figure out how eight is not redundant with five.

MR. TELFORD: That's easy. Back in the old No. 2, we said you have to have a written directive. It defines the dose for teletherapy. Now, as Bill has pointed out, this may involve 300 rads from here and 300 rads from here to get that line to the brain. This may require a lot of things. So that if you write the dose, you may say -- as the physician may say I want to deliver 6,000 rads to that tumor site. How you get there could be an elaborate process for your plan of treatment.

So all we're saying in No. 8, which will now come before the old No. 5, the old No. 8 will say make sure your plan of treatment and related calculations follow the lead of the written directive and carry it out, make sure that you actually have included in your plan of treatment how you're going to deliver that 5,000 rads to that site.

MR. COLLINS: Considering all -- as best you can, how to minimize the dose to all other organs or to all other tissues or something like that, which is really what you're trying to do.

MR. TELFORD: No, sir. That's not my business, not my responsibility.

MR. COLLINS: Yes. I don't think we should delve into that either.

MS. SALUS: By No. 8 we're requiring preparation of the treatment plan and that that treatment plan be in accordance with the written directive? Logically, yes. Intuitively, whenever we take any somewhat complicated action, we have to break it down into tasks, but I don't see where it says there has to be a plan, let alone that it be in accordance with the written directive.

MR. TELFORD: Well, let's back up a step here. Let's look at the overall rule. Back in Paragraph A, the lead-in sentence says, in essence, these are the eight good things to do. In other words, your program will include policies and procedures which addresses this.

So it doesn't say you have to have a treatment plan, but it says if you're going to have a treatment plan, then it ought to be in accordance with the written directive. But how they do that, how the licensee carries that out is up to them.

MR. SHARP: It's not mentioned, it's medicine just can't be practiced in this type of document.

MR. KULIKOWSKI: New York State regulations would require, all patients in a hospital are required to have a

treatment plan.

MS. SALUS: I was assuming implicit. So there is a requirement that a plan be prepared, that plan may have to change certain elements to ensure that it's in accordance, but we haven't talked about that.

MR. COLLINS: In the performance objective, no where else in the rule that it appears, just this one performance.

MR. SHARP: On the other hand, is that a problem?

MR. COLLINS: I'm just saying should there be something in the rule.

MR. SHARP: Is it a problem we want to address? Have we seen misadministrations caused by lack of treatment plans?

MR. TELFORD: If they didn't get the plan right.

MR. SHARP: Not because they didn't make the plan.

MR. COLLINS: Back when you had a prescription rule, it was a redundant plan.

MR. TELFORD: We've seen cases in brachytherapy. An authorized user in the State of Indiana was practicing at three facilities. I could name them if you like. The NRC responded to allegations that there were not proper records of either a directive or a plan. Therefore, you couldn't say that the patients had been receiving the radiation in accordance with any plan or according to any directive. So,

yes, we shut down that operation because they didn't have either directives or plans.

We've also seen cases when they had a plan, but they made a mistake and got the wrong dose to the patient.

MR. SHARP: Then I think Steve's point is well taken that you need to require a plan.

MR. TELFORD: Well, guys, wait a minute. Wait a minute. We have a performance-based rule here. What we're saying is that what you must have is this program, an overall program, whether we call it QA or quality management or whatever, we need to have the overall program. The program should have elements to it, like policies and procedures which address these things.

So it's just like you said while ago. The practicalities of doing this kind of treatment dictate you have to have a plan. So we don't need to tell these folks you have to have a plan.

MR. SHARP: But in the case of a gross violation, such as Indiana where they weren't even doing any, I guess as long as you have rules that you can cite, you don't need more. I don't recall the rules mentioning a treatment plan. This might be the place.

MR. COLLINS: It's in 701, whatever your paragraph is in Part 35, it talks about use of sealed sources for brachytherapy. The lead-in sentence of that is that the

licensee should use the following sources in accordance with the manufacturer's radiation safety and handling instructions. They say handle in accordance with the treatment plan.

MR. TELFORD: Bob, do you have a point?

MR. KULIKOWSKI: Getting back to the phraseology of the treatment planning seems to be -- you can interpret that as not requiring any physical plan, whereas if you change that to treatment plan, it becomes implicit in that what plan is required. If that's the case, you must state it.

MR. WOOD: Not only a treatment plan. I think each of us has a concept of what a treatment plan, a definition of what it is.

MR. TELFORD: We can add that.

MR. SHARP: It could be brief.

MR. WOOD: What everybody perceives, we're going to add it if it's already there and if everybody agrees with it.

MR. SHARP: I think you could require it in eight at the same time you're asking that it follow the order.

MR. CAMPER: Let me ask a broader question about definition in general. We are going back to definitions again at some point?

MR. TELFORD: Yes. Yes, we must, because we have

to define event and whatever we call the misadministrations. We have to define those things.

MR. CAMPER: I assume, if that's the case, that is good. Perhaps at that time, we could discuss in a little more detail what might go into that treatment plan. As I recall, when we talked to the ACR, one of the physicians suggested that it was any document which contained -- the first time he said document or graphic plan, basically he surmised that in the treatment plan you could have a computer-generated document or a graphics with tables. You could have a handwritten calculation. You could have a written prescription. There are so many various ways people plan for treatment, not to be confused with treatment planning which generally is perceived as a plan generated via a computer program.

Treatment planning can be part of a plan of treatment.

MR. TELFORD: At the end, they said something like that describes the specific parameters for the delivery of the dose.

MR. CAMPER: The plan of treatment was something that he brought up that seemed to make sense.

MR. WOOD: Which may not include isodose curves, computer-generated isodose curves.

MR. TELFORD: I have a quote now. A document or

graphic that represents the details of the specific treatment. That's probably a good first cut.

MR. SHARP: Question. Do you want to say when this plan should be made; i.e., before treatment?

MR. WOOD: Some you can't. It happens during surgery, like brachytherapy. In fact, they were talking about how long after brachytherapy did they actually have to generate that; within a few days, within a couple weeks. They weren't going to take it out, so what did it matter.

MR. SHARP: We're talking about the final. So you want it within a month after therapy? When is timely? There's another aspect to this we can cover. We could state if a treatment plan is needed, it should be prepared by such-and-so a date and it should follow the order.

MR. ANDERSON: I think it ought to be before because the only one exception is brachytherapy and who gives a damn once it's done.

MS. ALDRICH: But one of the things that's been said by the physicians and physicists in New York is that once the treatment plan is generated, it essentially becomes part of the prescription as far as they're concerned. For example, a physicist who generates the plan wants that physician to sign off on that plan. Maybe it's passing the buck a little bit, but, on the other hand, to be sure this is what was intended. So I guess I'm conceptually having

problems separating the two.

MR. KLINE: We had the same comments by individuals from ACR which indicated that -- even some of the volunteers -- that indicated that their plan was signed by the authorized user and it became part of the written prescription. So that data was used.

MR. WOOD: Some ordered it and some didn't.

MR. KLINE: Yes. So actually the written prescription ought to contain all this information or parts of it are then further filed as the total prescription, or written directive, I guess.

MR. SHARP: Perhaps you ought to say the treatment plan is incorporated into the written directives prior to treatment.

MR. KLINE: But it's not in all cases. Everybody does things slightly different. Some people do it vastly different. So we start getting prescriptive. The regulatory guide does address this, by the way, and we do talk about what time during the treatment process do we have the dose calculated, verified, things of this nature.

MR. KULIKOWSKI: The bottom line is that we have one now.

MR. TELFORD: We get to the timing issue. In the reg guide, we say you have to double-check these calculations. Sometimes we say after a certain amount of

dose or within a certain amount of time or before the completion of the plan. If they're going to use one of these, they not only have to establish it, but they have to check it prior to completion.

MR. SHARP: Suppose they said that their brachytherapy and teletherapy final treatment plans are prepared and are in accordance with the written directives.

MR. TELFORD: The final treatment plans and related calculations.

MR. SHARP: Are prepared in accordance with the written directives. You cause their existence and you cause them to be in accordance with the written directive.

MR. TELFORD: Do you want to cause their existence?

MS. SALUS: Do you want to require that they be generated? That was the question we started with. Are these plans required or is it just a matter of if you happen to be stupid enough to do one and acknowledge you've done it, you better make sure it matches the prescription. The reason why I say you're stupid enough is because if you're smart enough to not do it and call it that, then you don't have to worry about ever blowing that objective, unless we're saying you've got to have one.

MR. SHARP: Considering the example out in Indiana, I think you ought to require it.

MR. TELFORD: Okay.

MR. COLLINS: I think the way the NRC had it was you made a requirement, which you put in your reg guide to do your rule, and some of us can't do that. So we're basically saying go ahead and put it up in the rule.

MR. SHARP: And then the final wording would be that brachytherapy and teletherapy final treatment plans and related calculations are prepared and are in accordance with the written directive.

MR. TELFORD: We can certainly try that.

MR. CAMPER: Does that cover your timing?

MR. SHARP: That's what we've got. It didn't address timing at all.

MR. KLINE: That pretty much is inherent in the process. I would speculate 98 percent of the people have some sort of plan on paper.

MR. SHARP: That was understood, but the two questions are the stop laws would realize they don't have to prepare a plan. You can't be out of accord if you don't. In the real case they didn't.

MR. KLINE: It's not a bad suggestion.

MR. COLLINS: Anybody that's doing a decent job is going to be doing one.

MR. DUNDULIS: Just as kind of a clarification. Something that I've seen from talking to at least one

practicing oncologist in Rhode Island, a lot of times, particularly if it's a very unusual or complex case, the oncologist and even the dosimetrist or the physicist, they might map out some general strategies and actually the dosimetrist will prepare three or four alternate plans. They'll have a conference and then the oncologist will sign off on the one that he wants to use.

So I think it's not just he's responsible, but if there have been multiple alternatives generated, which one of the multiple alternatives had he or she chosen to actually be the one to implement the prescription. They might have all done an equally -- they might have all done an equal job of implementing the prescription, but because of other considerations that are outside this rulemaking, like dose to other non-target organs and so forth, one plan might be more appropriate.

Not that I'm saying put this sign-off in the rule, but a lot of times that's why the sign-off -- because of multiple generations. Yes, this is the one I want to implement my prescription or written directive.

MR. KLINE: Well, they do capture that or John has captured that a little bit in calling it the final treatment plan.

MR. DUNDULIS: Right, and I agree.

MR. KLINE: Your point is well taken because often

it goes the other way where people will combine different plans and literally overlap plans based on the dynamics of the computer system and its ability to generate the necessary treatment parameters you're looking for. So, yes. That can be a problem or it can also compliment the plan itself.

MR. DUNDULIS: And another thing that the states are going to have to look at when they're implementing it is that we're also probably going to be applying these to machine-produced radiation and while you're limited to what you can do with a teletherapy unit, some of these multi-voltage neutron, photon, electron multi-mode LINACCS, you can get some really complicated treatment plans.

I know it's not a problem for NRC, but it may be a problem for the states if they're going to apply it to machine-produced. I think that's where we're coming from in some of these concerns.

MR. KLINE: That's a good point. We should consider that and we realize the mistakes made about this since it would be less cumbersome than to dissect out Cobalt-60 and not apply it across the boards in your program. That's a good point.

MR. TELFORD: We're addressing that in two ways. The first way is to talk about the final treatment plans. The second way is to allow written directives to be changed.

So would you agree or disagree that that's sufficient?

MR. DUNDULIS: Yes, that's fine.

MR. TELFORD: Is that all the comments that we have about this last objective? Can we move to the Paragraph (b)?

[No response.]

MR. TELFORD: Paragraph (b) of 35.35, we got a lot of questions about what do you mean audit, what do you mean comprehensive, who can do this, do you have to hire an outside agency to come in and do this audit. In the reg guide, we said words to the effect that it's not a good idea to audit your own work. We said you shouldn't -- the person that was involved in the activity shouldn't audit that activity, which was maybe a little too far to go, but it was the right idea, the idea being you shouldn't audit your own work because you're probably blind to your own mistakes, if you made any.

So let me give you a rewrite, which is a distillation of the suggestions we've had to date. One other thing I'd like to mention is that in Paragraph (b) we're talking about the licensee shall do this. But in the reg guide, we talked about licensee management and our volunteers pointed out that that might mean the administrator of the hospital or somebody that's not exactly a technical type that's going to come in and do this audit

and, therefore, they didn't like it.

So we have listened to all these suggestions. Let me lay out just a few key ideas to give you kind of an outline of what I'm going to say to you. One idea is we do want to do what I call a program review, annual program review, rather than an audit. We want that review to be based on a sampling of cases, of looking back over the past 12 months and pulling up some cases and making a comparison between what was administered and what was prescribed.

We want the department chairman or RSC or a quality committee or somebody to be involved in making a determination that the program is still sufficient. On the viewgraph here, I'm saying management, but keep in mind that that could be any one of a number of appropriate places that could -- evaluate the findings of this program review, make a determinatior that the program that the program is still effective, and then make modifications. Let's just leave it at that for now.

Those are the key ideas that we're trying to incorporate here. There's one idea that I want to kind of foreshadow for you, too, that our volunteers have told us that, you know, JCAHO allows kind of an optimization of programs. They encourage that if you're spending time and personnel effort in one area and it's not a problem, then why don't you stop that, why don't you put your resources

where the problems are.

So it's kind of an effectiveness or efficiency kind of idea that I'm going to attempt to incorporate. So here I go with a new (b) paragraph. I'm going to say the licensee management or its designee shall, number one, develop procedures for and conduct a program review at intervals no greater than 12 months -- that's our legal counsels talking there -- including an evaluation of a representative sample of patient administrations during from the last 12 months; to verify price of all aspects of the program. That's number one.

Number two would say evaluate each of these program reviews, this one here, to determine the effectiveness of the program. Then I jump to maintain the records. Three is maintain records of each program review, including the evaluations and findings, and keep those for three years.

So I have three steps in the program review. Going to go back and look at a sample of patient administrations from the last 12 months; examine these cases for compliance with all aspects of your program, meaning you're going to look to see whether -- the licensee is going to look to see whether the byproduct material was administered as prescribed. Secondly, they're going to look at their program. They're going to look at the procedures

that they have to see if they still think that they're sufficient or if there's a mistake that they have discovered from this sample of cases that has slipped through the crack.

Second is they're going to evaluate each of these program reviews to make the determination that the program is still effective. Thirdly, maintain records

Comments? Bill?

MR. DUNDULIS: The first one is, number one, it kind of implies a random selection. What I might want to do is that in addition to the random selection, to automatically include, and realizing the term misadministration may be changed later on, that any reportable misadministrations during that time period automatically go into the review process.

In other words, you take a random sample and if, by whatever randomization process, you didn't pull out all of your misadministrations, the no should be added in when it goes to the management review. That's point number one.

Point number two, one thing NRC is very involved with is reactors and reactors have to have aggressive quality assurance programs that have to go through some sort of internal audit. Is this audit procedure consistent, realizing that medical licensees aren't reactors, is it consistent with what NRC is requiring of audits of reactor

operations. Those are my two points.

MR. TELFORD: Point number one, the misadministrations or whatever we call them that occur during the year will be covered in reporting requirements. The reporting requirements will say go investigate, go figure out what's wrong, write us a report. They will have already handled the misadministration when it occurred or just after it occurred. So they don't need to go back and look at it. They've already looked at it.

MR. SHARP: Yes and no. They're handled on a case-by-case basis, but not in terms of its impact.

MR. TELFORD: As to determine whether or not they have deficiencies in the procedures.

MR. SHARP: Right. So I think you could say include those very easily. Program review of patient administrations and misadministrations.

MR. TELFORD: Okay.

MR. SHARP: Administrations and misadministrations.

MR. SHARP: You want to pick those out to see how the system handled them.

MR. KULIKOWSKI: Right. In other words, if you had six in the first six months, after that point, are you still getting more.

MR. TELFORD: Six in six months, wow.

MR. KULIKOWSKI: But see if after the first one or two if you have a correction mechanism in place and it's working. So I think you've really got to look at them again in an aggregate.

MR. SHARP: That's program implications.

MR. TELFORD: I didn't think of that before. What you're saying is re-look at the procedures to see if that tells you something now. I guess logically a person would do that, but we ought to just spell it out if that's what we really want.

MR. SHARP: In the heat of the misadministration, they forget to take a long look as well as a short look.

MR. TELFORD: Okay. No problem with that. David?

MR. WOOD: I think if any misadministration occurs and such that it has to be reported, researched, and etcetera, that you're definitely going to conclude that there is a procedural problem that needs to be intervened in. I agree also that at the end of the year it would be good to reflect on whether statistically it proved out, it was successful.

An evaluation is not worth much if you don't evaluate whether your response to it is effective.

MR. TELFORD: Kirk?

MR. WHATLEY: In Item 1, if I heard you correctly, you said make an evaluation of samples of patient

administrations for the past 12 months, something to that effect.

MR. TELFORD: Yes, sir.

MR. WHATLEY: I assume that would include, if you in a multi-disciplined facility, that that would include diagnostic, brachytherapy and teletherapy.

MR. TELFORD: Yes. The word that I used was including an evaluation of a representative sample, meaning you have to represent teletherapy, brachytherapy, radiopharmaceutical therapy, and diagnostics. And you have to take a sufficient size in proportion to the number of cases you had that year.

Now, I didn't answer Bill's second question. I believe the answer to your question is yes. In general, we are in conformance. There is a gentleman that works in my division who wears the hat that says quality assurance and he's all focused on reactors, and I gave him this rule at one point and said tell me what you think. He came back and said you're following the book. This is the steps that I would expect to see.

But in particular for this taking a sample of past cases, as a reactor case, before you would accept the base mat of the containment building, and we're talking umpty-ump feet of concrete down there that has to be in accordance with a lot of specifications. So they go around and they

take samples of this concrete before they're going to buy off on this; etcetera, on welds, for piping welds. We're talking huge pipes.

My belief is yes. Now, there's a second part to the (b) paragraph. I gave you the first part. The second part is on modifications. We say that the licensee may make modifications. This would be based on the findings of these program reviews. May make modifications based on the findings of the program reviews to the approved program to maximize the program's efficiency without NRC approval, provided the modifications, first of all, do not decrease the effectiveness of the program, and, second, are supported by the findings of the program reviews.

Now, let me stop there and say for a misadministration, when it occurs, it would be reported, investigated and reported to the NRC. We will also put in a requirement to say what are you going to do about it. So we wouldn't let that go on. If you investigate that misadministration and the licensee determines that they had a deficiency in their program and they had fixed it then. So these modifications are not those kind.

MR. SHARP: If you are going after a performance-based rule, have you given much consideration to not asking the licensee to submit the details and to allow him to make the changes that he sees fit so long as he follows the

requirements of the rule?

MR. TELFORD: Well, almost, because in this part of the (b) paragraph we're saying you can make modifications to the program if, number one, they're supported by the findings of these program reviews; two, they don't decrease the effectiveness. In other words, you don't leave holes in your programs.

MR. SHARP: So you've given him a free hand in his wording and his judgment of the effectiveness of changes. That's almost a complete free hand. The only thing you've asked him to do is where he wants to compromise safety and effectiveness which is as he wants to do. That's like impugning the flag or apple pie and motherhood. Then he has to come to you. So in coming to you, he's always self-incriminating. I don't think you'll get much response that way.

MR. TELFORD: I don't follow you.

MR. SHARP: Well, a licensee will presume to make changes especially based on performance aspects of the rule as we're progressing toward it, to try to improve it either by maintaining the same level of safety at minimized cost or by increasing the level of safety with level costs. He will always -- he or she will always view his changes once he's granted the necessity of having such a program as being improvement.

MR. TELFORD: The only thing I didn't mention was we said, oh, by the way, send us a copy of your modifications after the fact.

MR. SHARP: All right. That's what I'm suggesting, but what's the timing.

MR. TELFORD: Within 30 days.

MR. SHARP: Now, these are --

MR. TELFORD: If the modifications that you want to make are supported by the findings of the program reviews and if, in the licensee's opinion, it doesn't decrease the effectiveness, make the changes and 30 days later tell us what the changes are.

MR. SHARP: The thrust of this so far has been the performance-based minimums and it seems to me that review upon inspection of the program and its results would be enough, would be consistent with a performance-based rule.

MR. CAMPER: Remember it is a performance-based rule. They will not submit them to us, their program. They will be a part of the licensing record.

MR. SHARP: And I'm suggesting that they submit their QA program to you. They don't submit details.

MR. TELFORD: In other words, they just -- the rule goes into effect six months after publication and we say every licensee send us a letter that states you have a program in place that meets these.

MR. SHARP: That meets these requirements or where deviations, where you believe deviations occurred, explain.

MR. CAMPER: Let me ask you a question in terms of inspection. Do you not have a concern that your inspector will then be going on-site making a complete judgment call, an assessment on the site without prior review of the program?

MR. SHARP: Yes. So we didn't adopt 10.7, the guide. We didn't approach licensing that way. We might not approach a QA rule that way either, but you did. You approached licensing medical users with a check-off system that is verified by on-site inspections. With a performance-based rule here, you could approach it the same way.

You could even go so far as in the guide have an adoptable QA program, much the same way that 10.7 has adopted sections; dose calibrator.

MR. TELFORD: That sort of skips the licensing step, doesn't it?

MR. SHARP: So does 10.7. That's why I say you have adopted that philosophy and point of view in medical licensing.

MR. KLINE: Are you talking about 10.8 or 10.7?

MR. SHARP: 10.8.

MR. KLINE: This is identical to the 10.8

licensing process. I don't quite understand it. We have a regulatory guide with this document, too, and we incorporate it and if the licensee wants to use it by reference, it's an option as long as he minimally meets the guidelines. So it's not a requirement that they use a reg guide, but there's a licensing process required in order that we do capture by regulation the program he submits to us, so then our inspectors can prepare by reviewing the program prior to going on-site, and also to review their QA program and make sure it meets the minimum guidelines before they just jump in and start doing the QA program.

This is going to be new to a lot of people. It's going to require quite a bit of even our own people training at what our inspectors are going to look for in a performance-based program. So it's kind of complimenting each of those.

MR. SHARP: I tend to agree with that approach of having them submit it.

MR. TELFORD: Could I ask us to partition here. What I've done is thrown out a new idea, which is the licensee has the ability to make modifications on their own based on the findings of his program reviews. That's a new idea. That was not in the proposed rule. As a matter of fact, that's kind of a foreign idea to some of our licensing folks or some our enforcement folks.

The tendency there is to say -- let me put it this way. When this came out as a proposed rule, what we said was no modifications.

MR. FRAZEE: But what I'm pointing to is 35.31, radiation safety program changes, ministerial, etcetera.

MR. TELFORD: That's ministerial. We don't mean just ministerial.

MR. WHATLEY: Well, this includes making surveys and things like that. I don't --

MR. TELFORD: Wait a minute, guys. I'm not arguing with you. I'm just saying, look, I'm being honest, I'm saying, to me, what we're really talking about here is different from what we proposed. So I just want to lay it on the table and, first of all, there was this idea of making program modifications. That's idea one.

Idea two is how do we license. Should we require the submission of the plan. That's a separate question I think we ought to look at.

MR. SHARP: If you didn't require a submission, you wouldn't worry about changes.

MR. TELFORD: Yes. So let's take the first one first. What do you think about modifications in the manner I described?

MR. FRAZEE: It's supposed to be a performance-based rule and you're giving them the ability to perform

actions on their program to meet the objectives. So let them go to it.

MR. SHARP: I don't think you'd find a licensee making a change that they thought was deleterious to the program. So all the changes they would make they would consider non-reportable changes.

MR. TELFORD: Kirk?

MR. WHATLEY: I support that. I don't think that the reporting requirement -- I support the fact that they need to submit the changes to NRC or to anybody, but I don't think it's consistent with other areas that NRC has addressed in nuclear medicine, specifically 35.31.

MR. TELFORD: Let me make sure that you understand what I'm saying. In the rewrite of this (b) paragraph, it says the licensee may make modifications on their own without prior approval from NRC.

MR. WHATLEY: I support that.

MR. TELFORD: Okay.

MR. WHATLEY: Did you hear the rest of what I said?

MR. TELFORD: Yes.

MR. WHATLEY: About submitting the changes to NRC. I just don't think that's -- I agree that they should. I just don't think that's consistent policy in other areas in nuclear medicine, specifically 35.31.

MR. TELFORD: So you would modify --

MR. WHATLEY: I would change 35.31.

MR. TELFORD: In what way, Kirk?

MR. WHATLEY: I'd require they submit all procedures such as when you make surveys of waste disposal and calibration survey estimates and such.

MR. CAMPER: So you would eliminate the flexibility for ministerial changes.

MR. WHATLEY: I just don't call those things ministerial changes.

MR. CAMPER: I see.

MR. WHATLEY: But we've been through it before. That's just --

MR. DUNDULIS: When we adopted our Part 35 equivalent, we kind of compromised on it. We adopted the language for ministerial changes. However, what we said was anytime you implement one of these changes, all of the rationale that you had to go through, RSC approval, alternatives, that a copy of all deliberative documents be forwarded to us within 30 days and we reserved the right to review it and determine is it ministerial or is it not and is an amendment required.

That was kind of the compromise that we struck. It gives them flexibility. We can look at it. If we agree it's minor, then we'll just send them a note saying, yes,

it's fine. But if, on the other hand, we think they've gone off the deep end, we're going to say that's not a ministerial change, you're going to have to come in with an amendment.

And I think if you adopt what Jon is proposing, yes, allow them to implement the changes, notify the NRC within -- it says 15 days here, you said 30 days, I think 30 days is more reasonable, and then put some qualifying language; however, NRC reserves the right to say these are not minor changes, they do have a very significant potential to decrease overall safety.

I think that might be a compromise.

MR. WHATLEY: I was just making a statement. I support what you've done here and I think it's improvement over 35.31.

MR. KELLEY: I think the plans and the changes should be submitted.

MR. TELFORD: Okay. Would you allow them to make the modifications on their own without prior approval?

MR. KELLEY: I think it should be for review.

MR. TELFORD: Submit the suggested modifications for review.

MR. KELLEY: Right.

MR. TELFORD: And only make the modifications after approval.

MR. KELLEY: After approval, right.

MR. TELFORD: Okay. Rita?

MS. ALDRICH: I think this is a very ambitious rulemaking. I think it's going to result in licensees being -- who don't already have it in one place perhaps, a fairly comprehensive program. We foresee that being in the form of a quality assurance manual and then possibly other manuals, like treatment planning procedures manual. And, no, I wouldn't want those things submitted. I think that I would prefer to develop some guidance for the licensee on what parts of the program we want submitted.

To me it would be like having the licensee -- I don't whether you do or don't do this -- submit their radiation safety manuals, say, for a large broad license, which generally comes by the pound. We already have a problem getting through the workload that we've got. That's one thing.

The second thing is you tend to wind up rewriting their manual for them, either editing or some other way. So, no, I would not want the entire program submitted. I think I'd rather rely on asking them for specific aspects of it in response to questions.

MR. TELFORD: The question now is would you --

MS. ALDRICH: And changes -- yes. I would --

MR. TELFORD: Would you want to review the

modifications prior to letting the licensee make the modifications?

MS. ALDRICH: Following on what I just said, no, I would not. I'd expect them to be able to revise their manual. Again, it's a performance-based rule. If the change is to improve their performance, I don't think I'd necessarily agree that they would tend to rationalize the change that they were making. But, again, if they made a change and that resulted in something occurring, a misadministration or whatever we're going to be calling it, then clearly they would have -- I think that its 1f, the fact that the performance was graded, would then result in your declaring them to be in non-compliance with the rule. That could be tricky.

But I don't think that in this instance that we really do want to see every single change that they're going to be making. I think it would be hard to judge whether or not it's a major or a minor issue and I would rather leave it to the evaluation at the time of inspection or as follow-up to an incident if they did have an error or misadministration.

MR. TELFORD: Let me summarize what you said to make sure I understand it. For modifications to the program based on these program reviews, you would say, yes, let them make the modifications without prior approval.

MS. ALDRICH: With the understanding --

MR. TELFORD: But you only want to see some of the modifications. You don't want to see all the modifications given as a copy to you.

MS. ALDRICH: The modifications I think that they should be able to make on their own, but the understanding is that they are to improve performance after a review that identified something in their program that was a weakness. As far as seeing the original program itself, I don't necessarily want to get their entire quality assurance manual, which is what I envision them developing for themselves.

I would rather ask for specific information. I'm answering the question in two parts. One is do I want the program submitted and two is do I want the modifications.

MR. TELFORD: I was really looking for an to the first part, which is do you want to see the modifications prior to, and you say no.

MS. ALDRICH: I'm saying no.

MR. TELFORD: Dave?

MR. WOOD: I don't have a real strong opinion, but I'd be inclined to say I'd want to review them first.

MR. TELFORD: Okay. You agree with Rick, then. Dave?

MR. ZALOUDEK: I think I'm going to go back to

where Kirk was a minute ago. It sounds like a departure from -- if you're saying that the changes would not have to be submitted prior to implementation, it appears to be a change -- not a change to NRC's current policy. You're requiring this to be submitted initially or plan to be submitted as part of a licensing process. Changes don't have to be submitted.

MR. TELFORD: Let's look at the overall picture here. What we're saying is this is a performance-based rule and realize that they must have a program. They've operated their program for two or three years. They've had program reviews annually. They have determined that they can make a change for the sake of efficiency, but not decrease effectiveness.

This idea says if the modification that the licensee wants to make is supported by those program reviews and does not decrease the effectiveness, yes, they can make those changes without prior approval.

Now, just stay with this rulemaking. Let's not broaden the issue to all of NRC. Let's not broaden over to Part 40 or 70 or 50. Let's just stay right here on 35.35 for a minute. This is how we have to run the show here. We've got a yes, we've got a no, we've got a no, we've got a yes.

So on its merit, forget policy, just give me

merit, do you like it or not? Simple as that.

MR. ZALOUDEK: I'd be inclined to go with the review prior to.

MR. TELFORD: Okay. Dave?

MR. WOOD: I'd have to qualify. After hearing your description, I would say I'm almost inclined to agree that you -- you hand us such a nice scenario. I think this particular institution could have done it, but I think there's too many institutions that are too much smaller in my state that I don't feel like I could give that kind of respect to their changes and their ability to review internally and make those changes.

A big place that had the personnel to do it and do it right, yes, but not the majority.

MR. TELFORD: Okay. Larry?

MR. ANDERSON: I think because it's performance-based that we have to let them do that. I wonder what other circumstances are in the other states. I don't have the people to sit down and review every one of these things that somebody is going to be sending in to me. It's not going to happen. I can't even review things that the NRC sends to me to review.

Where am I going to get the people to do this? It's performance-based, if they screw up, that's the way it's got to be.

MR. TELFORD: Okay. Steve?

MR. COLLINS: The only ministerial change I'd recognize is change in a post office box. Everything else is submitted to us for review.

MR. TELFORD: Okay. Jon?

MR. SHARP: I like the idea of a performance-based rule and I would try to enforce it the best I could. So I would let them make the changes.

MR. TELFORD: Give them enough rope to hang themselves.

MR. SHARP: I think we would have interaction with investigating misadministration, the inspections, so that once we had glanced, and I agree manpower, woman-power, person-power to review is going to be very tough. I would like to see the program they submit touch on the key points of how they're going to meet the objectives and not give any great detail.

So I'd like what they submit to be performance-based descriptions. So I would let them make the changes, but I don't think anybody is going to admit to hurting that QA program. So they're going to make all the changes, even ones that hurt the program a little bit, in fact. But I'm prepared the pay the price. I don't think it's much of a price to pay for getting a QA program started and I think we need all the selling points that we can to have them

addressed in a confidential way and a detailed review, there's no way to sell it to a licensee.

MR. TELFORD: Okay. Bob?

MR. KULIKOWSKI: I guess I feel similar to the way Jon does. There are two components to it initially when you have them submit a QA program. There's a performance-based meeting of the objectives. Then there are all their detailed procedures of how they're going to do that.

One, I agree with Larry. I don't have the manpower to go through every single procedure to make sure it's going to do what they say it's going to do. I think I'd make some change in the performance-based side of it, then they should at least submit it to us for information so that their license file is up to date. We have enough encompassing things in our regulations currently so that if we look at that -- I mean, we may decide that there's no action that's necessary.

However, if we see that there's something, that we have the authority to go and say, look, you can't do this, you've got to change it back. I think that's maybe for us to strike a happy medium where we have some feel for what they're doing, we can head off real major disasters within a certain period of time, but let's leave most of the legwork up to the field people and let them evaluate it as they see it in the field. They're going to get a better context of

it anyway.

MR. TELFORD: Bill?

MR. DUNDULIS: I think what I said before, the way we're doing it now, ministerial changes, and I think that some of that is -- if you can make the case, implement it and send it to us within 30 days and we reserve the right -- if you guessed wrong -- you know, it's clear in the statute that we have a right to get back to you and say, no, we don't think that's a minor change.

MR. TELFORD: Okay.

MR. CAMPER: Can you go back and revisit the language which, that after they conduct the program review, they can only send in certain types of information to NRC? I'd like to explore the point that Jon had raised. Basically, I think I heard him saying that no one is going to send to NRC or to any regulator a bad idea, an amendment that's going to be based upon --

MR. SHARP: And the way the rule is written, that's the only idea -- so they're guilty before --

MR. CAMPER: Can we just review that language for a minute?

MR. TELFORD: The follow-on language --

MR. CAMPER: Only send us a certain kind of information for prior approval.

MR. TELFORD: We said if the modifications that

you want to make are supported by the findings of the program reviews and do not decrease the effectiveness, make the modifications, but send us a copy in 30 days. Of course, we reserve the right to say nice try, but no cigar.

Now, we also say that if you're going to make modifications that are not supported by the findings or decrease the effectiveness, you cannot make them without prior approval.

MR. CAMPER: What I'm saying is no one is going to do that.

MR. SHARP: Those modifications that are made that might have done that, I think, are a small price to pay before you increase the saleability of this whole idea. So I would not review them.

MS. SALUS: I'd like to make a related point, which is that earlier you were saying that the JCAHO has a general philosophy that you can take an integrated approach to whole operation where you're not finding problems, you start shifting resources and pay attention to areas where you are.

It seems to me given the number of misadministrations relative to other medical procedures, the result of these annual audits is going to them, hey, we don't have problems here, and constantly going to find that relative to other hospital activities, at least in a

hospital setting.

So you're going to be constantly getting changes. Let's reduce these procedures. Let's make them less burdensome because the effectiveness isn't going to be really significant if it's not going to be required in the regulation.

MR. TELFORD: Well, let me see if I understand what you're saying. You're saying this hospital operates along with no problems and it has a program review and says, gee, we --

MS. SALUS: A whole year, no problems.

MR. TELFORD: A whole year, no problem. Okay. Decision to make. Let's keep the program the way it is. In a second year, no problems. Let's keep the program the way it is. Third year, no problems. Gee whiz. Looks like we could cut back the application of some of these resources. Yeah, let's do that. Fourth year, no problem. Fifth year, no problem. Now what?

MR. SALUS: Maybe we ought to cut back some more.

MR. TELFORD: Pardon me?

MS. SALUS: Maybe we're going to decide to cut back even more resources.

MR. TELFORD: The hospital?

MS. SALUS: Sure.

MR. TELFORD: Okay. By definition, you've got no

problem, you've got an effective program. As long as that keeps up through ten years, you could be down to almost nothing, but you must have some great people there not making any mistakes.

MS. SALUS: Given the statistical probability of one of these events occurring, I think most of these hospitals, if all we had were the procedures and requirements that are in place today, they'd keep coming up no problem, no problem, no problem.

MR. SHARP: Let me give you an idea. David, how many procedures of brachy would you do in a year?

MR. WOOD: Several thousand, two or three thousand.

MR. SHARP: So even an error rate of one-in-10,000 in a well run institution is going to have a few problems.

MS. SALUS: One every five years.

MR. WOOD: And the program still falls flat on its face. You cut it back to a pretty minimum load. The RSO left or a couple of key technologists left and you're now scuttling with a couple of cross-trained x-ray techs, radiologist who is not too hip on things, and you've suddenly got a whole different program overnight. These are small organizations.

MR. SHARP: I think there's a potential to pay a price with not having them submitted. I just think it's

small and I think it's worth the chance to increase the palatability of the program. But I think all these things are true. I think we need to know that price if we're going to buy off on this. We need to know that price so we're not surprised by it later and overly concerned as to what's going to happen, going in with our eyes open.

MS. ALDRICH: I was thinking, too, that not all facilities will start from a level place. There will be some that will really extend resources and do far more than they need to. So it wouldn't be inappropriate for them to decrease resources over time if they found that they had been -- if they promised more than they really need or is reasonable, and obviously we're not going to tell them, no, you don't need to do that much, cut it down. It's just now the regulatory approach.

But there will be some that will start from a level at which they could reasonably decrease the resources or time devoted to it and then there will be others that will have only a minimal program. Well, I wouldn't say minimal, but they'll have an adequate program, but certain not overkill.

MS. SALUS: I guess my concern is that because of the statistics, you're going to be -- you're not going to know any changes that reduce effectiveness until you've gone past it. Almost any change I could propose wouldn't be

anticipated to reduce effectiveness given --

MR. TELFORD: Can you give me an example?

MS. SALUS: I'm probably the wrong person. Maybe somebody else can.

MR. TELFORD: You must be thinking something.

MS. SALUS: No. I'm really not. I was just listening to -- you were saying earlier about shifting resources. I know absolutely nothing about what goes on in the nuclear medicine department.

MR. TELFORD: Don't say that. You'll lose credibility.

[Laughter.]

MR. TELFORD: Let's focus it. We've got a bunch of procedures that try to carry out these objectives. Now, let's say that for patient identification they had a criply redundant system.

MS. SALUS: We go down to double.

MR. TELFORD: Yes.

MS. SALUS: Now we go down to singly then.

MR. TELFORD: The objective says at least two. You can't back off totally now.

MR. CAMPER: I think a point to be made here is when we tried to restructure this particular language, we were trying to incorporate the concept that JCAHO used in that the indicators that the hospital relies upon from time

to time can change.

Frankly, if you start off in a QA program and you're expending X amount of resources and you look at your program a year later, two years later, and you say, gosh, we're doing a great job, let's take it X minus something and divert those resources somewhere else, and you achieve the same level of efficiency or the same level of objectivity. So what?

Now, on the other hand, let's take the case that David raises. Going on three of four years, you've got a great program. You lost two of your technologists. You know intuitively that you've got to readjust some resources. You've now taken a hit in this area. You're probably going to step up those resources to maintain a safe level of efficiency.

That's fine. Our thought was that the licensee should have the flexibility to do those types of things in a fashion that maximizes the effectiveness of the program, without having to say the regulator will make these changes.

But the question that I was really getting at a moment ago that Jon had raised was more one of the language that we have as the follow-on there about submitting those changes which are not supported by the program review. My question really was I'm wondering if that's necessary. I don't know if anyone is going to send us something that has

a big negative associated with it.

MS. SALUS: Curiously enough, even if they do, how is NRC going to decide whether or not to approve it? We know this might cause one in X thousand excess health effects and the purpose for this rule is to prevent --

MR. TELFORD: Wrong rationale. We would -- our license reviewers -- let me kill two stones with one bird here. Let me pick up Jon's second point from before and say what we had in mind was the rule will have an effective date six months later. At that date, all licensees would send us a letter saying we have a program in place.

Upon license renewal, which is basically a five-year cycle with us, they will send in their QA program. Then we would do the license review. We would say, okay, here are your procedures, here is the rule, and we believe it meets the rule. We don't look at what you're talking about, no. We look at the rule.

We say do we believe your procedures are effective in meeting the objectives of the rule. We'd say, yes, we agree or, no, we don't and pretty soon we iterate until, yes, we do, and they get a license to operate. When they get inspected, they get inspected against that license.

MS. SALUS: But that's not what this says. This says modifications that decrease or potentially decrease the effectiveness of the program may not be implemented --

MR. TELFORD: I'm sorry. You can't look at that language. Listen to what I'm saying. When I started off, I started off saying this is a new Paragraph (b). We can throw out the old Paragraph (b). So I explained that they're going to have program reviews. They're going to evaluate these program reviews. They're going to maintain records.

Secondly, we said the licensee may make modifications based on the findings of these program reviews to the approved program to maximize the program's efficiency without NRC approval provided, one, the modifications do not decrease the effectiveness; number two, are supported by the findings of the program reviews. Then, by the way, within 30 days, send us a copy.

The second statement after that, if you make any modifications which decrease the effectiveness, you may not make modifications which decrease effectiveness or, two, are not supported by the findings of the program reviews. Okay?

So the question I wanted to get to was the thought that Jon brought up a while ago. Do we go through the licensing review process. My inclination is to say yes, but do it on a license renewal schedule.

MR. SHARP: I'm sure that would be the only thing possible for us.

MR. TELFORD: That way we see 20 percent of 2,000

every year.

MS. SALUS: And then if the licensee wanted to change the program in such a way that might decrease or potentially decrease, could it demonstrate won't decrease effectiveness, they'd have to apply for amendment or change the program?

MR. TELFORD: If they want to make a modification which they think will decrease the effectiveness or maybe more importantly we would think would decrease the effectiveness, they have to submit that prior to.

MS. SALUS: If they want to make a modification that they can't support based on their findings, won't --

MR. TELFORD: Right. Bill?

MR. DUNDULIS: One important thing that when you said they've reviewed the program and you said won't decrease, some of the original language, or potentially decrease. That appears to have been -- the or potentially decrease appears to have been a conscious omission on your part and I'm just wondering why in the revised language you decided to drop that.

MR. TELFORD: Well, it's kind of like almost anything could be judged to be potentially. So we probably went a little too far with that proposed language.

MS. SALUS: Let me ask another question related to this. Suppose I'm a hospital that uses triple ID and I find

after five years no problems with identifying patients. So I say double it. The third step is not necessary. And in one or two years before I go to renew again, the only problem I had is I had a bad ID. Have I done the bad thing, which is change my program in a way that reduced the effectiveness?

MR. TELFORD: You stepped over the line is what you did. When you went to identifying patients with only one method, you sent that to NRC within 30 days. The next thing you're going to get is a letter.

MS. SALUS: No. I said three to two. I started with three, no problem.

MR. TELFORD: But then did you go from two to one?

MS. SALUS: Not this time. This is hypothetical. This hypothetical is I go three originally, no problem. I say, great, no problems, ID is not an issue, go back to two.

MR. TELFORD: Okay.

MS. SALUS: Then after I implement two, that's where I get a misadministration. I just got the wrong patient. I don't know how it happened, I had the picture, I asked another question, what's your address. Does it decrease the effectiveness?

MR. CAMPER: And your misadministration in this case resulted from a lack to properly identify them? The argument could be made that you have --

MR. SHARP: One of the problems is asking them to guess whether it's intentional. It's a long lead time, a long evaluation time required to see what these changes might mean. It's put them in a Catch-22 situation in making a change and perhaps finding out later that that did impact the program.

MS. SALUS: Especially with the low incidents of these misadministrations.

MR. KLINE: If that's the case, do you think that possibly the licensee will submit every change to you?

MR. SHARP: I think we should be content with them submitting their changes because most of the changes because most of the changes will be improvements and we should not force them to admit that a change is deleterious, because I don't think they will and live with those that three years down the pike prove to have been mistakes, but there was no way of telling at the time they made the change. Going from three to two would have been accepted even on review, but it proves to be the wrong loop perhaps.

MR. ANDERSON: I agree with you, Jon. None of this goes on in a vacuum. We're going to be seeing these people. If they're starting to have some problems, we're going to see them. We're going to be --

MR. SHARP: Drop the wording about deleterious changes. I don't think they'll intend to make any of those.

MR. TELFORD: Steve?

MR. COLLINS: I like the wording that you've come up. I would think that each time a true misadministration occurred, we always follow that up with a letter that's just like a notice of violation that says what actions did you take to prevent recurrence. That always has a qualifier that based on your response, we may incorporate this into your license.

So in the way we handle that, it's already covered anyhow.

MR. TELFORD: We would do the same. We haven't gotten to reporting requirements yet, but that's where that particular step that you just described would be contained.

MR. COLLINS: So what I'm really saying is -- are we through with the discussion on this part?

MR. TELFORD: I think we are. Jon, did you want to say some more about whether or not maybe we should go through the licensing step?

MR. SHARP: I think each state is going to make a decision on that because I think we're going to have a hard time selling it. I think dropping the changes at least makes some sense. I don't know how it's going to come out. I know what I'd like to do, but if you want to compare a program on renewal to the precepts here, I think that's probably about the best cut you can make to review these

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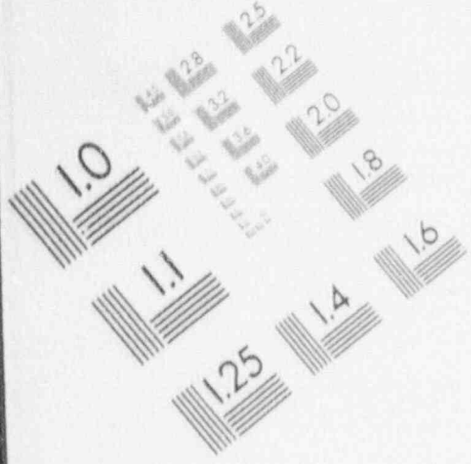

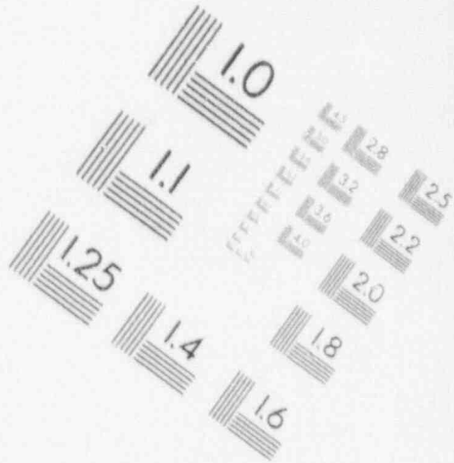

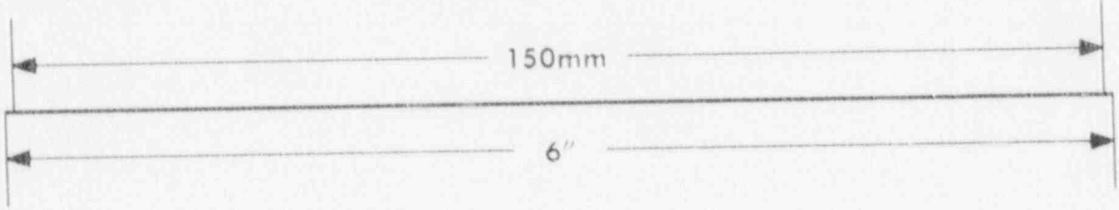

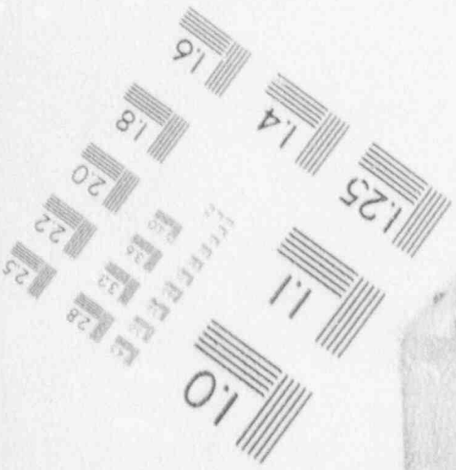

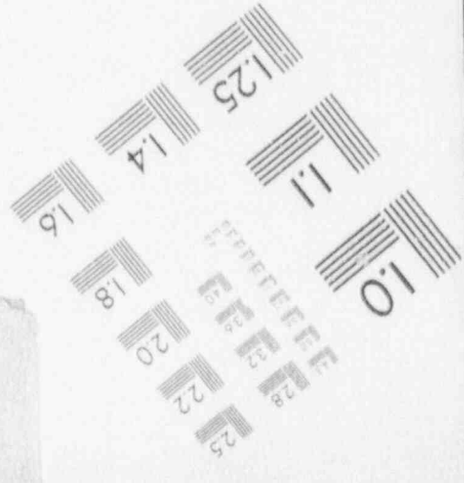

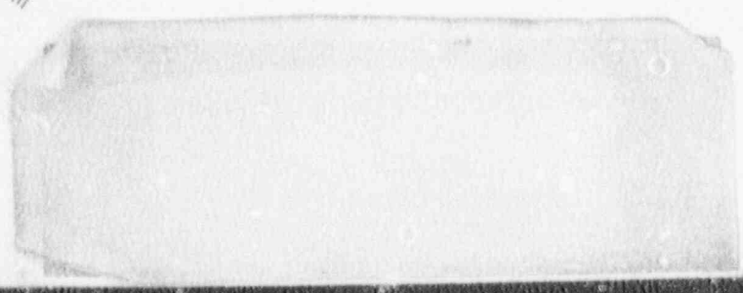

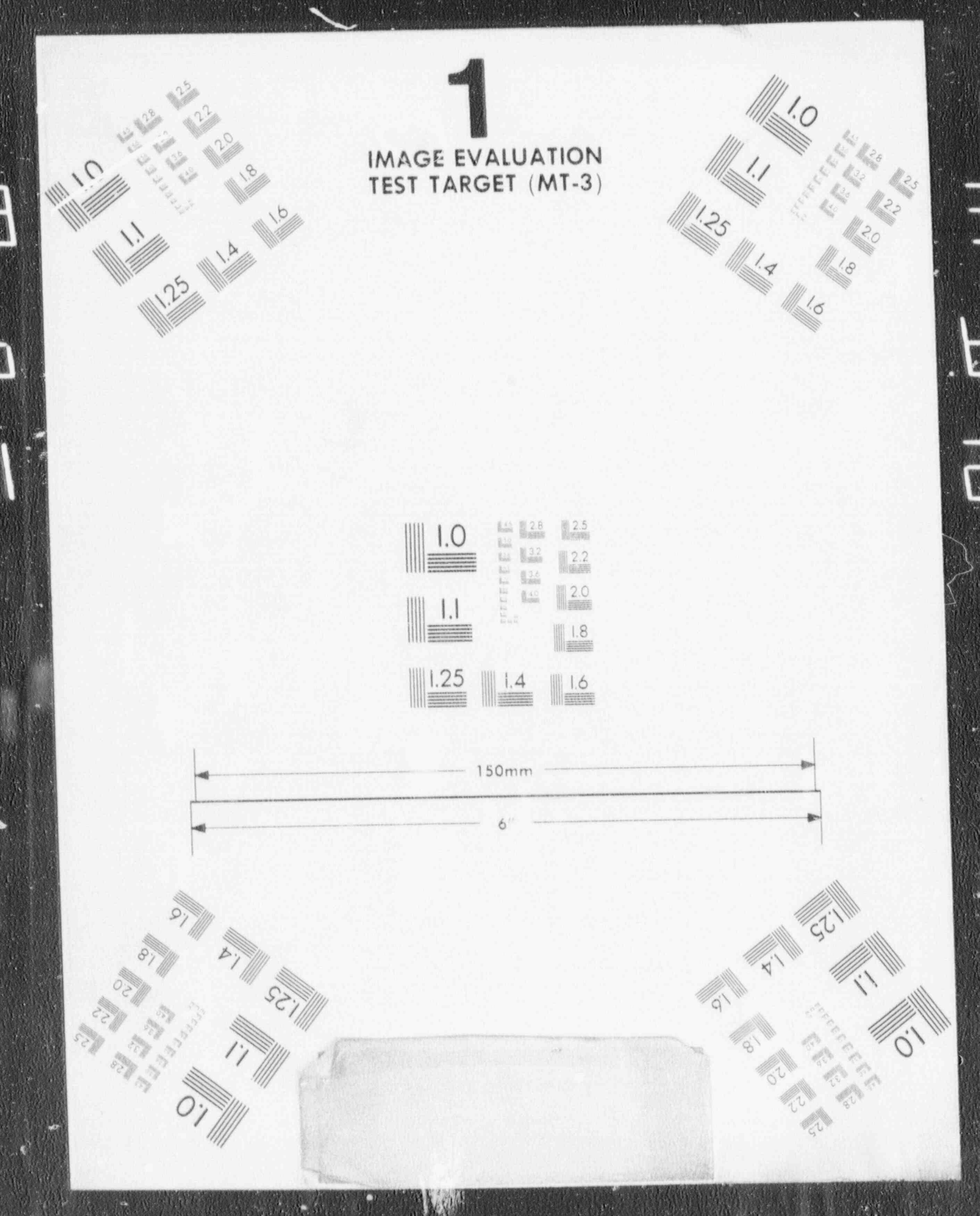
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programs and let them maintain.

We do put our compliance people in a somewhat precarious position going out to inspect a program we may have changed in detail, so they won't be able to hold people and they'll be able to make a field judgment about how well this fits. But if we look at it every five years on renewal, I think -- we're just starting into this quality assurance program. Maybe we ought to -- if this doesn't work well enough, then we'll have a review and changes later on. But I think we ought to establish a lead for it.

MR. FRAZEE: We have a 50-50 split here.

MR. TELFORD: Do we have a 50-50?

MR. FRAZEE: Roughly.

MR. TELFORD: Let me phrase the question. Do we do the licensing step? Is that the question? Do we ask them -- the rule has passed, we have an effective date. They send us a letter on the effective date saying they have a program. Now, upon license renewal, do they submit their program for licensing review? Is that the question?

MR. FRAZEE: That wasn't the question. That's a good question. The 50-50 split was whether or not we would have them send the changes in.

MR. KULIKOWSKI: This is logically a better first question. Let's deal with that.

MR. TELFORD: Okay. Let's take this one. We'll

come back to that one. You've got the question? You're going to test me now. Can I remember it? Okay. There is an effective date of the rule. Six months after it's published. On the effective date, the licensees send a letter saying we have a program.

Upon license renewal date, licensee submits program for licensing review. Yes or no? Terry?

MR. FRAZEE: What is the extent of our review?

MR. TELFORD: Licensing. You've got to look at the program and you're going to --

MR. FRAZEE: Am I looking at it and saying yes they actually have one or --

MR. COLLINS: This is your five-year renewal application.

MR. FRAZEE: One of the items on your QA program. Am I looking to see, yes, they have a QA program or am I looking to see if it fits the rule and how well?

MR. TELFORD: It meets the rule acceptably to your licensing reviewer. So your answer is?

MR. FRAZEE: We review it.

MR. TELFORD: Upon license renewal.

MR. FRAZEE: Yes.

MR. TELFORD: Okay. Kirk?

MR. WHATLEY: I don't think you can issue a license without them meeting the requirements of the regs.

The only way to do it is review it. So I yes.

MR. KELLEY: Yes.

MS. ALDRICH: Yes.

MR. WOOD: Yes.

MR. ZALOUDEK: You review it.

MR. ANDERSON: You review it.

MR. COLLINS: Yes.

MR. SHARP: Yes.

MR. KULIKOWSKI: Yes.

MR. TELFORD: That's the first question. Okay. Take a deep breath. The next question is modifications to the program. Modifications that are supported by the findings of the annual program reviews and modifications which do not decrease the effectiveness of the program in order to maximize the efficiency of the program. Do we let the licensees make these modifications without prior approval? Yes or no?

MR. DUNDULIS: Clarification. You said annual. Yet, the review says intervals not to exceed 12 months. If, for whatever reason, they want to do it -- they want to call a special meeting for the purpose of reviewing it and it's less.

MR. TELFORD: We mean they shall do a program review at intervals not to exceed 12 months. If they want to do those reviews every month, fine. Stack up 12 of them.

If they want to do them every quarter, fine. Stack up four of them.

MR. DUNDULIS: So your question was prefaced with after the annual review.

MR. TELFORD: Based on the findings of the annual reviews, plural. Okay. Question, yes or no?

MR. FRAZEE: Yes.

MR. WHATLEY: Yes.

MR. KELLEY: Can I pass?

MS. ALDRICH: Yes.

MR. WOOD: I agree, but there is one thing that bothers me. If it happens to be four or five years before I get around to reviewing it, if it happens to come up in sequence to see the project in its entirety and they had to change something after two years and they send me in their modification --

MR. TELFORD: Thirty days. You get a copy in 30 days.

MR. SHARP: But you don't have anything to compare it against.

MR. WOOD: If the original entire document in its entirety is not submitted upon renewal, which may happen to be four or five years down the line, then what do I have to know what it's compared with?

MR. CAMPER: That's a problem the first time

around.

MR. TELFORD: Let's go to the next time. Let's say you've already -- license renewal has already come up. You have licensed the program. Now you're a couple years after that. You've got two or three annual reviews. They want to make a modification. They make a modification and they send you a copy in 30 days. That's really the scenario I'm envisioning.

MR. KULIKOWSKI: Let me just clarify this a little bit further. Say we just renewed the license this month and the QA rule is effective next June. That license is not going to be reviewed until 1995. They wouldn't have to review the QA program until 1995. Any changes that they make to that program, we have no review base documents to compare it to. So is it necessary for them to submit that.

MR. TELFORD: If you want to call that a deficiency in the plan, okay, but it's there because we don't want to review all the licenses the first year. It has really nothing to do with making modifications. It has to do with the fact that we don't want to look at 2,000 licenses at once.

MR. KULIKOWSKI: Granted. But I'm saying we're looking at two separate points in time. The before event and the after event. Do we want changes submitted only after their plan has been reviewed and approved or any time

up to that point when they just said we have one?

MR. TELFORD: So it could occur. Like you said, you're not going to get the license renewal until that time. However, for our major licensees we inspect them every year and the other guys it's once every three years. So we're not going to go five.

MR. KULIKOWSKI: Yes, but from the license review process --

MR. CAMPER: It will occur the first time around. The only time you want to see that program is upon inspection.

MR. KLINE: The only consolation would be that if the inspector takes that review with him and compares it with the on-site program in its entirety, then if there's a conflict or problem, he can recommend that there has to be an amendment that needs to be reviewed by a license reviewer to determine the significance if it is detrimental to the program. But, yes, you're correct. This is a loop. This is a period of dormancy where you could literally get in these requests or these please review this and we have no basis for reviewing it.

MR. DUNDULIS: But if you take the suggestion that I offered earlier, is implement, submit with the option of the NRC or the state jumping in, then the way you could address it is you say, okay, this is a change compared to

what.

MR. CAMPER: Just ask the deficiency question.

MR. DUNDULIS: Right. So in other words, if you adopted this language with the option of NRC having the opportunity to say no, then the problem is resolved.

MR. TELFORD: We will reserve that option. We always do. If we go out and inspect and we haven't had license renewal yet on this licensee, but it looks pretty bad to us, pull that guy right out and say, okay, it's not your turn.

MR. DUNDULIS: But I'm saying in a case where a plan -- where they said you haven't reviewed our plan, we certify that we have a plan in place and now we want to amend it, and you're saying, well, amend it from what. So you as the licensing agent say even without making them submit a whole plan, you can say, all right, well, just send me the old text of this whole section.

MR. KLINE: Right. Exactly. If they want to amend it, they would have to submit their entire package so that we could review it.

MR. DUNDULIS: That's why I think it's important to have the agency review in the loop. If it looks fine, you can say fine, nothing happens. But if it doesn't look fine, then you can jump in.

MR. KLINE: That's a good point.

MR. WOOD: How much extra trouble would it be to say when you send in your -- within a six-month parameter -- your promise that you have it in place and are going to abide by it, that you also send in a copy of your document, whether we review it or not, whether it just goes in their file to be documented subject for review later if an inspector comes out and says something doesn't look quite kosher, can you review it. At least you have a copy on file. You don't have to review it the first time around. It's only for review on that five-year sequence. But at least you have it in your hands in their file.

MR. CAMPER: That could be easily accommodated by requiring that they submit a copy of it to you rather than letter certifying that they have it.

MR. COLLINS: Good point, Dave. I really like that.

MR. ZALOUDEK: Given that we thought this was important enough to adopt this rule through the rulemaking process, given that we went through all this and require the licensee to go through all these steps and establish a plan, I think we'd want to review it.

MR. ANDERSON: Yes.

MR. COLLINS: No.

MR. SHARP: David just switched my mind. You voted no? He doesn't want to review it.

MR. TELFORD: The question was are they allowed to make modifications without prior approval.

MR. ZALOUDEK: The answer to that is no.

MR. SHARP: I would say yes.

MR. KULIKOWSKI: No.

MR. DUNDULIS: Yes, within the parameters that I've discussed.

MR. KELLEY: No.

MR. TELFORD: I think we've got four no's. Okay. By my reckoning here, looking at the agenda, I think we have discussed the 9:15 item, which is the discussion of the proposed rule. I really think we've started the 11:15 item, which is the roundtable discussion of the suggested modifications. We did do the break. We did do lunch. The only thing that I think we've missed from the discussion of the rule is to allow many of the states to say they want to talk about the requirements which they either have or are thinking about which are in apparent conflict.

So let's ask if -- on the rule so far, from what we've talked about so far, do you either have requirements on the books or are working on them, such that you think they would be in apparent conflict with what we've discussed so far? Terry?

MR. FRAZEE: No.

MR. WHATLEY: No.

MR. KELLEY: No.

MS. ALDRICH: I don't think we'll have a conflict, but I think we're developing it differently, approaching diagnostic and therapy separately because they keep saying -- I think we feel this interim need to be a little more prescriptive with therapy than we are being with diagnostic. But that's the only thing. No conflict, just a different approach.

MR. TELFORD: Okay.

MR. WOOD: No.

MR. ZALOUDEK: Not at the present time.

MR. ANDERSON: No.

MR. ZALOUDEK: But we are working on some.

MR. TELFORD: Okay. Steven?

MR. COLLINS: You tell us.

MR. TELFORD: Oh, no. You're on the spot.

MR. COLLINS: We're still awaiting the NRC's official comments on something as of July.

MR. TELFORD: You know your proposed rule. We've spent the day talking about this one. In your judgment, do you have any apparent conflicts?

MR. COLLINS: I don't think we have any conflicts in the rule. I think we'll have an extremely hard time getting this one in place through our administrative procedures and requirements. But no conflicts currently.

MR. SHARP: No, with the proviso that if it is sufficient to compatibility.

MR. TELFORD: Okay.

MR. DUNDULIS: I think I would agree with -- I don't see any problem. However, the practical one may be if it's extended to medical accelerators and therapeutic x-ray machines, there may be some practical implementation problems by the states.

MR. TELFORD: Which would be the individual states' decision to do or not do.

MR. DUNDULIS: That's correct.

MR. TELFORD: And outside of our purview. Okay. It's about eight minutes of six. Larry?

MR. CAMPER: Two items, if I may. One is I think it would be worthwhile to at least float the idea of the JCAHO accreditation process as relates to diagnostic having now gone through the objectives, at least it's food for thought so that tomorrow morning can be productive on that issue.

MR. TELFORD: All right.

MR. CAMPER: The second point is purely an administrative item, but I do want it on the record. That is I would like for each of you to give some thought this evening to the possibility of another meeting which might occur in Washington on either the 12th or the 13th of

February, should it be necessary.

MR. TELFORD: Or both days, if you like, if it's necessary. So this is your advance warning.

MR. CAMPER: So perhaps tomorrow sometime we can get some idea of where you stand on that.

MR. TELFORD: Let's let the conference have a say in maybe the location.

MR. CAMPER: That's fine.

MR. TELFORD: As well as the dates. But we'd certainly like to offer the invitation at this time. We'd be happy to put the meeting on in Rockville on those dates. Mr. Bolling?

MR. BOLLING: I have a letter here from Ed Bailey in California who is a little upset. He'd like to have the meeting out there, if there is a second meeting. Any problems with that?

MR. TELFORD: That's why I said let's let the conference select the site, because I don't want to get in the middle of all this because these states are spread out. So I would prefer that the conference select the site just as they selected the site for this meeting. Steve?

MR. COLLINS: Are you referring to this group as the conference?

MR. TELFORD: No. Talking about the CRPCD.

MR. COLLINS: I'd like to poll this group to find

out what they think about us maybe starting at 8:00 in the morning instead of nine so we might get through a little earlier with this.

MR. TELFORD: Is 8:00 all right with everybody? All right, 8:00 it is.

MR. WHATLEY: I don't want to keep us here, but I want to just throw out one thing that concerns me and maybe think about it tonight and tomorrow you might want to discuss it or whatever. I think there's one error in quality assurance that we've overlooked perhaps that, in my opinion, from my experience working in facilities like this, that I think really contributes to misadministrations that you never hear about and so on, and that's supervised users.

A physician under the supervision of an authorized user in a hospital, no one has ever reviewed his training and experience, yet he's allowed to basically do anything he wants to in that hospital, the same as an authorized user does as far as prescribing doses and so on without the prior approval of an authorized user. I know it can be a long discussion. I don't intend to discuss it this afternoon, but I think that's something that needs to be looked at.

I know it's standard practice for training in hospitals. That's the way it's done. But if you really want to solve problems, that's one area of concern.

The second is what I've heard today is that the

primary cause of misadministrations and so on relates directly to technicians, problems with technicians. That's another group. There is nothing in this rule that I see that addresses their training and experience, their qualifications or whatever.

I think those two areas are a real concern. I just lay this out for future consideration.

MR. CAMPER: Let me add to that, if I may, Kirk. Those two areas, interestingly enough, are areas that we have a great deal of interest in and are concerned about, too. For example, the upcoming ACMUI meeting on the 14th and 15th of January, one of the topics that we're going to discuss is supervision.

There are really two categories of supervision. One is supervision as relates to physicians being preceptored, being supervised, and what constitutes adequate supervision. For that matter, should all authorized users be preceptored and, if so, what standards apply, and those types of things.

Similarly, in July of this year, we raised the question about training and experience, all players involved in the use of radioactive materials in the practice of medicine; i.e., technologists, physicists, dosimetrists, radiation oncology nurses, and on and on. At that time, we were told by the Advisory Committee to bring to them more

information to demonstrate that there was, indeed, a problem.

But a number of us have some concerns about what bearing training and experience has on misadministrations or, for that matter, other violations that occur, as well. So they are two issues we have a great deal of interest in. To the extent that the schedule will allow, any comments you might have will be helpful to us and to me in particular given that it is an issue in the upcoming ACMUI meeting.

So Kirk's concerns are our concerns, as well, and timely for that meeting in January.

MR. WHATLEY: Can I ask just one other question? There's a study out on human factors associated with problems in nuclear medicine. What's it called? Human factors study? What we're dealing with here in quality assurance is human factors. Do you anticipate that study -- what's the purpose of that study and do you anticipate the results of that study causing modifications in the patient QA rule?

It just sort of seems to me like you'd get the information first and then you'd take what you learned and apply it here.

MR. CAMPER: I think that the issue of -- there's no question we are currently looking at human factors issues and certain other quality assurance issues, as well, via

contracts. We don't feel, though, that information is necessary for this rulemaking. It is certainly conceivable, though, that as time marches on, results that would come out of those studies may have some impact on future changes in this quality assurance area or in the regulatory guide, for that matter.

MR. TELFORD: And those are details. You might find that particular operations are just not very efficacious in terms of human factors considerations. We could easily put those in the reg guide and say, in essence, do things the other way.

MR. WHATLEY: What are they looking for in that study? I mean, what's going to --

MR. CAMPER: Generally speaking what we're trying to do is look at what bearing human factors has to play in the misadministration phenomenon, quality assurance as it relates to the license, for example.

Primarily it's designed to see if we're devoting the attention to those areas that we should as a regulatory agency and to what extent we should modify regulatory guides and our regulations to consider whatever findings we can come up with. But those things are going to go on now for the next two or three years.

MR. TELFORD: Let me bring up the topic of our meeting with the JCAHO as sort of final information for you

today. Yesterday we met with JCAHO in Chicago. It was an all-day meeting. We went there with several purposes in mind. First of all, we had been told by our volunteers and others JCAHO has been doing something like this for several years. If you add on a little increment here, don't you realize, and somebody else adds on a little increment there, pretty soon we're over-burdened, why don't you try and work together.

We went to JCAHO and said let's talk about how what your organization, what its purpose is and how you do business and we'll talk about our organization and how we do business. Then we'll get down to details as a comparison for the relevant objectives in this rule, of which there are seven out of eight.

For each objective, we had looked up the JCAHO standard. So we listed the applicable standards. We went through this comparison, boom, boom, boom, boom, boom, right through our seven objectives that are applicable. We asked the question, this is on a regulation level. We asked the question do your standards have the same intent as what we want to do in this QA rule and do they have the same effect.

In other words, do we have equivalency on a regulation level. We found that we were very close, that with a few word changes here and there that we probably could achieve equivalency without a lot of difficulty on

their part, let's say.

We asked two other questions of how do we compare on what we call licensing and what they call accreditation. That's the second question. The third question is how do we compare on what we call inspections and what they call surveys. On the regulation level, we said we're close, we could achieve equivalency.

On the licensing level, they said we don't do that, we don't look at programs, we only look at programs when we get there during a survey. So we don't have equivalency there. On the inspection versus survey level, it appears that they spend less time in the nuclear medicine departments currently than our inspectors do. However, they indicated that they would be willing to consider a change in the amount of attention they devote to the nuclear medicine department.

So we examined the comparison at each of those three levels. We really asked the question how they would react to the NRC proposing that licensees be allowed to substitute JCAHO accreditation in lieu of submitting a plan to the NRC for nuclear medicine diagnostics. To our surprise, it was a pretty positive reaction.

Then we talked about the difficult questions of what do you do if you discover a bad actor. They again surprised us and told us that they would be willing to

submit reports to the NRC on those folks that they put on their six month probation or those that they would recommend for this program. It would probably work well for accreditation just for that department, because we would say to the licensee you have your choice; for nuclear medicine diagnostics, you can obtain and maintain JCAHO accreditation or you can submit your program to NRC.

Now, the licensees would still be subject to reporting requirements for what we'll discuss tomorrow as events and reportable events. But that's what we're talking to them about. They have some questions that they want to discuss internally and they will get back to us on the response of whether or not they really want to pursue this any further, but that's the basic idea.

Questions?

MR. WOOD: Was any mention made of compatibility between agreement states and the fact that a certain percentage of the U.S. is covered by agreement states in lieu of NRC?

MR. TELFORD: Well, what do you mean?

MR. WOOD: You said they were considering the possibility of diagnostics being covered in an either/or situation between them or NRC, but you didn't mention the agreement states in that scenario.

MR. TELFORD: Well, I think I'm including

agreement states.

MR. WOOD: All right.

MR. CAMPER: That's our assumption, because it would be an area of compatibility.

MR. FRAZEE: But on the other hand, some agreement states may not choose to buy that option.

MR. CAMPER: You mean the use of JCAHO?

MR. FRAZEE: Yes.

MR. CAMPER: That's certainly conceivable.

MR. TELFORD: Agreement states could do that. But I wanted to express to you, give you a little progress report on that now. After we finished the discussion with the JCAHO, there was a member of the public who happens to be President of AC&B, made the suggestion that if we allow that for nuclear medicine diagnostics, we should also allow it for nuclear medicine therapy, radiopharmaceutical therapy.

So that the nuclear medicine department, the guys that use the radiopharmaceuticals, are watched over by one organization. So you can't give me any reaction to that, but I'm just putting that on the table because that was also suggested.

MR. KULIKOWSKI: In the either/or situation, Licensee A chooses to go with the program submitted to NRC; Licensee B chooses the accreditation process. How do you

inspect against the QA rule? It looks like you might be given the potential for, I think, two different standards with two different licensees, or by accreditation you automatically assume compliance.

MR. TELFORD: By accreditation, the licensee for the nuclear medicine department would obtain accreditation, would be subject to JCAHO surveys, not our inspections.

MR. ANDERSON: Are we going to get an agreement with JCAHO?

MR. TELFORD: But it would be subject to our reporting requirements for what we're now calling misadministrations.

MR. CAMPER: JCAHO indicated yesterday a willingness to modify their standards and the accreditation process in this area to reach a comfort level with the NRC. But in those cases, Bob, to expand upon what Jon has said, our inspectors would not inspect against the QA program in those institutions that have opted for the JCAHO accreditation process as their vehicle for addressing this regulatory criteria.

In those cases, in those institutions where they have not, they have chosen to submit a program to us. Bear in mind, if you will, that, of course, private practice scenarios would be in that case. They would be inspected by NRC.

MR. KLINE: If you took that a step further in some of the problem areas, when you run into enforcement problem areas, how do you handle those if it's a JCAHO -- let's say alerting to the NRC that this licensee under JCAHO certification has a problem. The NRC then at that point would have to decide how to handle whether or not the enforcement criteria would specifically follow a special inspection at that point, review pursuant to what JCAHO feels are possible problem areas.

There's a lot of logistics and problems. We are trying to use an organization which has been voluntary, though whose standards are almost used as an enforcement tool in themselves.

MR. WOOD: JCAHO has always graded very heavily on physician intervention where we've kind of shied away obviously in this meeting. I'd be very reluctant to think they're in favor of turning inspections of nuclear medicine departments over to NRC when we have not agreed to look at physician intervention as strong as they are used to doing.

MR. TELFORD: I don't follow you.

MR. WOOD: The practice of medicine from a medical MD or authorized user's evaluation, they look more into criteria of how the authorized physician oversees that procedure and how his standards and evaluation of referring physician, things that we haven't touched on. The referring

physician's use -- I don't know how to word it.

MR. TELFORD: It seems like you're talking about things that they would do in addition to --

MR. WOOD: Yes.

MR. TELFORD: -- the objectives of the QA rule.

MR. WOOD: Yes, in addition to.

MR. COLLINS: Do you want to pose the question of those of us here again to go around the table and vote, who would be in favor of sharing this enforcement with anybody else, the JCAHO or anybody else?

MR. TELFORD: No, not really. I don't want to be accused of three months now, John, why didn't you tell me this. So I'm telling you this now.

MR. COLLINS: We're willing to provide you some input now.

MR. ANDERSON: I'm willing to tell you that I oppose it.

MR. COLLINS: I oppose it also.

MR. TELFORD: All right. We'll go around the table. Start here. Steve?

MR. COLLINS: No.

MR. TELFORD: Jon?

MR. SHARP: I'd be inclined to go along with it.

MR. KULIKOWSKI: No.

MR. DUNDULIS: Some of the JCAHO reviews are kind

of wimpy. I'd say no.

MR. CAMPER: Excuse me for a minute. I think what I'd like to do on this, if you don't mind, is I'd like for you to state the state as we go around.

MR. TELFORD: Okay. Let's start over.

MR. ANDERSON: Utah, no.

MR. COLLINS: Illinois, no.

MR. KULIKOWSKI: New York City, no.

MR. FRAZEE: I've got to clarify my vote. When we go out and inspect hospitals that are JCAHO accredited or not, my inspectors find out and they ask the questions. As far as our state is concerned, it probably doesn't make a big difference one way or the other. We're going to ask the questions anyway. We're going to find out about their program anyway. The proof is in the pudding. We're going to looking for, A, let's find out whether or not there are misadministrations and whether or not they're being reported, anyway.

So in a sense I can hear what you're saying, we don't trust them either, but it's probably a moot point because we're looking at the effects of the program. And whether JCAHO accredits a program and blesses it and comes in and does their survey and whatever or whether we occasionally look at, every five years, look at their QA program, that's not the bottom line.

The bottom line is how effectively is it working and that's what my inspection team is out there taking a look at. So I guess I'd say yes, I could live with that. So the answer is that.

MR. TELFORD: State, please?

MR. FRAZEE: Washington.

MR. WHATLEY: Alabama. I personally don't know enough about JCAHO to make a decision on the concept right now. I think we've got the same reservations as we always had about any third party inspections. We have the same reservations about this as we do about industrial radiographers right now, third party certifications and so on. So I'm not in a position to say yes or no.

MR. TELFORD: Okay. Rick?

MR. KELLEY: Arkansas. I kind of agree both with Kirk and Bill. When the JCAHO went out to the nuclear medicine facility and did an inspection, it was on the wimpy side. I won't give you the name or not, but basically that's what I've heard. But I'm going with his thought that I'm really not sure as to what that means right now at this point.

When we go out, we do our inspections and from we hear, they say you all are really coming out doing -- you spend like three or four hours, the guy from JCAHO will come in and spend maybe an hour or so and then he kind of looks

around and maybe doesn't ask the proper questions. That's what we're getting.

So I have to say I don't know enough at this time to make a -- if I had to make a yes or a no answer, I'd rather not.

MR. TELFORD: Yes. Well, I appreciate your impression of the JCAHO inspections, but what we really have in mind is we would want to achieve some level of equivalence that we believe that the JCAHO standards would do exactly the same thing that our objectives would do. Second, their survey, what they call a survey would be equivalent to our inspections. So before we would say, that's what we're looking for.

I'm not trying to influence what you're saying, but I'm just saying that from our point of view that's the way we would look at it.

MR. KELLEY: Well, I'd say if their survey or whatever they want to call it comes out to the quality or to the level of which we're doing now, in that case I would say yes. Other than that, I would say no.

MS. ALDRICH: I'd have to go back and talk to other people in the state. New York, in the health department, we have two agencies. We have the Office of Public Health and we have the Office of Health Systems Management. Health Systems Management does surveys at

hospitals that are equivalent to the JCAHO.

Health Systems tried to do what you're suggesting now in the past or at least as sort of a joint effort to do their inspections with the Joint Commission. They found that it didn't work. Their problems were the frequency issue, as you've already pointed out, the frequency of inspection. Also, the depth of inspection.

But it could be in New York State that the Office of Public Health, for example, or the Office of Health Systems Management might fulfill the same function as the Joint Commission. I'll have to talk to them.

In some of the comments that we've gotten on some of our QA drafts, the Health Systems Management has made comments sort of to the effect that we don't need to ask this because they are. One of the things that we haven't really resolved with them is exactly what aspects they are looking at, perhaps we should be deferring some of that to them.

So I have to find out two things. One, what is their relationship right now vis-a-vis Joint Commission, and what our division of labor might be. But I wouldn't say no upfront.

MR. TELFORD: You wouldn't say no, but it requires --

MS. ALDRICH: I wouldn't say no upfront. I'd say

that it's a complicated situation. I'd have to find out.

MR. TELFORD: Okay.

MR. WOOD: Texas has already responded, so I will pass. May I make one quick clarification? When we make reference to inspections, we're talking about trading off reviewing, are we talking just the QA portion of the nuclear medicine department or are we including their inspection to encompass what our inspection covers for nuclear medicine? Is it just QA?

MR. CAMPER: Just QA.

MR. WOOD: Just QA. Okay.

MR. ZALOUDEK: As a general recent experience, I don't have enough experience to give an answer. From past experience, as far as Joint Commission or JCAHO, I'd be inclined to think we wouldn't be able to work it out. Louisiana.

MR. CAMPER: Let me explain something. The reason we're asking for state is not that we're looking for a binding commitment from you obviously, but it was because I know that there's an element of the physician community that believes that this JCAHO accreditation process is the way to go. We recognize, on one hand, it's going to require a great deal of discussion and interaction and coming to some conclusions between our agency and the JCAHO organization if it is to be at all.

On the other hand, even if one recognized that we might come to such an understanding, we look at the fact that there are 49 agreement states out there and some of which may have some problems with using the JCAHO accreditation process and some of which may have a large number of licensees. It is important I think to be able to say to those in the medical community that strongly advocate this process that, look, recognize that this may be the way to go for NRC licensees, but should you may have a lot of trouble with a lot an awful lot of institutions out there that are in agreement states.

So that's the reason we're seeking that point, just purely as a sampling. That's my reason for that.

MR. ANDERSON: I suspect that in almost all the states the JCAHO inspections are conducted the same way and that's with public health nurses out of the Department of Health. We've had direct experience with these people. I think it's incredible that we sit here and require that we have this much training of our inspectors and then we're willing to dole out this portion of that to a nurse who doesn't know what a rad -- she couldn't tell you a rad from an napkin.

MR. CAMPER: Two points I would make. One is this is only about the quality assurance for diagnostic nuclear medicine uses, not the overall radiation safety program, not

all the things that we go to inspect and that you to go inspect. Secondly, the use of public health nurses, the scenario is contrary to what we heard yesterday from the JCAHO representatives as to what constitutes their inspection team or their accreditation team.

MR. ANDERSON: I'll guarantee in the state of Utah they have no health physics people available even.

MR. KLINE: As a matter of fact, JCAHO insinuated that at the physician level, after possible training or after review, of how the NRC inspection would inspect QA program and after the agreement on the amount of time necessary to do a comprehensive review of that program, as we would expect, that they would be individuals, not the nurse, not the administrator that also goes with that team, and also not any other ancillary type person, allied health person.

MR. ANDERSON: I understand that most physicians think that the MD degree qualifies them from anything from nuclear physics on through -- most of them know the difference between a rad and a napkin.

[Laughter.]

MR. KULIKOWSKI: I have a question. I have to agree with Larry. Just a rhetorical question. Given the emphasis that the Commission has placed on misadministrations and the QA rule, how well do you think

they would buy this?

MR. CAMPER: I would not even purport to speak for the Commission on this issue. This is an area that we are exploring. It has been raised by certain elements of the physician community and at this point we're just trying to see if it's feasible, can it be done, is there a possibility. But how the Commission would take it, I really can't say. It would be pure conjecture.

MR. KULIKOWSKI: I think that plays some importance on this rule given these other timeframes. It's just a possible savings.

MS. ALDRICH: One point that may be of interest or may not is I don't know if this has happened in other states, that the Joint Commission has in the past in New York at least when they have inspected hospitals asked for examples for the most recent inspection report on their x-ray program for the hospital and taken that to be something in support of their own inspection.

I have never heard of them doing it with the materials program, only with the x-ray program.

MR. CAMPER: The only thing I can say about that, Rita, is that I think most of us who have been around in this area for a while are familiar with what the JCAHO has historically looked at when they come in to do accreditation review as relates to nuclear medicine. On the other hand, I

think that most of us came away yesterday with the feeling that JCAHO, at least the group we talked to yesterday, and recognizing they have to go back and talk to their management and what have you, was prepared to modify their inspection process and to modify their standards to accommodate NRC's concerns for this area.

Again, this is only on the quality assurance program. Now, clearly if we end up pursuing this, there would have to be additional discussion, a meeting with JCAHO to nail down the specifics. To that end, we have suggested, at least at this point, a tentative meeting in February for the next round of discussion. But, again, how this will ultimately play out or will it fly, I have no idea.

MS. SALUS: Did you go the other way and ask the JCAHO if they would recognize NRC licensure as evidence of sufficient QA or accreditation --

MR. CAMPER: No. We did not.

MS. SALUS: That might be a valuable question. There's certainly something to be said for minimizing redundancy, except when you're trying to identify patients, but at the same token I'm not sure you're going to have the mandatory regulator --

MR. CAMPER: My initial reaction to that, Betsy, would be that it would not be appropriate to even ask that question because our QA program, by no stretch of the

imagination, is designed to accredit any medical institution. Furthermore, the scope of this QA program is very limiting. Again, it deals with the misadministrations. So the question doesn't seem to fit.

MR. ANDERSON: My only concern is what in the world do they think they're going to get out of this. They're not doing this just because. They're not nice guys. They expect to get something out of it. I suggest to you that there's enough concern in the medical community about Part 35 that they were going to try to get around it one way or the other, and maybe this is the other.

MR. CAMPER: I'm not prepared to discuss their motive.

MS. ALDRICH: I would have to say, though, that, in all honesty, what I've seen from the Joint Commission on their QA requirements -- I'm more familiar with their requirements in therapy -- is a fine set of requirements and could easily serve as -- would certainly be acceptable to me as a QA program for the facility.

So I don't have any problem with the formats and the programs that they come up with. I guess the thing that we're probably a little uncertain about is the follow-through.

MR. CAMPER: Well, we appreciate your input on it. It clearly is a difficult question. We are only exploring

the possibility.

MR. TELFORD: Let's adjourn the meeting until tomorrow at 8:00.

[Whereupon, the workshop was recessed, to reconvene the following day, December 19, 1990, at 8:00 a.m.]

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: Meeting with Agreement States on Proposed QA Rule and Reporting Requirements

DOCKET NUMBER:

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were held as herein appears, and that this is the original transcript thereof for the file of the United States Nuclear Regulatory Commission taken by me and thereafter reduced to typewriting by me or under the direction of the court reporting company, and that the transcript is a true and accurate record of the foregoing proceedings.

Betty Hogan

Official Reporter
Ann Riley & Associates, Ltd.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

January 16,1990

MEDICAL USE DISTRIBUTION LIST

The NRC has proposed amendments to 10 CFR Part 35, "Medical Use of Byproduct Material," that would require medical use licensees to establish and implement a basic quality assurance program and that would modify the reporting and recordkeeping requirements. The NRC staff is developing Draft Regulatory Guide DG-8001, "Basic Quality Assurance Program for Medical Use," for guidance on the proposed Section 35.35.

Both the proposed amendments to Part 35 and Draft Regulatory Guide DG-8001 are enclosed here for your convenience.

Bill M. Morris, Director
Division of Regulatory Applications
Office of Nuclear Regulatory Research

Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

RIN 3150-AC65

Basic Quality Assurance Program, Records and Reports of Misadministrations or Events Relating to the Medical Use of Byproduct Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The NRC is proposing amendments to 10 CFR part 35 that would require medical use licensees to establish and implement a basic quality assurance (QA) program. The objective of the basic QA program is to provide high confidence that errors in the medical use of byproduct material will be prevented. The proposed amendments would enhance patient safety while allowing the flexibility necessary for proper medical care. The NRC is also proposing certain modifications to the definition of "misadministration" and to the related reporting and recordkeeping requirements.

DATE: Comments must be received by April 12, 1990. Comments received after this date will be considered if it is practicable to do so, but assurance of consideration cannot be given except for the comments received by this date.

ADDRESSES: Submit written comments and suggestions to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch.

Copies of the draft regulatory analysis and the comments received on this proposed rule may be examined at the Commission's Public Document Room at 2120 L Street NW., Lower Level, Washington, DC. Single copies of the draft regulatory analysis are available from Dr. Anthony N. Tse, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

FOR FURTHER INFORMATION CONTACT: Dr. Tse, see ADDRESSES heading, telephone: (301) 492-3797.

SUPPLEMENTARY INFORMATION:

I. Byproduct Material in Medicine

Medical Use[1]

Radioactive materials are used in drugs in the field of nuclear medicine. Drugs labeled with radioisotopes are known as radiopharmaceuticals. In diagnostic nuclear medicine, patients receive these materials by injection, inhalation, or oral administration. Physicians use radiation detection equipment to visualize the distribution of a radioactive drug within the patient. Using this technology, it is possible to locate tumors, assess organ function, or monitor the effectiveness of a treatment. An estimated 7 million diagnostic nuclear medicine procedures are performed in this country annually. In therapeutic nuclear medicine, larger quantities of radiopharmaceuticals are administered to treat various medical conditions (e.g., hyperactive thyroids). An estimated 30,000 therapeutic procedures are performed each year.

Sealed sources that produce high radiation fields are used in radiation therapy primarily to treat cancer. A radioactive source in a teletherapy machine can be adjusted to direct a radiation beam to the part of the patient's body in need of treatment. An estimated 100,000 patients receive cobalt-60 teletherapy treatments each year. Smaller sealed sources with less radioactivity are designed to be implanted directly into a tumor area or applied on the surface of an area to be treated. This procedure is known as brachytherapy. About 50,000 brachytherapy treatments are performed each year.

Sealed sources can also be used in machines that are used for diagnostic purposes. The source provides a beam of radiation that is projected through the patient. A device on the other side of the patient detects the amount or spatial distribution of radiation that goes through the patient. This can provide information about tissues within the patient. This is a relatively new development in the field of medicine and the NRC has no estimate of the number of these diagnostic procedures performed annually.

State and Federal Regulation

Medical use is regulated through State or Federal regulations. Twenty-nine States, known as Agreement States, have been delegated the authority by agreement with the NRC to regulate the use of byproduct material, including medical use (this type of agreement is authorized by Section 274 of the Atomic Energy Act). These States issue licenses for medical use and currently regulate about 5,000 licensees.

The NRC regulates medical use in twenty-one States, the District of Columbia, the Commonwealth of Puerto Rico, and various territories of the United States and has licensed 2,200 medical institutions and 300 physicians in private practice.

II. NRC's Regulatory Program

NRC's Policy Regarding Medical Use

In a policy statement published February 9, 1979 (44 FR 8242), the NRC stated:

1. The NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public.

2. The NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate.

3. The NRC will minimize intrusion into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine.

The NRC has the authority to regulate medical use to protect the health and safety of patients, but also recognizes that physicians have the primary responsibility for the protection of their patients. NRC regulations are predicated on the assumption that properly trained and adequately informed physicians will make decisions in the best interest of their patients.

[1] "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." Wherever this term is used in this rulemaking, this definition applies.

*The pen and ink changes correct typographical errors that occurred in printing.

NRC's Responsibilities in Medical Use

The NRC draws a line between the unavoidable risks attendant to purposefully prescribed and properly performed clinical procedures and the unacceptable risks of improper or careless medical use. The NRC is obliged, as part of its public health and safety charge, to establish and enforce regulations that protect the public from the latter.

Reports of Therapy Misadministrations and Diagnostic Misadministrations That Resulted in Doses in the Therapy Range

The NRC has reviewed 65 therapy misadministration reports over the period November 1980 through December 1988. The following analysis of these events provides the basis for determining that a potential benefit can result from this rulemaking. The specific causes of these therapy misadministrations, listed in Table 1, are related to the specific treatment modality. Nonetheless, there are three common problems related to all of these misadministrations: inadequate training, inattention to detail, and lack of redundancy.

Table 1—Therapy Misadministrations Reported to NRC from November 1980 Through December 1988

A. Teletherapy

Prescription

- Total daily dose was delivered from each port. (2 events)
- Oral and written prescriptions were different. (1 event)
- Boost dose of 500 rad/3 day was interpreted as 500 rad per day on each of 3 days, rather than 166 rad per day. (1 event)
- Proper body side was not clearly indicated. (1 event)

Treatment Planning

- Tumor depth was incorrectly measured. (1 event)
- Tumor depth was incorrectly recorded. (1 event)
- Dosimetrist used wrong computer program. (1 event)
- Dosimetry tables for wrong unit were used. (2 events)
- Error was made in dose calculations. (11 events)
- Incorrect formula used in computer program—21 patients affected. (1 event)

Records

- Arithmetic mistakes were made. (1 event)
- Poor handwriting of numerals caused misunderstanding. (1 event)
- Dose calculation result was transcribed incorrectly. (2 events)
- Error was made in a patient's chart and the chart was not checked. (1 event)

Physical measurements

- Wedge factors were measured incorrectly—53 patients affected. (1 event)

Application

- Field blocks were prescribed but not used. (1 event)
- Incorrect area was treated. (2 events)
- Patient was improperly identified. (1 event)
- Rotation switch on the machine was set incorrectly. (1 event)
- Co-60 machine was used instead of a linear accelerator. (1 event)
- Treatment time was misread. (1 event)
- Patient set up was not in accordance with the treatment plan. (1 event)

B. Brachytherapy

Treatment Planning

- Dose rate was much higher than first estimated. (1 event)
- Error was made in dose calculation. (3 events)

Application

- Sources with wrong activities were loaded in applicator. (6 events)
- Source fell out of applicator. (2 events)
- Source was improperly seated in applicator. (2 events)
- Incorrect areas were treated. (1 event)
- Incorrect number of sources were loaded. (1 event)
- Leaking sources were discovered. (2 events)

C. Radiopharmaceutical Therapy

- Wrong radiopharmaceutical was administered. (3 events)
- Dosage was not assayed. (4 events)
- Patient was improperly identified. (1 event)
- Range switch for dose calibrator was set incorrectly. (1 event)
- The dosage of the radiopharmaceutical sent by the supplier was higher than the dosage ordered. (1 event)
- The dosage was improperly calculated. (1 event)

From November 1980 through December 1988, the NRC received 20 reports on diagnostic misadministrations involving I–131 that led to doses in the therapy range. In these misadministrations, patients were mistakenly administered 1 to 20 millicuries of iodine-131 with a resulting thyroid dose of about 1,000 to 20,000 rads. Many of the misadministrations demonstrated that the authorized user failed to review the medical history of the referred patient to determine the suitability of a particular clinical procedure. In many misadministrations, the referring physician, who is not a nuclear medicine expert, and the nuclear medicine technologist, who is not a medical expert, determine which radiopharmaceutical should be administered. Furthermore, in some misadministrations, technologists unfamiliar with the clinical procedure prescribed by the authorized user mistakenly administered a dosage that was not intended. It is apparent, therefore, that wherever radiopharmaceuticals capable of producing therapy doses are used, clear nomenclature, independent verification, and adequate training are essential.

Improved training of medical personnel who handle and administer byproduct material can reduce the potential for error. Training should clearly impress on each individual involved in medical use that clear communication of the prescribed medical use and the implementation of systematic checks to detect and prevent errors early in the process are essential for the delivery of quality care. All information integral to the diagnostic or therapeutic medical use, whether specific to the patient or to the clinic, should be carefully reviewed for clarity, applicability, and correctness. Each individual involved in the process should be instructed to ask for clarification if there are any unclear or nonroutine procedures or instructions.

Inattention to detail is often a significant factor in misadministrations. The NRC recognizes that this problem is not limited to medical use. Computerized radiation therapy treatment planning may reduce the number of mistakes in sealed source treatments, and "record and verify" systems that check teletherapy unit orientations and settings may reduce the number of mistakes in teletherapy administration. But even these systems must ultimately rely on quantities that are initially measured, recorded, and entered by workers.

Lack of redundancy means that there is no independent mechanism for detecting errors. Independent verification requires examination by a second individual of each datum entry, whether a physical measurement or a number copied from a table of values, as well as a check of arithmetic operations for correctness. Redundancy requires that two separate systems produce the same result. For purposes of planning radiation therapy, the best method for the early detection of mistakes may be a simple independent check. Independent verification may also need to be incorporated into procedures for measuring values of radiation parameters, treatment planning, and administering radiation to patients. In radiation therapy, for example, an independent auditor can detect mistakes in both process design and process application as well as recommend where a change in the process might reduce the chance of a future error.

These observations have led the NRC to some general conclusions regarding quality assurance. All medical use should be planned with the realization that individuals may make mistakes. Some simple aids may include using

tables and graphs that are clearly titled and easy to read, and using a written prescription. NRC inspections have revealed that about ten percent of teletherapy unit calibrations and periodic spot checks are incomplete. Checklists could be used to assure completeness.

Independent verification could be made an integral part of the design of the treatment process to detect errors. Some examples are: all entries and calculations in a treatment plan could be checked by an individual who did not develop the treatment plan; each patient's chart could be reviewed weekly to check for accumulated dose and implementation of prescription changes; and the teletherapy unit output could be checked periodically. Furthermore, the complete teletherapy process, including physical measurements, could be examined in detail occasionally by an expert in order to identify systematic mistakes and make system improvements.

A QA program that requires a physical measurement of the dose or amount of radioactivity actually administered to the individual patient would provide assurance that the administered dose is the same as the prescribed dose. Such measurements are currently required (10 CFR 35.53) for radiopharmaceutical therapy using photon emitting radionuclides, and occasionally are done for some teletherapy cases, but because of expense or the unavailability of equipment, these measurements are not commonplace in sealed source therapy.

Voluntary Initiatives

The NRC is aware of voluntary initiatives to improve quality assurance. A notable example is the "Patterns of Care" study managed by the American College of Radiology. In addition to comparing prescriptions and survival rates for certain diseases at various therapy facilities across the nation, methods of calculating and measuring applied dose rates are examined for accuracy. Such an examination can detect whatever procedural flaws may be present as well as determine the precision and accuracy of day-to-day service. Furthermore, the American College of Radiology is currently developing a comprehensive Quality Assurance Program for voluntary use in radiation oncology.

The NRC encourages initiatives by the industry to develop consensus standards and will consider endorsement of them in its regulatory guidance at an appropriate time. However, because of the lack of enforceability, voluntary programs alone are not considered to be an adequate vehicle to ensure that the NRC objective of reducing unnecessary exposure from byproduct material will be met. Consequently, the NRC is considering this rulemaking.

Earlier NRC Efforts

This is not the first time the NRC has examined the matter of QA in medical use. In 1979 the NRC issued some QA requirements for teletherapy (see 44 FR 1722, published January 8, 1979). This rulemaking was precipitated by errors committed by a teletherapy licensee which ultimately affected a very large number of patients. The output of a teletherapy unit was incorrectly calculated and the licensee made no physical measurements to determine whether the calculation was correct. These errors resulted in cobalt-60 teletherapy being incorrectly administered to 400 patients. The 1979 rule addressed the circumstances surrounding that event but did not critically examine the entire radiation therapy process.

III. Proposed Rule on Basic QA Published in 1987

On October 2, 1987, the NRC published a proposed rule (52 FR 36942) that would require its medical use licensees to implement some specific basic QA practices to reduce the number of misadministrations involving the use of byproduct material in radiation therapy and the use of radioactive iodine in diagnostic procedures. This proposed rulemaking was based on an analysis of misadministrations reported to the NRC by its medical use licensees concerning errors in administering byproduct material. The result of the analysis indicated that most of the events originated in mistakes made by individuals. Public comments received on the proposed rule indicated that, although these proposed QA practices might reduce the number of such errors, the imposition of the prescriptive directions given in the 1987 proposed rule might interfere with the practice of medicine because the proposed rule did not afford sufficient flexibility for clinical practice.

In a public meeting held on January 26, 1988, members of the Advisory Committee on the Medical Uses of Isotopes (ACMUI), an advisory body established for advising the NRC staff, also suggested that the 1987 proposed rule did not provide sufficient flexibility for clinical practice.

On April 7, 1988, members of the medical community, including several members of the ACMUI, briefed the Commission on their concerns regarding the 1987 proposed rule. They stated that a performance-based rule should be promulgated, rather than a prescriptive rule. They also suggested that a pilot program would be useful for determining whether the proposed QA steps would interfere with clinical practice. Furthermore, they stated that, under the existing NRC regulation, the definition of the term "misadministration" is unclear and that the related reporting requirements are confusing.

Subsequently, the NRC decided to develop a performance-based rule and a regulatory guide and, as a part of the same rulemaking, to review the term "misadministration" its scope and related reporting requirements. In addition, the NRC also decided to conduct a pilot program to determine the impact and efficiency of the proposed basic QA program and procedures developed by licensees based on the draft regulatory guide.

On November 7, 1988, the NRC held a public meeting of the QA Subcommittee of the ACMUI to assist in the development of a proposed performance-based rule, regulatory guide, and pilot program. On January 30 and 31, 1989, the NRC staff held a public workshop to discuss drafts of a revised basic QA rule and a regulatory guide. Medical use licensees' personnel representing different disciplines (e.g., physicians, physicists, and technologists) were invited to participate in a round table discussion with the NRC staff. On March 3, 1989 the NRC staff also met with the American College of Radiology (ACR) to discuss the NRC's draft regulatory guide and the ACR's draft QA program. The ACR's draft QA program is a comprehensive model QA program that is designed to be readily adopted, in whole or in part, by ACR members.

The NRC staff has used the information provided in these meetings in developing the performance-based QA requirements and new reporting and recordkeeping requirements. These actions are combined in a single proposed rule that is being published for public comment. A draft regulatory guide containing general guidance for licensees to develop a QA program that would be acceptable to the NRC staff for meeting the performance-based QA rule is also being published for public comment.

The proposed amendment for a basic QA program is designed to complement other QA requirements contained throughout 10 CFR part 35. 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."

IV. Discussion of Proposed Regulatory Text

Section 35.2 Definitions

The NRC is proposing to clarify the term "misadministration" and to add the following terms: "basic quality assurance," "clinical procedures manual," "diagnostic event," "diagnostic referral," "prescribed dosage," "prescribed dose," "prescription," and "therapy event."

The NRC is proposing to modify the definition of "misadministration" in the regulations by defining "misadministration" as those occurrences specified in proposed §§ 35.33(b) or 35.34(b). The Commission believes that a misadministration is indicative of inadequate quality assurance on the part of the licensee, and as such, additional regulatory attention, including special inspections, additional analysis and evaluation, or other NRC action, may be appropriate. All of the diagnostic or therapy occurrences currently defined as misadministrations are retained in the proposed amendment except a separate reporting threshold has been established for brachytherapy. Misadministrations will be specified under separate sections relating to either diagnostic or therapy medical use. In addition, an error in teletherapy fractional dose and medical use involving the wrong target organ or site will specifically be listed as misadministrations.

The proposed amendment also adds the terms "diagnostic event" and "therapy event" to include the events specified in proposed §§ 35.33(a) or 35.34(a) for which a record or report is required. These events essentially involve, for example, deviations from the procedures in the licensee's basic QA program. The proposed amendment thus distinguishes between misadministrations, which involve certain errors in the administration of byproduct material (or the radiation therefrom), and other events that essentially involve deviations from procedures in the administration of the byproduct material.

The other six terms, "basic quality assurance," "clinical procedures manual," "diagnostic referral," "prescribed dosage," "prescribed dose," and "prescription," are proposed to clarify the regulatory requirements.

The Commission would especially appreciate public comment on the proper use of the term "misadministration." Should the term misadministration be reserved for the most serious events that would include overexposures resulting in death, serious injury, or occurrences resulting in receipt of substantially more than the prescribed dose (i.e., perhaps double the prescribed dose for a therapy procedure, or a dose in the therapy range for a diagnostic procedure)? How should "events" be distinguished from "misadministrations"? Should the division of occurrences into "events" or "misadministrations" be done differently from those proposed in §§ 35.33 and 35.34?

Section 35.33 Records and Reports of Diagnostic Events or Misadministrations

The NRC is proposing to replace the existing 10 CFR 35.33, "Records and reports of misadministrations," with two sections: one for diagnostic events or misadministrations and the other for therapy events or misadministrations (§§ 35.33 and 35.34, respectively). Thus, depending on whether a diagnostic or therapy medical use is involved, licensees would be able to refer to one section of the regulations in order to determine whether an error in medical use constitutes a misadministration, a diagnostic event, or a therapy event, and to determine the related recordkeeping and reporting requirements. In the existing regulations, it is necessary to refer to one section (10 CFR 35.2) to determine what constitutes a misadministration and to another section (10 CFR 35.33) for the applicable recordkeeping and reporting requirements.

Paragraphs 35.33(a) and (b) set forth the types of diagnostic events or misadministrations, respectively, for which a record and, under certain circumstances, a report would be required, pursuant to §§ 35.33(c) and (d). The types of diagnostic misadministrations in proposed § 35.33(b) are essentially the same as the diagnostic misadministrations currently specified in the definition of "misadministration" in existing 10 CFR 35.2. In proposed § 35.33(a) three diagnostic events would be added. The first additional event, set forth in § 35.33(a)(1), is designed to identify any diagnostic medical use not authorized in the license. The other two additional events are designed to identify medical use without a prescription or a diagnostic referral [8] (in § 35.33(a)(2)) or without properly recording the radiation dose or radio-pharmaceutical dosage administered (in § 35.33(a)(3)). The NRC believes that prior to diagnostic administrations not involving I-125 or I-131, there must be a prescription or a diagnostic referral except under emergent situations; prior to diagnostic administration involving I-125 or I-131, there must always be a prescription. The prescription or the diagnostic referral is needed to communicate the instructions from the prescribing physicians to the individual administering the dose or dosage. Also, after the administration, a record must be made to indicate the administered dose or dosage. If these records are not properly completed, § 35.33(c) requires that the Radiation Safety Officer promptly investigate the cause so that actions can be taken to correct the deficiency in the QA program.

Paragraphs 35.33(c) through (e) specify the actions that a licensee would be required to take after the discovery of a diagnostic event or misadministration. Paragraph 35.33(c) requires an investigation by the Radiation Safety Officer. Paragraph 35.33(d) specifies the circumstances under which reporting of diagnostic events or misadministrations would be necessary. Paragraph 35.33(e) specifies the recordkeeping requirements. Although the requirements in these paragraphs are essentially the same as the requirements in the existing 10 CFR 35.33(c) and (d), there are certain changes, as discussed below. Paragraph 35.33(f) remains unchanged.

In proposed § 35.33(d), a requirement is added for the licensee to notify the patient if the diagnostic event or misadministration has the potential to cause serious harm to the patient. This change is being made to make proposed § 35.33(d) consistent with the patient notification provisions in the current regulations in 10 CFR 35.33(a) and proposed § 35.34(d). The NRC believes that if a diagnostic event or misadministration is serious enough to lead to a dose in the therapy range, then notice to the patient is also warranted, unless circumstances make notifying the patient inappropriate. Another change in § 35.33(d) is that provisions have been added describing the information that should be set forth in the written report, comparable to existing 10 CFR 35.33(b) and proposed § 35.34(e). A minor change is that the reference to NRC-Form 473 in existing 10 CFR 35.33(c) has been deleted from proposed § 35.33(d) since that form will probably be either superseded or updated to be consistent with the other modifications in the rule.

[8] The terms "prescription" and "diagnostic referral" are defined in the proposed § 35.2.

In proposed § 35.33(e), provisions have been added requiring that the licensee retain, in an auditable form, records of prescriptions, diagnostic referrals, and diagnostic clinical procedures for three years. These records may be part of medical records currently kept by the medical use licensees. These records are necessary to facilitate the inspection process.

Section 35.34 Records, Reports, and Notifications of Therapy Events or Misadministrations

The NRC is proposing to add § 35.34 that specifies reporting and recordkeeping requirements for therapy events or misadministration. Paragraph 35.34(a) lists five proposed therapy events for which records and a report to the licensee management would be required, and under certain circumstances, a telephone notification and a written report to the NRC would also be required. Paragraph 35.34(b) lists therapy misadministrations for which notification of licensee management and a telephone noufication and written report to the NRC would always be required. The therapy misadministrations listed in § 35.34(b) include the types of therapy misadministrations currently specified under the definition of "misadministration" in existing 10 CFR 35.2, as well as misadministrations related to teletherapy fractional doses and to brachytherapy.

Three therapy events (§§ 35.34(a)(1), (a)(2), and (a)(4)) are similar to those previously discussed under proposed § 35.33 but apply to therapeutic, rather than diagnostic, medical use. Paragraph 35.34(a)(1) provides that a therapy event includes a therapeutic medical use in which there was not both a prescription and a prior review of the patient's case by an authorized user or a physician under the supervision of an authorized user. Because a large radiation dose is involved in therapy cases, the NRC believes that both a prescription and a prior review of each patient's case are necessary before the byproduct material is administered.

An additional therapy event (§ 35.34(a)(3)) is related to teletherapy fractional doses and is intended to alert the Radiation Safety Officer and the licensee management of minor deviations from procedures in the basic QA program so that actions can be taken to correct deficiencies in the QA program.

The first two therapy misadministrations (§§ 35.34(b)(1) and (b)(2)) are the same types of misadministrations specified in existing 10 CFR 35.2. The following therapy misadministrations (§§ 35.34(b)(3) and (b)(5)) are intended to clarify existing 10 CFR 35.2. Paragraph (6), which states that the definition of a "misadministration" includes "a therapy radiation dose from a sealed source such that errors in the source calibration, time of exposure, and treatment geometry result in a calculated total treatment dose differing from the final prescribed total treatment dose by more than 10 percent." This definition implies that the total treatment dose applies to a combined dose from teletherapy treatment and brachytherapy treatment if both modalities were administered to the same patient. In the proposed amendment, teletherapy events and brachytherapy events are specified separately, and criteria for fractional doses for teletherapy treatment fractions are provided.

Furthermore, on its face, the language in the existing definition addresses only errors in total treatment dose and does not explicitly address errors in fractional doses that may have occurred during any one of many teletherapy treatment fractions. This definition causes confusion about whether certain events should be reported (e.g., if there is a significant error in a fractional dose but the administered total dose is still within 10 percent of the prescribed total dose).

The proposed modifications relating to a teletherapy event (§ 35.34(a)(3)) and a teletherapy misadministration (§ 35.34(b)(3)) are designed to identify any one of the following types of overdose or underdose therapy events: for any treatment fraction, the administered fractional dose differs from the prescribed fractional dose by more than 20 percent of the prescribed fractional dose (§ 35.34(a)(3)) but less than the percentage of fractional dose set forth in § 35.34(b)(3)(ii); the total administered dose differs from the total prescribed dose by more than 10 percent of the prescribed total dose (§ 35.34(b)(3)(i)); for any treatment fraction, the administered fractional dose is greater than twice or less than one-half the prescribed fractional dose (§ 35.34(b)(3)(ii)); or for the fractions administered to date, the sum of the administered fractional doses differs from the sum of the prescribed fractional doses by more than 10 percent of the prescribed total dose, i.e., the prescribed dose for all fractions, not just for the fractions administered to date (§ 35.34(b)(3)(iii)).

It must be emphasized here that the purpose of §§ 35.34(a)(3) and (b)(3) is to identify therapy events in which the administered dose is significantly different from the prescribed dose as a result of errors made in the source calibration, the time of exposure, treatment geometry, or other errors. Neither the current requirement nor the proposed requirement are intended to preclude a prescribing physician from properly changing the prescription if, based on medical judgment, such changes would benefit the patient. For the purpose of the reporting requirement, such a change will make the most recent prescription the prescription of record that supersedes the original prescription. For example, a prescribing physician might prescribe a certain fractional dose for the first few treatment fractions and later, depending on the reaction of the patient, might make a new prescription for a different dose for the remaining fractions. However, assume that a physician prescribes a fractional dose of 200 rads, and the licensee discovers after the fifth fractional dose is given that, due to an error, the administered fractional dose was 250 rads for each of the five fractions. Because the error in dose exceeded 20 percent of the prescribed fractional dose, regardless of whether a new prescription is written by the authorized user for subsequent fractions, the Radiation Safety Officer would be required to investigate the cause of the error, make a record for NRC review, retain the record as directed in § 35.34(f), and notify licensee management to take corrective action.

The following examples illustrate the kind of therapy events that fall within the scope of §§ 35.34(b)(3), (b)(3)(ii), and (b)(3)(iii). The prescribed total dose for a patient is 5,000 rads to be given in 25 daily fractions of 200 rads per fraction. If, as a result of an error, the patient is given less than 160 rads or more than 240 rads (but less than the percentage of fractional dose set forth in § 35.34(b)(3)(ii)) for any one fraction, such an event would constitute a therapy event under proposed § 35.34(a)(3). Under proposed § 35.34(c), the Radiation Safety Officer would be required to investigate the event and to report such an event to licensee management, but not to the NRC, the referring physician, or the patient because subsequent fractional doses could be adjusted to compensate for the error.

Under § 35.34(b)(3)(ii), using the same example given above, if the administered dose for any fraction is more than 400 rads (greater than twice the prescribed fractional dose) or less than 100 rads (less than one half of the prescribed fractional dose), the licensee would be required to report to NRC and

others as required under proposed § 35.34(d).

Paragraph 35.34(b)(3)(iii) addresses a therapy misadministration involving cumulative errors in fractional doses for several treatment fractions. Using the same example given above, if 16 fractions have already been administered, and the administered dose for each fraction is found upon recheck to have been 240 rads instead of the prescribed fractional dose of 200 rads, the sum of the prescribed fractional doses is 3,200 rads and the sum of the administered fractional doses is 3,840 rads. The difference is 640 rads, which exceeds 500 rads (10 percent of the total prescribed dose). The event would constitute a therapy misadministration under § 35.34(b)(3)(iii) and would be reported to NRC, the referring physician, and the patient (after conferring with the referring physician). Continuing the same example, if for 6 fractions the individual administered doses varied about 200 rads, i.e., 210, 190, 205, 195, 215, and 185, the sum of the administered fractional doses would be 1,200 rads, which would equal the sum of the prescribed fractional doses. This would not be a therapy misadministration under § 35.34(b)(3)(iii). In fact, any combination of such small variations is not reportable if the criteria of §§ 35.34(a)(3) and (b)(3) are not exceeded.

With respect to brachytherapy, if a sealed source is leaking or lost during the patient's treatment, questions have arisen whether this constitutes a "misadministration" under existing 10 CFR 35.2. To clarify the reporting requirement, § 35.34(b)(4) is being proposed to make it explicit that the definition of a therapy misadministration includes all cases in which a source is leaking during treatment, regardless of the cause, or in which a source is lost during treatment, or mistakenly is not removed from the patient upon completion of the treatment. Of course, for purposes of this regulation, sealed sources that are permanently implanted are not considered to be "lost."

Also regarding brachytherapy, the intent of § 35.34(b)(5) is to identify significant mistakes that are made during treatment planning or execution so that these mistakes may be prevented in the future. The sealed sources for brachytherapy are implanted inside the tissue or placed in close contact with the tumor. The dose distribution changes significantly with even a few millimeters change in distance from the source. In many instances, the physician may not be able to determine the exact size and shape of the tumor until the patient is in the operating room. During the implant operation, the physician may not be able to implant the sealed sources at the precise location planned. Therefore, the NRC believes that a criterion of a 20 percent difference between the prescribed treatment parameters and the administered treatment parameters (rather than 20 percent) is appropriate for brachytherapy. This proposed requirement is not intended to preclude a physician from properly updating the prescription after the implant to reflect the actual loading of the sealed sources or from properly changing the prescription if, based on the medical judgment of the physician, such changes would benefit the patient.

Paragraphs 35.34(c) through (e) specify the actions that a licensee would be required to take after the occurrence of a therapy event or misadministration. These paragraphs are comparable to proposed §§ 35.33(c) through (e) for diagnostic events or misadministrations. The requirements in these paragraphs are substantially the same as the requirements currently specified in existing 10 CFR 35.33(a), (b), and (d). In § 35.34(f), provisions have been added requiring that the licensee retain, in an auditable form, records of prescriptions for three years. These records may be part of medical records currently kept by the medical use licensees. Paragraph 35.34(g) is the same as the existing 10 CFR 35.33(e).

Proposed § 35.34(d) retains the requirement to notify the patient or the patient's responsible relative (or guardian) when a misadministration involving a therapy procedure occurs. The Commission continues to believe that patients have a right to know when they have been involved in a serious misadministration, unless this information would be harmful to them. See "Misadministration Reporting Requirements," 45 FR 31701, 31702 (May 14, 1980). This is an important requirement which is parallel to other NRC requirements that licensees report to an individual certain radiation exposure data pertaining to that individual. Furthermore, Federal legislation, such as the Privacy Act of 1974, recognizes the right of individuals to learn information about themselves which is contained in the records of institutions both inside and outside of the Federal sector. The NRC encourages the authorized user or a physician under the supervision of the authorized user, upon obtaining the patient's consent or before administering the radiopharmaceutical or radiation, to advise the patient or the patient's responsible relative (or guardian) that a record of the treatment will be available if requested.

During the QA Subcommittee meeting held on November 7, 1988, an attendee from the medical community questioned the appropriateness of the dose criterion, which is based on a percentage of the prescribed total dose, for determining whether a therapy event must be reported to the NRC. As an alternative, the attendee suggested the use of a radiation tolerance dose for each specific organ as a criterion for determining whether an event must be reported. The attendee stated that since the tolerance dose is selected as the dose that might cause damage to an organ not in the treatment volume, any dose in excess of the tolerance dose should be reported.

The NRC staff has considered this comment. However, a criterion based on a percentage of the prescribed total dose has been retained for the following reasons:

(1) The NRC's purpose in requiring reporting errors in medical use is to identify their causes in order to correct them and prevent their recurrence. The NRC can expedite this by notifying other licensees if there is a possibility that they could make the same errors. Reporting is designed to identify events that could have generic significance for medical use licensees and to indicate whether a licensee has QA problems. The types of events that must be reported may indicate a breakdown in the licensee's QA program. Although a difference of 10 percent or more between the administered total dose and the prescribed total dose for teletherapy may not necessarily indicate harm to the patient, it exceeds the normal uncertainties of the treatment planning and delivery system. If the cause of the event is not determined and corrected, similar errors may occur in the future that could harm patients. Because the uncertainties in most teletherapy administrations are 2 to 3 percent, the staff believes the criterion of a 10 percent difference would avoid identifying events that are part of the normal uncertainties of the treatment planning and delivery system.

(2) The tolerance dose system may be unwieldy. If this approach were adopted, a table of the ranges of acceptable doses for each organ would need to be published. However, there would be many exceptions to the published dose ranges for a variety of reasons. The amount of tolerance to radiation depends on the specific organ, the dose rate, fractionation schedule, the volume exposed, oxygen supply, written

the organ, heterogeneity of dose, the patient's age, adjuvant therapy, genetic makeup, and other medical conditions. When all these factors are taken into account, there is still a large uncertainty in what is currently known about individual organ tolerances. In some cases, based on a physician's medical judgment, exceeding the accepted tolerance dose to normal tissues or organs not in the treatment volume may be appropriate if the need exists to provide definitive treatment to a cancer that threatens the patient's life, that causes unendurable pain, or that causes unacceptable loss of normal life capacities.

In summary, the NRC believes that the proposed modifications in reporting and recordkeeping requirements would continue to address the purpose of the current regulations and to provide the NRC with information that may be used to assess the effectiveness of the licensee's basic QA program.

Section 35.33 Basic Quality Assurance Program

In 1987, the NRC published for public comment a proposed amendment to 10 CFR part 35 (52 FR 30942, October 2, 1987). The proposed amendment prescribed certain QA procedures that the NRC believed should be incorporated into each licensee's medical program to prevent the most common errors in medical use involving therapy and iodine. These QA procedures were based on a review of QA publications and case reports of the incidents. Many commenters stated that certain requirements in the 1987 proposed amendment might be disruptive, uneconomical, or difficult to comply with because of factors such as patient compliance, available staff, or medical care considerations. They recommended that, instead of prescriptive requirements, a performance-based amendment should be promulgated and that the details of the basic QA procedures should be left to the licensees.

The NRC has adopted this recommendation in this proposed amendment. The NRC would require that a medical use licensee establish a written basic QA program to prevent, detect, and correct the cause of errors in medical use.

A draft regulatory guide has also been prepared by the NRC staff. The regulatory guide provides guidance for licensees to develop a basic QA program that would be acceptable to the NRC staff for meeting the performance-based amendment (the proposed § 35.33). Many licensees may [illegible] already have implemented a basic QA program that would substantially meet the requirements of proposed § 35.33. Medical use licensees will be expected to use the guidance in the regulatory guide as they develop a program specific for their clinical situation. However, a licensee may propose a basic QA program based on other source of guidance; the NRC staff would review these proposed QA programs on a case-by-case basis.

Under the 1987 proposed rulemaking, specific QA procedures would have been applied only to radiation therapy and to diagnostic procedures involving radioactive iodine. However, under this broad performance-based amendment, the QA program will cover all diagnostic and therapeutic procedures because a licensee has the responsibility to administer the prescribed dose or dosage to the correct patient in the manner prescribed. The NRC recognizes that implementation of a basic QA program is more likely to have the desired effect if it establishes a consistent performance requirement for the organization and all personnel involved in the medical use. NRC would appreciate comment on whether exemptions to the proposed QA requirements should be granted to medical use licensees who only perform diagnostic procedures and do not possess I-125 or I-131.

V. Enforcement

In addition to amending the regulations to require medical use licensees to establish a written basic QA program covering both diagnostic and therapeutic procedures and clarifying, modifying, and strengthening the misadministration reporting requirements, the Commission intends to modify the NRC Enforcement Policy in 10 CFR part 2 in conjunction with the final rulemaking. The Commission views the occurrence of misadministrations and other reportable events as evidence of inadequate quality assurance in the medical use of byproduct material and may subject the licensee to enforcement action. The enforcement policy will be modified by amending current examples dealing with misadministrations and adding specific examples of violations of the Commission's QA requirements to Supplement VI of Appendix C to 10 CFR part 2.

Such examples would include: At Severity Level I, failure to follow procedures in a QA program that results in a death or serious injury to a patient; at Severity Level II, failure to follow procedures in a QA program that results in substantial overexposure to the patient; at Severity Level III, failure to establish a written QA program, failure to conduct adequate audits of a QA program or take prompt corrective actions for deficiencies identified through such audits, failure to follow procedures of a QA program that results in therapy misadministrations, failure to follow QA program procedures that results in a number of diagnostic misadministrations over the inspection period, or a recurrent violation from the previous inspection period that results in a diagnostic misadministration, and failure to make a report as required by proposed § 35.34(d) or (e); at Severity Level IV, failure to follow procedures of a QA program not amounting to Severity Level I, II, or III, or other violation resulting in a diagnostic misadministration, and failure to make a report as required by proposed § 35.33(d).

VI. Implementation Plan and Agreement State Compatibility

The NRC is proposing the effective date of the amendment to be six months after the publication date of the final amendment in the **Federal Register**. On or before the effective date, all medical use licensees must have their basic QA programs developed and implemented, and submit to the NRC a written certification that the QA program has been implemented. As part of NRC's inspection program, NRC contract inspectors will determine whether the QA program has been fully implemented. An application for a new medical use license or renewal submitted to the NRC will have to include a written basic QA program as part of the license application. Medical use licensees will be subject to the revised reporting and recordkeeping sections of the amendment on the effective date.

Because the proposed amendment has safety significance for the Agreement State licensees as well as the NRC licensees, it will be a matter of compatability for the Agreement States.

VII. Administrative Statements

Finding of No Significant Environmental Impact: Availability

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in subpart A of 10 CFR part 51, that this amendment, if adopted, would not be a major Federal action significantly affecting the quality of the human environment, and therefore an environmental impact statement is not required. The proposed amendment would require NRC medical use licensees to establish a written

basic QA program to prevent, detect, and correct the cause of errors in medical use. The proposed QA requirements and a regulatory guide have been developed to include generally accepted good practices in basic medical quality assurance and include specific measures intended to prevent many of the kinds of human error observed and reported to the NRC over a number of years. Based on analyses of reported therapy misadministrations the Commission expects that the proposed requirements will provide assurance that the safety of patients received in medical use will be enhanced by reducing the frequency of certain types of misadministrations. The NRC is also proposing to modify the reporting and recordkeeping requirements for medical use.

The proposed amendments, if adopted by the NRC and implemented by licensees, would likely result in fewer errors in medical use and, thus, would likely reduce unnecessary radiation exposures. It is expected that there would be no increase in radiation exposure to the public or to the environment beyond the exposures currently resulting from delivering the dose to the patient. The draft environmental assessment and finding of no significant impact on which this determination is based is available for inspection at the NRC Public Document Room, 2120 L Street NW., Lower Level, Washington, DC. Single copies of the draft environmental assessment and the finding of no significant impact are available from Dr. Tse (see **ADDRESSES** heading).

Paperwork Reduction Act Statement

This proposed amendment modifies information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). This rulemaking has been submitted to the Office of Management and Budget for review and approval of the information collection requirements.

Public reporting burden for this collection of information is estimated to be about 64,650 hours per year (for 2,500 NRC licensees and 5,000 Agreement State licensees) or an average of about 9 hours per licensee, including the time for reviewing instructions, searching existing data sources, collecting and maintaining the data needed, and reviewing the collection for completeness. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Records and Reports Management Branch, Division of Information Support Services, Office of Information Resources Management, U.S. Nuclear Regulatory Commission, Washington, DC 20555; and to the Paperwork Reduction Project (3150-0010), Office of Management and Budget, Washington, DC 20503.

Regulatory Analysis

The Commission has prepared a draft regulatory analysis for the proposed amendment. The analysis examines the benefits and impacts considered by the NRC. The draft regulatory analysis is available for inspection at the NRC Public Document Room at 2120 L Street NW., Lower Level, Washington, DC. Single copies are available from Dr. Tse (see **ADDRESSES** heading).

The Commission requests public comments on the draft regulatory analysis. Comments are specifically requested on (a) factors affecting the balance between benefits to patients from lower rates of human errors and the values of resources that would be needed to produce these lower rates and (b) whether these resources could be used in other ways to better optimize patient safety and treatment than could be accomplished through development and implementation of QA programs for medical use. Comments on the draft analysis may be submitted to the NRC as indicated under the **ADDRESSES** heading.

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission certifies that this amendment, if adopted, would not have a significant economic impact on a substantial number of small entities. The proposed amendment affects about 2,500 NRC medical use licensees under 10 CFR part 35. Of these, about 2,200 licenses are issued to institutions and 300 are issued to physicians in private practice. Under the size standards adopted by the NRC (50 FR 50241, December 9, 1985), some medical use licensees could be considered "small entities" for purposes of the Regulatory Flexibility Act (average gross annual receipts do not exceed $3.5 million for an institution and do not exceed $1 million for a private practice physician). The number of medical use licensees that would fall into the small entity category is estimated to be a very small percentage of the total number of licensees and does not constitute a substantial number for purposes of the Regulatory Flexibility Act.

The proposed amendment would require NRC medical use licensees to establish a written basic QA program to prevent, detect, and correct the cause of errors in medical use. The NRC is also proposing to modify the reporting and recordkeeping requirements relating to such medical use. The Commission believes that most licensees currently have a quality assurance program that is designed to prevent errors in medical use. Furthermore, all medical use licensees are currently subject to the existing reporting and recordkeeping requirements which, except for certain clarifications, are not significantly different from the proposed reporting and recordkeeping requirements. Therefore, there should not be a significant economic impact on these small entities. (See the Regulatory Analysis for the anticipated economic impact of this regulation on licensees.)

There is a potential that the gains in patient protection will outweigh the economic impact for medical use licensees, including the small entity licensees. However, because there are uncertainties in the analysis of these benefits and impacts, the NRC is seeking comments and suggested modifications because of the widely differing conditions under which medical use licensees operate.

Any small entity subject to this regulation who determines that, because of its size, it is likely to bear a disproportionately adverse economic impact should notify the Commission in a letter that indicates the following:

(a) The licensee's size and how the proposed regulation would result in a significant economic burden or whether the resources necessary to establish a QA program could be more effectively used in other ways to optimize patient safety, as compared to the economic burden on a larger licensee.

(b) How the proposed regulations could be modified to take into account the licensee's differing needs or capabilities.

(c) The benefits that would accrue, or the detriments that would be avoided, if the proposed regulation were modified as suggested by the licensee.

(d) How the proposed regulation, as modified, could more closely equalize the impact of NRC regulations or create more equal access to the benefits of federal programs as opposed to providing special advantages to any individual or group.

(e) How the proposed regulation, as modified, would still adequately protect the public health and safety.

Backfit Analysis

The Commission has determined that the backfit rule, 10 CFR 50.109, does not apply to this proposed amendment, and thus, a backfit analysis is not required for this proposed amendment, because it

does not involve any provisions that would impose backfits as defined in 10 CFR 50.109(a)(1).

VIII. List of Subjects in 10 CFR Part 35

Byproduct material, Drugs, Health devices, Health professions, Incorporation by reference, Medical devices, Nuclear materials, Occupational safety and health, Penalty, Radiation protection, Reporting and recordkeeping requirements.

IX. Text of Proposed Regulation

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the NRC is proposing to adopt the following amendments to 10 CFR part 35.

PART 35—MEDICAL USES OF BYPRODUCT MATERIAL

1. The authority citation for part 35 is revised to read as follows:

Authority: 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 35.11, 35.13, 35.20 (a) and (b), 35.21 (a) and (b), 35.22, 35.23, 35.25, 35.27 (a), (c) and (d), 35.31(a), 35.35, 35.49, 35.50(a)–(d), 35.51(a)–(c), 35.53 (a) and (b), 35.59(a)–(c), (e)(1), (g) and (h), 35.60, 35.61, 35.70(a)–(f), 35.75, 35.80(a)–(e), 35.90, 35.92(a), 35.120, 35.200(b), 35.204 (a) and (b), 35.205, 35.220, 35.310(a), 35.315, 35.320, 35.400, 35.404(a), 35.406 (a) and (c), 35.410(a), 35.415, 35.420, 35.500, 35.520, 35.606, 35.606, 35.610 (a) and (b), 35.615, 35.620, 35.630 (a) and (b), 35.632(a)–(f), 35.634(a)–(e), 35.636 (a) and (b), 35.641 (a) and (b), 35.643 (a) and (b), 35.645 (a) and (b), 35.900, 35.910, 35.920, 35.930, 35.932, 35.934, 35.940, 35.941, 35.950, 35.960, 35.961, 35.970, and 35.971 are issued under sec. 161b., 68 Stat. 948, as amended (42 U.S.C. 2201(b)); and §§ 35.14, 35.21(b), 35.22(b), 35.23(b), 35.27 (a) and (c), 35.29(b), 35.33(a)–(f), 35.34(a)–(g), 35.36(b), 35.50(e), 35.51(d), 35.53(c), 35.59 (d) and (e)(2), 35.59 (g) and (i), 35.70(g), 35.80(f), 35.92(b), 35.204(c), 35.310(b), 35.315(b), 35.404(b), 35.406 (b) and (d), 35.410(b), 35.415(b), 35.610(c), 35.615(d)(4), 35.630(c), 35.632(g), 35.634(f), 35.636(c), 35.641(c), 35.643(c), 35.645, and 35.647(c) are issued under sec. 161o., 68 Stat. 950, as amended (42 U.S.C. 2201 (o)).

2. In § 35.2, the term "misadministration" is revised and the terms "basic quality assurance," "clinical procedures manual," "diagnostic event," "diagnostic referral," "prescribed dosage," "prescribed dose," "prescription," and "therapy event" are added to read as follows:

§ 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 event means any medical use for which a record, and under certain circumstances a report, are required pursuant to § 35.33(a).

* * * * *

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.

* * * * *

Misadministration means any error in medical use as described in §§ 35.33(b) or 35.34(b) for which a record, and under certain circumstances a report, are required pursuant to §§ 35.33 (c) and (d) or 35.34 (c), (d), and (e).

* * * * *

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.

* * * * *

Therapy event means any medical use for which a record and a report are required pursuant to § 35.34(a).

* * * * *

3. § 35.33 is revised to read as follows:

§ 35.33 Records and reports of diagnostic events or misadministrations.

(a) A diagnostic event for which a record, and under certain circumstances a report, is required (as set forth in paragraph (d) of this section) consists of the following:

(1) Any diagnostic medical use not authorized in the license;

(2) Any diagnostic medical use without a prescription or a diagnostic referral; or

(3) Any diagnostic medical use without daily recording the administered radiation dose or radiopharmaceutical dosage in the appropriate record.

(b) A diagnostic misadministration for which a record, and under certain circumstances a report, is required (as set forth in paragraphs (c) and (d) of this section) consists of the following:

(1) Any diagnostic medical use other than the one stated in the prescription or in the diagnostic referral [1] and clinical procedures manual. Incorrect medical use would include treatment of the wrong patient, administration of the wrong radiopharmaceutical or radiation from the wrong sealed source, administration of a radiopharmaceutical or radiation to the wrong organ or site, or via the wrong or unintended route of administration; or

(2) Any diagnostic medical use such that errors result in an administered dosage differing from the prescribed

[1] 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 authorization 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.

dosage by more than 50 percent of the prescribed dosage.

(c) For any diagnostic medical use that results in a diagnostic event or misadministration as described in paragraphs (a) and (b) of this section, the Radiation Safety Officer shall promptly investigate its cause, make a record for NRC review, retain the record as directed in paragraph (e) of this section, and notify the licensee management to take appropriate corrective action.

(d) The licensee shall notify the referring physician and the appropriate NRC Regional Office in accordance with 10 CFR 30.6 in writing within 15 days of the discovery of the diagnostic event or misadministration if it involved the use of byproduct material not authorized for medical use in the license, administration of a dosage differing by at least five-fold from the prescribed dosage, or administration of byproduct material such that the patient is likely to receive an organ dose greater than 2 rem or a whole body dose greater than 0.5 rem. Licensees may use dosimetry tables in package inserts, corrected only for the amount of radioactivity administered, to determine whether a report is required. The written report must include the licensee's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the patient; what improvements are needed to prevent recurrence; actions taken to prevent recurrence, and for a diagnostic event or misadministration for which notification to the patient is required (as set forth below), whether the licensee informed the patient or the patient's responsible relative (or guardian), and if not, why not. The report to the NRC must not include the patient's name or other information that could lead to identification of the patient. If the diagnostic event or misadministration involved the administration of iodine and has the potential to cause serious harm to the patient (e.g., a microcurie amount was prescribed but more than 1 millicurie was administered), the licensee shall also notify the patient or a responsible relative (or guardian) within 24 hours after the licensee discovers such a diagnostic event or misadministration, unless the referring physician agrees to inform the patient or believes, based on medical judgment, that telling the patient or the patient's responsible relative (or guardian) would be harmful to one or the other. If the referring physician, patient, or the patient's responsible relative (or guardian) cannot be reached within 24 hours, the licensee shall notify them as soon as practicable. The licensee is not required to notify the patient or the patient's responsible relative (or guardian) without first consulting the referring physician; however, the licensee shall not delay medical care for the patient because of any delay in notification.

(e) Each licensee shall retain the following records:

(1) Each prescription, diagnostic referral, and record of administered radiation dose or radiopharmaceutical dosage, in an auditable form, for three years after the date of administration;

(2) Each written diagnostic clinical procedure, in an auditable form, for three years after its last use; and

(3) The report of each diagnostic event or misadministration for ten years. The record must contain the names of all individuals involved in the event (including the prescribing physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a brief description of the event or misadministration, why the event or misadministration occurred, the effect on the patient, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence.

(f) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, patients, or responsible relatives (or guardians).

4. § 35.34 is added to read as follows:

§ 35.34 Records, reports, and notification of therapy events or misadministrations.

(a) A therapy event for which a record and report to licensee management are required consists of the following:

(1) Any therapeutic medical use without both a prescription [1] and a prior review of the patient's case by an authorized user or a physician under the supervision of an authorized user;

(2) Any therapeutic medical use without daily recording in the appropriate record the administered radiation dose or radiopharmaceutical dosage;

(3) A teletherapy administration from a sealed source such that errors in the source calibration, the time of exposure, treatment geometry, or other errors result in an administered fractional dose differing from the prescribed fractional dose by more than 20 percent of the prescribed fractional dose, but less than the percentage of fractional dose set forth below in paragraph (b)(3)(ii) of this section; or

(4) Any therapeutic medical use not authorized by the license.

(b) A therapy misadministration for which records and reports to the NRC and licensee management are required consists of the following:

(1) Any therapeutic medical use other than the one stated in the prescription, including treatment of the wrong patient, administration of the wrong radiopharmaceutical or radiation from the wrong sealed source, administration of a radiopharmaceutical or radiation to the wrong target organ or treatment site, or via the wrong or unintended route of administration;

(2) Any therapeutic medical use of a radiopharmaceutical such that errors result in an administered dosage differing from the prescribed dosage by more than 10 percent of the prescribed dosage;

(3) A teletherapy administration from a sealed source such that errors in the source calibration, the time of exposure, treatment geometry, or other errors result in any of the following:

(i) The administered total dose differing from the prescribed total dose by more than 10 percent of the prescribed total dose;

(ii) For any treatment fraction, the administered fractional dose being greater than twice or less than one-half of the prescribed fractional dose, or

(iii) For the fractions administered to date, the sum of the administered fractional doses differing from the sum of the prescribed fractional doses by more than 10 percent of the prescribed total dose;

(4) A brachytherapy administration with a sealed source that is leaking, is lost, or is unrecoverable during the brachytherapy treatment; or

(5) A brachytherapy administration such that errors in brachytherapy treatment planning or execution result in the prescribed dose differing from the administered dose by more than 20 percent of the prescribed dose.

(c) For any medical use that results in a therapy event or misadministration as described in paragraphs (a) and (b) of this section, the Radiation Safety Officer shall promptly investigate its cause, make a record for NRC review, retain the record as directed in paragraph (f) of this section, and notify the licensee management to take appropriate corrective action.

(d) For any medical use that results in a therapy event as described in

[1] If, because of the emergent nature of the patient's condition, a delay in order to provide a written prescription would jeopardize the patient's health, an oral instruction may be acceptable, but a written record (containing the information specified in § 35.3 for a prescription) shall be made in the patient's record within 24 hours.

paragraph (a)(4) or a misadministration as described in paragraph (b) of this section, the licensee shall notify by telephone the appropriate NRC Regional Office listed in Appendix D of 10 CFR part 20 no later than the next Federal Government working day after discovery of the therapy event or misadministration. The licensee shall also notify the referring physician of the affected patient and the patient or a responsible relative (or guardian) within 24 hours after the licensee discovers the therapy misadministration, unless the referring physician agrees to inform the patient or believes, based on medical judgment, that telling the patient or the patient's responsible relative (or guardian) would be harmful to one or the other. If the referring physician, patient, or the patient's responsible relative (or guardian) cannot be reached within 24 hours, the licensee shall notify them as soon as practicable. The licensee is not required to notify the patient or the patient's responsible relative (or guardian) without first consulting the referring physician; however, the licensee shall not delay medical care for the patient because of any delay in notification.

(e) Within 15 days after an initial telephone report to NRC of a therapy event or misadministration, the licensee shall report, in writing, to the NRC Regional Office initially telephoned and to the referring physician and shall furnish a copy of the report to the patient or the patient's responsible relative (or guardian) if either was previously notified by the licensee under paragraph (d) of this section. The written report must include the licensee's name, the prescribing physician's name, a brief description of the event or misadministration, why the event or misadministration occurred, the effect on the patient, what improvements are needed to prevent recurrence, the actions taken to prevent recurrence, whether the licensee informed the patient or the patient's responsible relative (or guardian), and if not, why not. The report must not include the patient's name or other information that could lead to identification of the patient.

(f) Each licensee shall retain the following records:

(1) Each prescription and record of administered radiation dose or radiopharmaceutical dosage, in an auditable form, for three years after the date of administration; and

(2) The report of each therapy event or misadministration for ten years. The record must contain the names of all individuals involved in the event (including the prescribing physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a brief description of the event or misadministration, why the event or misadministration occurred, the effect on the patient, what improvements are needed to prevent recurrence, and the action taken to prevent recurrence.

(g) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, patients, or responsible relatives (or guardians).

5. § 35.35 is added to read as follows:

§ 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 [8] is made for any therapy procedure and any diagnostic radiopharmaceutical procedure involving more than 50 microcuries of I-125 or I-131;

(3) Ensure, prior to any medical use, that a prescription or a diagnostic referral [8] is made for any diagnostic procedure not involving more than 50 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.

(b)(1) The licensee shall develop procedures for and conduct a comprehensive audit at intervals no greater than 12 months to verify compliance with all aspects of the basic quality assurance program. The licensee's management shall evaluate each of these audits to determine the effectiveness of the basic quality assurance program and promptly implement modifications within 30 days that will prevent the recurrence of errors in medical use. The licensee shall maintain records of each audit and management evaluation, in an auditable form, for three years.

(2) The licensee may make modifications to the approved basic quality assurance program without NRC approval only if the modifications do not decrease or potentially decrease the effectiveness of the basic quality assurance program. The licensee shall furnish the modification to the appropriate NRC Regional Office in accordance with 10 CFR 30.6 within 15 days after the modification is made. Modifications that decrease, or potentially decrease, the effectiveness of the approved basic quality assurance program may not be implemented without prior application to and approval by the NRC.

(c)(1) Each applicant for a new license shall submit to the appropriate NRC Regional Office in accordance with 10 CFR 30.6 a basic quality assurance program as part of the application for a license and implement the program upon issuance of the license by the NRC.

(2) Each existing licensee shall submit to the appropriate NRC Regional Office in accordance with 10 CFR 30.6 by (insert effective date) a written certification that a basic quality assurance program designed in accordance with this section has been implemented.

(3) Each licensee shall maintain the written basic quality assurance program, in an auditable form, for the duration of the license.

Dated at Rockville, Maryland, this 8th day of January, 1990.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

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[8] 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.

U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REGULATORY RESEARCH

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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" (55 FR 1439, January 16, 1990), 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.

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 (55 FR 1439), 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 55 FR 1439.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555