OFFICIAL TRANSCRIPT OF PROCEEDINGS

Agency: Nuclear Regulatory Commission

Title: NRC Meeting with AAPM, ACMP, ACR, AES, and ASTRO of the Proposed QA Rule and Reporting Requirements

Docket No.

LOCATION: Reston, Virginia

DATE: Saturday, December 15, 1990 PAGES: 1 - 310

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

UNITED STATES

NUCLEAR REGULATORY COMMISSION

NRC MEETING WITH AAPM, ACMP, ACR, AES, AND ASTRO OF THE PROPOSED QA RULE AND REPORTING REQUIREMENTS

Saturday, December 15, 1990

9:00 a.m.

Hyatt Recency Hotel

Lake Audubon Room

Reston, Virginia

PROCEEDINGS

[9:17 a.m.]

MR. TELFORD: Good morning, and welcome back for the second session of our workshop and roundtable discussion. I would like to go through the introductions again, just for the record. You can please state your name and what organization you represent. This time, if you would, state the hospital or clinic that you usually work for so we can identify you with a medical center.

My name is John Telford. I am the Section Chief, in charge of the group trying to do this rule. I will move this way.

MR. CAMPER: Larry Camper, Section Leader of the Medical and Academic Section, NRC Headquarters.

MS. PICCONE: Josie Piccone, Senior Project Manager in the Medical Section of Headquarters.

DR. BRICKNER: Jerry Brickner, Director of Radiation Oncology, St. Francis Hospital, Tulsa, Oklahoma representing the American College of Radiology.

DR. SMITH: Al Smith, University of Pennsylvania Hospital in the Foxchase Cancer Center. I represent the AAPM.

DR. PAYNE: Tom Payne, Medical Physicist at Abbott Northwestern, Minneapolis. I am Chairman of the Commission of Physics of the ACR.

DR. SUNTHARALINGAM: Suntharalingam, Chief of the Division of Medical Physics at Thomas Jefferson University Hospital, representing ASTRO and the American College of Medical Physics.

DR. DEYE: Jim Deye, Director of Medical Physics at Fairfax Hospital. I am representing the American College of Medical Physics.

DR. SVENNSON: Svennson, Director of Physics from the Joint Center for Radiation Therapy at Harvard in Boston. I represent the American College of Radiology.

MR. SHORT: I am Brad Short, with the ACR Staff.

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

MR. TSE: Anthony Tse, NRC Research. I am the Project Manager of this project.

MR. TELFORD: We have a proposed agenda here. In our discussions with Brad Short --

DR. DEYE: Do we have a visitor?

MR. TELFORD: We do have a visitor. Would you like for her to identify herself?

DR. DEYE: Yes.

MS. SERELL: Sharon Serell, Manager of the Department of Nuclear Medicine here at the Washington Hospital Center. I represent the government relations chairman for the technologist section of the Society of

Nuclear Medicine.

MR. TELFORD: We have sort of a proposed agenda before you, and this is based on conversations with Brad Short who allegedly talked to all of you and got your input. First, let's focus on the agenda to see if there are any other items that you want to put on the agenda or take some off, if you like.

How about the order of the agenda, is everybody happy with what is on there?

DR. DEYE: I guess I would almost like to see the 10:45 and 11:15 moved near the top of the agenda, since it would be nice to know what we all perceived the November 19th meeting to have accomplished before we get into further discussions on some of the specifics today. I don't know how the rest of the group feels.

In other words, the 10:45 and 11:15 are talking about summarizing our discussions of November 19th.

MR. TELFORD: The 10:45 is. The 11:15 is to continue discussion.

DR. DEYE: Yes, but continuing from what point, I guess is my point. I am not sure where we all felt we left those discussions. At any rate, a summary of November 19th near the head of the agenda today seems like it might be, from my perspective, a good idea.

MR. TELFORD: That's fine with me. With whom

would you like it?

DR. DEYE: I don't know how the rest feel.

DR. BRICKNER: That would be grand.

MR. TELFORD: Would you like it first?

DR. DEYE: Maybe. It looks like you have brought transcripts too. Obviously, if that's the transcript, we are not about to read all of that this morning. Maybe particular sections of it we might look at. If we move that to the top of the agenda along with us taking a quick look at the transcripts to see if there is really any significant item we personally thought we mentioned that either got misphrased or didn't get heard or whatever -- I don't know.

MR. TELFORD: Whatever you like. We can do that first if you like, or we can do that second.

DR. SMITH: I think that's a good idea. Also, I would like to, if you have a current document -- because our understanding is that you have a revised document that we really weren't looking at the last time we were here -- it would be nice if you have an updated document for us to look at while we are having these discussions.

MR. TELFORD: Actually, that's only partially correct. What is in the Federal Register -- that's one of the questions on here by the way at 10:15. That's the next to the last bullet that says most recent draft of the QA rule. Why don't we just do that bullet right now.

What appeared in the Federal Register in January of this year is the most recent draft of the Rule. That is the official version. In your package that we handed out at the November meeting if you look at the version of 35.35, those words that redescribe the objectives, for instance objective number two where it says for a prescription, you need a prescription for A, B, C -- A, teletherapy, B, Brachytherapy, C, Radiopharmaceutical therapy.

What we did was, we polished the English or did a little word engineering, whatever you want to call it, so that those folks that we were talking to about this rule could more easily understand it. We learned something right away which was that if you use compound and complex sentences, it causes people to stop and think and have to puzzle out as to what is the meaning of the sentence.

So, all we did was modify the sentence structure to call out A, B and C, and we did that in a couple of places for a couple of the objectives so that if you looked at a comparison of the Federal Register with our handout package you will not see the same sentence structure. It's slightly different. What I would suggest is that it's more easy to understand, what we handed out.

DR. SMITH: You don't actually have another draft from all of the statements and responses that were made in April, you didn't produce then another draft of the document

since that time?

MR. TELFORD: That's correct. By April, are you alluding to the public comments?

DR. SMITH: Right. Can that be interpreted as a kind of -- I don't want to use inflammatory language -- a non-response to all of those comments that you didn't use those comments to redraft the document?

MR. TELFORD: I don't want you to read anything sinister or unresponsive into that. Our normal process of rulemaking is in accordance with the Administrative Procedures Act, so we have certain requirements to follow. Internally, working within Headquarters, we developed a proposed rule which was requested by the Commission or by one of the user offices. We circulate that internally for what we call office concurrence.

The rule gets office concurrence, and then it goes to our Executive Director of Operations. If approved, then it goes on to the Commission. It will be considered and debated by the Commission, a decision is reached. We get what we call a staff requirements memorandum that tells us the changes to make to this proposed rule before it is published, and then it's published. The minimum time that it can be published is 75 days. It can be 75, 90, 120, depending upon the nature of the rule.

It goes out for public comment, as this one did.

At the close of the comment period we collect the comments, we categorize them, we evaluate them, we analyze them, we respond to each of the categories of comments. What we are really doing is, we are re-writing the rule, we are going to write the final rule now.

Once we have our final Federal Register package together it will contain a response to each of the categories of comments. I am saying categories of comments because on this rule we had about 80 comments. We can have 200, 400 or 600. You can't respond to each comment in the Federal Register individually but rather, you attempt to categorize them and respond to the category. Like on this rule for instance, several of the gentlemen sitting at this table said this will be expensive because you are having the RSO go and investigate, write a report on events. That is probably a waste of money. That was what was said between the lines, that's probably a waste of money.

You can look for that in the Federal Register, because I promise you it will be there. I can almost promise you -- at least I can say I intend to make a change to that, to certainly reduce that cost.

Let me go back to the process here. Typically that's all the airing that a rule gets, is a public comment period. When you write the final rule it goes back for what we call office concurrence. All the offices agree to it,

and then it goes to the Executive Director of Operations and back to the Commission. A decision is made, we get another staff requirements memorandum that says make these changes and publish it final, it will be effective in six months or whatever.

This rule is quite different. The Commission is, I think, very concerned that we want to do the right thing here. Several times the Commission has told us, go work with the medical associations, go and work with the agreement states. There are 29 agreement states for which this rule will be a matter of compatibility. The interpretation is that they will have to do at least as much as this rule requires. They have also said, go do a pilot program.

The rule was published in January. Three months later we could have been analyzing public comments and writing a final rule, and we could have already been back to the Commission by now and had a final rule out. But no, we have to do all these extracurricular activities which, as it turned out, has provided us a lot of information.

There's one other thing, now that I have described this process, that you have to be aware of. That is that the things that we develop -- let's say that when we get to the point where we have written a draft of the final rule, it's what we call predecisional information. It's sort of a

level of classification. I am duty bound not to show it to anybody because the Commission has not voted on it. However, there is one small exception here that is not so small. Next month the Advisory Committee for the Medical Uses of Isotopes will have a meeting in mid-January. It will be a public meeting, we are going to present the staff's version of the final rule. That's where you will see the results of all of this.

DR. SMITH: That's what makes the whole process frustrating, because it is inconceivable that if your intent is to go to the March deadli[illegible]'t have a revised document in your hands now. If we are not addressing the language in a revised document and still addressing the language in the original document, it seems like we are kind of spinning our wheels, John. It puts in a large amount of frustration, knowing that you have changed the document probably considerably. You must have, if you are approaching a March deadline.

You must have another document in your hands and yet, we are still looking at revising the original document.

MR. TELFORD: It's in my head. I am really very sorry that it appears frustrating to you.

DR. SMITH: It doesn't just appear frustrating. Your perception is reality. It is terribly frustrating.

MR. TELFORD: What I would like to do is, for

instance this 10:45 item that Dr. Deye has put his finger on, I hope to show you the summary there of the comments that I heard. This is a copy of the transcript from our first session. We brought a copy of that transcript for each of you because it may be helpful to you during this meeting.

This document will appear in the Public Document Room at some point, as will all the other transcripts. I have a collection now of 15 or so of these. There is a wealth of information. Dr. Smith, I am going to attempt to convince you that I am hearing what you are saying. When we discuss further the reporting requirements, I can certainly tell you what I am thinking and what I am inclined to do. I can't promise you that will happen, because this is the staff.

DR. SMITH: Of course, we have already traveled a long way down this road, but when we come to specific language that we are addressing, if you have in your head -- if that's the only place it is -- decided on a revised language, would you please tell us what your current concept of the language is so that we won't be talking about something that is obsolete. That is what I am really trying to address.

DR. BRICKNER: There are several places in there where I have a feeling that we made an agreement, but I

don't know that you and I understand we made the same agreement.

MR. TELFORD: Let's move to the 10:45 item. First, let's hand out the copy of the transcript to each of you, and then we will give you a copy of --

DR. BRICKNER: Let me tell you while you are handing it out, I had my physicist and my nuclear medicine director look at this. They are, I thought, reasonably intelligent people. The first reaction that I got from both of them was not swearing at the NRC or the government can't do this to me, but the contrary.

They interpreted this as saying there would be a written prescription following the review of the chart for every diagnostic procedure done, which is totally impossible. When I read it, that's not what it says at all. As we talked about it, I think we agreed that a telephone call from the internist was a referral. If it met the referral and if it met the procedures book, that is all that was required.

Boy, that was an obscure fact to them because neither one of them visualized that at all. When this is written, it certainly needs to be written in a clear fashion or you are going to have people trying to put programs in place that aren't asked for that are horrendously expensive.

MR. TELFORD: We have experienced that very same

phenomenon several times. It seems like that a lot of people try to read more into these rules than are really there. We have also learned that we have to write things very simply. In my Exhibit A that we are responding is the package that I gave to you back in November of re-writing this statement of the objectives.

DR. BRICKNER: The way I look at it, as the way that I understand what we have talked about, a lot of these things really aren't problems. For instance, if I call up and say I want a bone scan and if they give the dose that's in their procedure manual, that doesn't interfere with rapid patient care or anything else. To me, that meets all your requirements.

Other people are looking at it and saying, you mean I have to get your chart and review it and write out a prescription. That's what they are interpreting.

MR. TELFORD: Let's hand out what I call the summary of comments made on the November 19th meeting. This is two pages of comments on the QA Rule itself, 35.35. The third page is some information on definitions. Let me give you some feedback here, I think that's what you are asking for.

Under 35.35, the first bullet there -- does everybody have a copy of this now? This is where I am, on this summary. Let me direct your attention --

DR. DEYE: Do you have any extras there, for the people back there?

DR. BRICKNER: In your proceedings for at least this next time, could I be a Doctor? You have me as a Mister the last time.

MR. TELFORD: I noticed that when I was reading this, that everybody is referred to as Mr. or Ms., and that's sort of a request that we could make to our Court Reporter, to refer to all of you as Doctors. That would be fine with me.

DR. BRICKNER: Thank you. It's a little thing, but I have --

MR. TELFORD: You worked for it a long time, so I think you are due. Under 35.35, first of all, the first bullet I have is what I heard each of you say that you thought it was important to have a QA program. That wasn't the question, but rather was how you go about it. Under the 35.35(a) heading I have several bullets, and I pulled these out of the transcript. For a while I am referencing the person that said it.

We were talking, you will recall in the first paragraph about what is the objective or what is the goal of this program. We were debating, if you will, whether or not we should say minimize, use ALARA, or prevent. It was a fairly long discussion that ensued. Dr. Flynn said use

minimize, detect and correct. Dr. Payne said, I cannot guarantee, but I can develop programs to prevent. Dr. Deye said JCAHO encourages optimization.

Dr. Brickner said QA is to detect, correct and verify. Dr. Bogardus said use ALARA. Dr. Deye said, our QA program is set out to minimize errors. Dr. Deye says there is a point of diminishing return. Dr. Smith said there should be objectives, whether they are realized or not, we tend to accept that concept. Dr. Smith made that remark after we had discussed what is the real purpose of quality assurance. In the transcript you will find Mr. Kline made a statement about you really ought to have an objective or a goal that you are trying to reach, whether it is achievable or not. You should be striving for that, and you shouldn't set an acceptance rate for defects. I think Dr. Smith's comment was an acknowledgement of that. In the end, Dr. Deye said do something with the word error.

The way I interpreted that whole discussion is that, in the end, you thought it was not too bad to use the concept of saying prevent errors if we would tell you what we mean by errors, and if we will make it clear that we don't mean we expect everybody to have zero errors, but rather, that's the goal that your program should provide high confidence that that's what you are after. Your program should be designed for that purpose, to detect the

errors, to prevent them, and to correct the cause and learn from it.

If you will, when we get to the paragraph on what I call audit here in the proposed rule, that's the point that I think we can bring in the idea of optimization. That's what I heard, and now let me clear up error. For the purposes of our discussion let's say that error is what we did call here an event or misadministration. This is a mistake that is made that has exceeded some threshold. Keep in mind that we should get to the definition of event and misadministration before we can say --

DR. BRICKNER: The definition of error is those two elements, period, nothing else.

MR. TELFORD: Yes. That's what your program should be designed to prevent. Prevent misadministration, prevent events. However, I think we said last time that events that should be reported should be handled internally. It should go back to your Radiation Safety Committee, back to your Quality Assurance Committee or whatever you have, and discussed internally and addressed internally. It should be a blameless feedback loop to the institution, to the department, not reported to the NRC but we will have to define them, that that's what an error is.

Is everybody happy with that? May I go to objective one?

DR. BRICKNER: I'm happy.

MR. TELFORD: Did I miss something?

DR. SUNTHARALINGAM: Did we agree on what was your understanding or is it still open for discussion, about the distinction between prevent and minimize?

MR. TELFORD: The distinction between?

DR. SUNTHARALINGAM: Are we going to? In the original doc nt the word prevent is used, and we had a discussior about an hour. I thought the recommendation from this group was essentially to delete the word prevent and rephrase it with minimize.

MR. TELFORD: That's not what I just said, and several of your colleagues are shaking their head no. This was a long discussion in which we grappled with what is the concept we are after here. What I am saying to you is that we would like to retain the word prevent. Please understand that is the goal of your quality assurance program, the goal is to prevent misadministration and events.

We will say provide high confidence. The way you should interpret that is, we don't mean 100 percent confidence. If we didn't want any wiggle room in there at all, we would have said prevent. We have not even mentioned high confidence, we just say do it, absolutely do it. So, there is a big difference between provide high confidence and do it.

DR. SUNTHARALINGAM: As soon as you allow for interpretation, that's where the ambiguity arises. You are saying you want to prevent and do it, and then you say you can interpret it.

MR. TELFORD: No. I'm sorry, Dr. Suntharalingam, you are not following me. I am saying that the version of the final rule that I have in mind is to say the goal of your QA program will be to provide high confidence that misadministration and events are prevented, not minimized, prevented.

DR. PAYNE: You have to have the emphasis -- I understand your emphasis for our lawyers and for us -- we will focus on the program. If we have a program in place that is designed to prevent and yet one occurs, we will -- and if we get fined our recourse -- if all of a sudden my adminstration says we are going to fire Tom Payne, I will say we had a program in place. It is well documented, it's written, and yes we had a misadministration and we will have the circumstantial information. I will say I don't think I should be fired, because I didn't directly cause this misadministration.

I mean, I am really getting down to the --

DR. DEYE: I would not accept the word prevent, in the context you just used it, as representing my feelings either certainly not personally and hopefully not speaking

for the ACMP. I think you are still -- if we try to think of this numerically, you are still shooting for zero but with very narrow error bars. That is your level of high confidence.

I could accept that your high confidence statement is acceptable but zero should not be the numerical value we are shooting for. Rather, some minimized numerical value. I know that is Ed Kline's problem, where do we set the value if it is not zero. I would only suggest that the standards of the field can be looked at -- and I know studies are underway not only by NRC but elsewhere, by ACR, by other professional organizations -- what is the standard of practice.

This is even the standard that is looked at in the case of liability in a court of law. You are not held to in a single error in the treatment of a patient, you are held to the standard of practice in the community when you are discussing issues like medical liability. Likewise, I would hope before this comes out that the value we are shooting for is not zero with high standard of confidence but rather some minimized value determined by the standards of the community in concert with the professional organizations that study these things.

I know it makes it difficult to inspect and that's where my comment about some of the dichotomy that I see

between regulation and QA comes into play. There is a dichotomy there between those two concepts. Part of the dichotomy is that regulation wants something concrete to inspect on and QA wants minimization and programmatic types of objectives that can be looked at and reviewed. That is part of the problem that I see.

I still, from my standpoint in ACMP, I hope we don't settle on prevent meaning zero.

MR. TELFORD: Excuse me --

DR. SMITH: Can I tell you why I agree with what you say?

MR. TELFORD: Let me -- for the record, we have two thoughts going on here. Dr. Payne has one thought and Dr. Deye has a second thought. Now Dr. Smith wants to bring out a third thought.

DR. SMITH: It's not a third thought. I think if you tell us you will put in high confidence, I think I can live with that. You are not saying certainty of high confidence. Actually in a QA program that I have put in place, it is designed to give me a high confidence that errors will be prevented. I have no problem -- if you tell us you put in high confidence because that is not the same thing as certainty. You have not said with a certainty there will be zero errors. High confidence means that you anticipate there will be some errors made.

I can live with the --

DR. DEYE: I think he's saying that you have a high confidence that you can detect the errors. That would make sense, if that is what he were saying. If he saying you have a high confidence that no errors will --

DR. SMITH: It does not mean 100 percent uncertainty. High confidence means that you are going to strive as hard as you can to prevent errors. That really is something that I can live with. As long as you say high confidence, that is a very important distinction.

MR. TELFORD: Yes, I second the motion --

DR. BRICKNER: How about low confidence --

[Laughter.]

DR. SUNTHARALINGAM: I have two comments before we go onto some other topic, so that there is no misunderstanding. I am back staring at the first bullet. I want to emphasize what every participant though it important to have a QA program is certainly different from every participant thought it important to legislate a QA program. That should be clearly understood, that I think what we felt is that it is important that every facility have a QA program.

Legislating by rulemaking at QA program is certainly something that I, representing ASTRO and ACMP, didn't think it important. I want to clarify that.

The second thing is that even this first purpose, I think a QA program primarily is directed towards detecting and correcting. A spinoff of that is the attempt, therefore, of follow up procedures to try to prevent, minimize, whatever word you want to choose. The emphasis should be on detection and correction. The way it is now written and maybe in the order in which it is written, you may want to give thought to that. My thinking is that a QA program is put into place to detect and correct. A spinoff of that is what comes in terms of what is a follow up action, how would you try to sort of keep this going and thereby minimize.

So, that is where I would put the emphasis on it.

MR. TELFORD: We now have three thoughts on the table. Let me respond to these before --

DR. SVENNSON: Let me give you a fourth one.

MR. TELFORD: A fourth one, okay.

DR. SVENNSON: I think the discussion here illustrates that we are up against terrible semantics because I have absolutely no confidence, zero confidence, that errors can be prevented. I have significant confidence, high confidence, that they can be minimized.

I think the fact that the small group of us here cannot quite agree on how to interpret the concept is a terrible situation to begin with.

DR. DEYE: I agree with you 100 percent. If you try to achieve zero, your confidence interval has to approach 100 percent uncertainty. I agree.

DR. SVENNSON: It is impossible to deal with this.

DR. DEYE: That's exactly right. I can't have high confidence I am going to prevent. I can have high confidence that I am going to minimize to within some standard set by the community and that's what you are saying. Your point --

DR. PAYNE: We can take that one further, the so-called Deming concept. That is, not to just maintain a standard of a community but continued quality improvement, namely we can get better than somebody else so we can have continued quality improvement.

DR. DEYE: Exactly.

DR. PAYNE: I think most of us are certainly in agreement with that. The JCAHO, of course, is pushing for that.

DR. DEYE: Then, when you try to regulate that -- they are pushing for the implementation of quality improvement programs.

DR. PAYNE: Right.

DR. DEYE: They do not regulate that you achieve zero defects.

DR. PAYNE: Correct.

DR. DEYE: Again, I say there's a dichotomy with the concept of regulation and the concept of quality improvement.

DR. SMITH: I think if you are getting into these kinds of arguments -- if you are saying that you are willing to accept a certain amount of error, then you have to start quantifying. What are you willing to accept? I think that's immensely problematic. Are you willing to accept ten percent of what kinds of errors, five percent or one percent.

Once you get into those kind of semantics, if you are willing to accept errors, then you have to say how many and what kind of errors am I willing to accept.

DR. SVENNSON: It is not a matter of willing, it's a reality of life. You cannot technically, physically, mathematically or clinically achieve and prevent errors.

DR. SMITH: I know that.

DR SVENNSON: The other problem is the difficulty you brought up is, in fact, no difficulty. You already know that the error rates reported by NRC is on the order of five times ten to the minus six. No one in the society today considers that a high error rate. In fact, they consider it a very, very low, socially acceptable error rate.

That has been accepted by the NCRP, by the ALARA concept. In practice, your concern is not a valid one.

MR. TELFORD: We have four different ideas on the table. Could we attempt to deal with some of them?

DR. DEYE: I would suggest that you really have two. There is just different phrasing on the one about you can't achieve. I think a number of us are saying you can't regulate zero error rate, we are just saying it in different ways.

DR. SMITH: I agree with that, although I think we have to somehow come across with some language.

DR. DEYE: I think some of us suggested that if you put the emphasis on detect and correct, an accepted corollary of that will be to prevent some -- not all -- errors rather than making that the objective of the program. The objective is the detect and correct, and a corollary and natural spinoff will be to prevent some -- hopefully an acceptably large number of some -- then that's the way the wording might go that could meet all the needs of the people around the table.

I do think it's going to leave the NRC with a difficulty in regulatory framework.

DR. SMITH: Let me ask you a question. Why are you detecting and correcting? Those are actions that lead to what?

DR. DEYE: To make sure that we are within the standards of the community.

MR. TELFORD: What is the standard of the community?

DR. DEYE: There, you hit the nail on the head. That is not well defined at this time, I will grant you.

MR. TELFORD: Let's say that --

DR. SVENNSON: In a sense --

MR. TELFORD: You say that the claim that the misadministration rate is one in 10,000. Would you like one in 10,000 applied to your hospital? The follow on to that is, if the JCAHO is after quality improvement, how much are you going to improve each year from the one in 10,000 rate. I mean, you have to start counting patients, and you can only have a misadministration for one out of 10,000. The second one, your program is no longer acceptable.

That is what Dr. Smith is saying, that there is all kinds of practical problems associated with that.

DR. DEYE: I am only saying that you probably should not be using words like quality improvement and quality assurance for this program. Call it regulation of therapeutic administered errors or diagnostically administered errors with byproduct material. Don't get into the semantics, the problems, the philosophy of quality assurance and quality improvement and also throw us into the situation of having to run two or three different quality assurance programs that have different objectives within our

department.

If you didn't call your program a quality assurance program, if you just regulate as you now do byproduct material and say each and every of these needs to be reported in the following format and each and every of these needs the following follow up action, most of my -- I might not like it, but my philosophical problems with it would disappear.

MR. TELFORD: What if we called it quality management?

DR. DEYE: At least you would take it out of the context of what is understood to be quality assurance and quality improvement.

MR. TELFORD: Our goal is to make sure that the byproduct material is administered as prescribed. If you do that, you don't have any misadministration. You don't have any events. That is administering it correctly, which is preventing mistakes, preventing errors. We know that they occur, so we have to say we want you to prevent them. Design some procedures so that if the procedures are followed, these mistakes are not made. If they occur, detect them.

Dr. Flynn made very perceptive remarks in his public comment letter, and I'm sorry he's not here. I will attempt to bring them up later on detection. But then, once

they occur figure out what went wrong, alter your procedures and try not to let it happen again.

If you really want to talk about minimization -- I don't care what we call it, we can call it quality assurance, we can call it quality management -- the objective is still there.

DR. SMITH: Dr. Deye makes a very important point, because none of us would take this document and accept it as a quality assurance program. None of us would, because it simply is not what we define in our professions as quality assurance. It has some elements, but to call this a quality assurance program is a big mistake. It is not a quality assurance program. It is really something else.

MR. TELFORD: Let me say what you said a different way, so that you can understand that I am hearing you. For instance, when you say quality assurance, I think you have the association of a JCAHO type of quality assurance program that is on the entire hospital and every department within the hospital --

DR. SMITH: No, we are talking -- I am talking the viewpoint of what we understand quality assurance in our every day practice and the quality assurance programs as we now have them placed in our departments.

MR. TELFORD: Okay.

DR. SMITH: This would never even begin to satisfy

anybody's basic definition of a quality assurance program on the level of practice in our departments.

MR. TELFORD: May I guess that it's because the focus is so narrow.

DR. SMITH: Yes.

DR. DEYE: And, I think you could guess that the philosophy is -- again, I have to keep saying -- different than the way we run a quality assurance program. I don't want to belabor the point, you know what I mean by that. I have said it enough times the last time and today.

DR. BRICKNER: Would there be an acceptable use of the word prevent i. the goal number two read to provide high confidence that errors in medical use will be prevented to the greatest degree possible; would that make it happen?

DR. DEYE: How would you say that?

DR. BRICKNER: To the greatest degree possible.

DR. SMITH: That's your ALARA concept actually.

DR. DEYE: What's the lead in?

DR. BRI.NER: Exactly what I read, to provide --

DR. GUNTHARALINGAM: Handling and medical use will be prevented -- and then a close to that.

DR. SMITH: Again, ALARA concept is really what this is directing towards. ALARA really is, I think, extremely appropriate in these situations, and what I think is a concept that has a precedent. It is understood, it is

accepted, and we practice ALARA in our institutions. I don't understand why you don't take that concept which you have accepted and which the community accepts and use ALARA in that same context in this program.

DR. SVENNSON: Credibility is important for the utilization of this.

DR. DEYE: I think the key is, where do you take action. That is the key difference. Do you take action on a single event, or do you take action on some standard ten to the minus sixth or ten to the minus fifth. We can't seem to get past that point. I know it's a problem for you, and it's a problem for us in a practical sense. It is not quibbling over words.

It is going to relate to how we report, what we report, how often we report, it's going to relate to how many notices of violation practically speaking we finally get out of this. If the standard is ALARA, we get no notices of violation if we only have one event over a year's worth of treatment let's say. If the standard is zero events, we definitely will get a notice of violation for a single event that occurred during the past year if this goes into play.

MR. TELFORD: I am not sure about that.

DR. DEYE: It's going to be up to the inspector and what severity level they give us. We have the anecdote

that I think was given forward at this meeting on November 19th of an institution that had three years worth of morning checks on their cobalt unit. Only three instances were those documents not signed -- they were done but not signed -- and they got a notice of violation.

I think within the standards of ALARA, their program was totally non-culpable. It was an excellent program. Yet, it got a notice of violation because three days out of three years the technologist performing that test had not put her or his initials on the document.

MR. KLINE: Dr. Deye, how long ago was this?

DR. DEYE: A month and one-half, two months ago.

MR. KLINE: Were there other circumstances surrounding that event?

DR. DEYE: I don't believe so, but I can't speak -- I have heard this from --

MR. KLINE: Do you know where?

DR. DEYE: Yes. It's a good institution.

MR. KLINE: Without knowing the exact detail behind the inspection, I can't speak on behalf of the region that did the inspection, they do have a measure to institute corrective action which we have discussed before regarding non-cited violations which is a mechanism by which the NRC will review your program and you can institute corrective action at the time of inspection for minor offenses, which

it appears that you are alluding to a minor event with signatures missed on three documents over a number of years.

That would not be written up as a violation, but I don't know the history. There could be other chronic problems in the past associated with that licensee. There could be a performance program for similar violations.

DR. DEYE: I understand what you are saying. We are in an awkward situation. You inspected us until a month ago out of the Atlanta office, so we could get into specifics here. I think if we stay with generalities -- by the way you were extremely reasonable when you came through. The problem is that it is up to the individual who comes through.

An individual event can be -- you and I both admit there was the one event at Fairfax four months ago or so -- you had to make a decision, you and the people in Atlanta. You decided it's so small, no NOV. It could have been, in the hands of another inspection, it will could have been a single event out of a very good program. It could be listed as a notice of violation.

MR. KLINE: One thing that the NRC has realized is that over the years that some of these minor violations have become a paper chase, very cumbersome and time consuming, tax dollars, inspectors, agency goals with more significant events and not minor events. That philosophy -- there was a

decision to go to this basis by which you institute corrective action for minor problems. NRC notes it, but they don't make a violation out of it in the sense that there's no document that comes to you.

That document is what alerts your administrator and other inspectors, whether it be JCAHO -- we have a problem. A lot of times they don't look at the severity level, they just see a violation. In an attempt to minimize these sort of things and look more to safety significant issues, they have alloted this latitude to correct the problems at the time of the inspection.

This is relatively new. We introduced -- I don't know if this one institution if there was a misunderstanding of what some minor violation or more significant. I don't think you are going to see many institutions in the future for many inspections by NRC people in the future that will be uncovering large multitudes of severity level five violations. That is not the intent of what we are trying to do.

We do have the requirement for that and we do have the latitude, for example, for severe level five violation to issue a notice of violation.

DR. DEYE: Could I ask that the names of those two institutions be left out of the record. Would you agree with that?

MR. TELFORD: Yes.

DR. DEYE: I think that is really -- I was forgetting this was being taped.

MR. KLINE: Getting back to what you were talking about on these threshold values that -- if I could prescribe to you or ask you at what point do you quantify and who would venture to say which objectives should be quantified, what errors are acceptable, an error acceptable to you might not be to your colleagues or to your patient, nor to the administrator of your hospital.

It gets into a very humongous problem of quantifying what is an allowable error. I think it is more reasonable to have an objective -- a goal which you strive to do the best that you can. I think that's the intent of what this --

DR. DEYE: That is not what you are saying. Doing the best you can is different than prevent.

DR. SMITH: You have language which you have told us that you feel comfortable with, and that really is a step better than you had last time. If you will after your statement put a qualifier that the NRC recognizes that zero error is not attainable but the objective here is to make error as low as can be reasonable attained -- really it is the ALARA concept -- if you will, after your high confidence of prevention make a qualifying statement that you

understand -- show us that you understand, demonstrate that you understand that zero prevention is not humanly possible.

If you will do --

DR. BRICKNER: Is that any problem?

MR. TELFORD: I think that there are words like that in the statement of considerations for the proposed rule, but we can certainly put --

DR. SMITH: If you make it clear that you understand that zero is not attainable, then I think we can do it.

MR. TELFORD: Could we revisit ALARA and minimize for just a couple of minutes here?

DR. SUNTHARALINGAM: Could I just make a comment prior to that? Again, I want to -- the fact that the prevention part has been identified as a second purpose is putting too much emphasis on prevention. To me, a QA program that we are asking everybody to activate, the primary goal is to detect and correct.

The fact that you are putting a second purpose and only indicating now provide high confidence that it will be prevented is putting too much emphasis on prevention.

MR. CAMPER: Let me interject, if I may. When you talk about detect, correct and what have you, those terms are all worthwhile terms in your --

DR. SMITH: But then, you --

MR. CAMPER: Let me just finish. You are correct that they are terms and concepts typically associated with quality assurance. I don't want you to misunderstand, the objective of this so-called quality assurance program thus far has been to prevent misadministration. That goal has not changed since its beginning.

DR. SUNTHARALINGAM: Then it's not a QA program.

MR. CAMPER: Let me come to that. This is a point -- I think your point about the use of the term quality assurance is a very valid point. It is a concept that we have wrestled with just as recently as this week, as we are literally re-writing the rule at this time.

For example, I can share with you -- I would qualify if I may, again, what John said earlier. Please understand that the things we are telling you now are conceptual and they are staff level, and by no stretch of the imagination final. One of the things that we have looked at is the use of the term basic, for example. Why basic? Basic implies that comprehensive may follow. There is a tendency amongst those of us writing the rule to eliminate the word basic entirely. There is also a concern about the use of the term quality assurance, for the very reasons that you are raising.

I suspect that if one went back and looked at the origin of the use of the term quality assurance it has, at

least in a significant part, to do with the idea that it would be performance-based. If it is going to be performance-based and there is this concept called quality assurance which is out there and it's used routinely and what have you, it could be that the term is not the right term.

Another thing that we have looked at in the 35.35(a) is the use of the term the objective of. We, thus far, are thinking of changing it to be the goal of a high confidence that -- and so forth. We are sensitive to the point you are raising, but I just want to emphasize again that the objective, the purpose and the reason for being is to prevent. We all recognize that zero is very difficult if not impossible. It may be that --

DR. SMITH: Can you just make a qualifying statement that you want to --

MR. CAMPER: It may well be that the way to handle that Dr. Smith, is to do something in the statements of consideration, a paragraph that addresses that point.

DR. BRICKNER: You have three points, all that may satisfy the thing. Number one is to change the name to quality management and make this a unique tool of NRC and not part of the quality assurance program in the hospital. This is a unique situation for NRC, of which everybody is probably used to.

Put the qualifying statement in. Glen used the word prevent because it seems to be one that is important to the fundamental goal of the NRC, but then with the statement that you realize zero is not an accomplishable goal or aim. Third, to change it to goal because goal implies something you strive for but are not mandated by law to achieve.

Those three things -- would those three things make everybody a lot more comfortable?

DR. SMITH: I can agree with that totally.

MR. CAMPER: Let me also add to that something else that may bring you some comfort on this particular point, to just kind of follow his thought process. The use of the term errors in our current thinking would no longer be there. We would specifically say misadministration.

DR. BRICKNER: Yes, I thought about that earlier.

MR. CAMPER: The term medical use would be replaced by the administration of byproduct materials.

DR. BRICKNER: That's good.

MR. CAMPER: We can get back to the use of the term misadministration later. We can share with you some thoughts about that as well, which I think you will also find favorable.

DR. BRICKNER: That would be wonderful, because every time that I sit down with somebody and say you want to look at this, that's the first hassle.

MR. CAMPER: We are tuned into that concern, yes.

MR. TELFORD: Could I revisit the ALARA just briefly. The reason that I didn't pursue ALARA in the beginning was because if you take the licensee's point of view, if my license says that I always have to be ALARA and forever improving, that seems like a ratchet that goes on forever. Taking the licensee's point of view, that does not seem to be attractive.

DR. SMITH: The ALARA concept.

MR. TELFORD: ALARA makes sense when talking about standing in a radiation field of 40 R per hour. But we are talking about ensuring that the byproduct material is administered as prescribed.

DR. DEYE: I think ALARA is there too. I think a patient accepts a certain risk --

MR. TELFORD: Yes, it makes sense, Dr. Deye. But as you as a licensee, would you like an open ratchet?

DR. DEYE: We never like ratchets, but that was an objection we raised to ALARA when you brought that out in 1979 with regards to radiation levels and we have learned to live with it, not only from your standpoint but from that of the quality improvement process that other people are imposing on us. I think we have now understood how to deal with that philosophy.

I think it's easier to deal with the philosophy of

zero in prevent. I think prevent and zero is more difficult to deal with than ALARA.

DR. SMITH: ALARA is the quality of life, and I think we really have come to a position where we even understand and are participants in that concept.

DR. DEYE: Right, because we get to help define reasonable.

DR. PAYNE: On the other hand, I can appreciate what is being said here, in that fortunately in the specific situations that I live in, I have not had to demonstrate three years ago and ratchet down two years ago, ratchet down some more currently, ratchet down -- we could be ratcheted forever. I agree.

If the NRC wants to take that stand then ALARA is going to be an albatross around our neck, because we are going to be constantly taking where we are and going to have to demonstrate that it is as low as achievable. That's tough. You can always sit there and say can't you get a little lower. We can just focus on every single program. You can look at every area that we work in under a license, and you take each one of those and look at -- that means you have to have documentation of each area, and then you have to see where you are, and the question is asked show me that you can't get any lower or can't you get lower. That puts a lot of burden on us.

DR. DEYE: Zero is even worse, and ALARA doesn't work that way. ALARA works by the burden is on the other person. If you have established as low as reasonably achievable, then one has to prove that no longer is it reasonable to be that low but you have to go lower. In fact, that is the way it is working. It is working that way with the annual limits on radiation dose. The burden is upon the community that says the dose level should be lower to prove that what we presently have is not reasonable.

DR. SMITH: What you are hearing from us is that we don't feel ratcheted by ALARA.

DR. DEYE: That's right.

DR. SMITH: That is not really what happens.

MR. TELFORD: I am just confessing to you. If I take a licensee's point of view, that's the way it looks to me. I didn't want to do that to you.

DR. SMITH: Take it from us, we are the licensee's, our point of view is that it doesn't work that way.

MR. TELFORD: Let's come back to that. The minimization concept, I don't object to that but if we adopt that, then we have the responsibility to say how low is low enough. We talked about that a lot. If the rate that you want is like one in 10,000 or some small number -- one in 10,000, you see, the Commission has applied a safety goal to

other licensees, and it is one-tenth of a percent. We talked about how do you implement that.

When a rule gets published in the Federal Register then in six months everybody has to have a program. They submit an application, we say it meets the rule and you get licensed. You are going to get inspected according to that license. The inspector comes and says are they really doing these programs, do they have these in place, are they being carried out. That is what they look for evidence for. If you have a misadministration it could be because you don't have a procedure that covers that area. Okay, now you have to have a new procedure.

It could be that somebody wasn't following it, which we see a lot of. You have to convince the people to do it. That is the way it would go. If you tried to implement the minimization idea, then you have to say one in 10,000. I have to prove to this licensee that I have treated 10,000 patients and have --

DR. SMITH: Never put a number down, John. Never put a number down, because they are always arbitrary. Once they are arbitrary they are dangerous.

DR. BRICKNER: We are now at 10:15. Did we agree that the three modifications would make it something that you can live comfortably with gentlemen?

MR. TELFORD: Dr. Smith, I was just agreeing with

your statement that you just made in saying to you that I thought that was full of difficulty; therefore, I didn't initially go after minimization.

Let's go back to Dr. Brickner's suggestions. What if in the first sentence under the (a) paragraph, what if we kept there prevent and detect the cause of misadministration and events. Then, as Dr. Suntharalingam says, don't --

DR. BRICKNER: You are thinking of changing medical use?

MR. TELFORD: Yes, make sure that medical use says the application of byproduct -- and administration of byproduct material. In the second sentence I can think of a couple of alternatives there. We could say the goal of the quality assurance program is to prevent misadministration and events to the highest extent possible, or we could say the goal of the QA program is to ensure that the byproduct material is administered as prescribed. That is a positive way of saying it.

DR. DEYE: I like the positive way of saying it.

DR. BRICKNER: The goal of the program is to see that the materials prescribed -- that's what you said the goal was. That is really the goals --

DR. DEYE: Exactly what is here may be a --

MR. TELFORD: We can say as directed as user.

DR. DEYE: First of all, you are not going to say

basic quality assurance program. We are talking about quality management program without the word basic there.

DR. SMITH: You need to eliminate reference to what is perceived in our legal community as something other than -- your prescription is a legal entity in the legal parlance. I would hope you would shy away from those kinds of words.

MR. TELFORD: You will be convinced in just a couple of minutes that I am thinking that.

DR. DEYE: You are now saying the goal of the quality management program is to -- what did you say?

MR. TELFORD: Ensure that the byproduct material is administered as directed by the authorized user.

DR. DEYE: That's great.

DR. BRICKNER: Is everybody happy with that?

DR. DEYE: Yes.

DR. SMITH: Yes.

DR. BRICKNER: That's a major step forward.

MR. TELFORD: That's paragraph (a). Now, let's go to each objective in turn. I want to give you the feedback of what I heard. Objective one -- in the record I found Dr. Bonardus said number one is great. Dr. Brickner agreed with him. Let's jump to page three.

DR. BRICKNER: You are going all the way to page two?

MR. TELFORD: You keep bringing up these words, and I realize that I need to clear up some words. Let's clear up some words.

Instead of prescription on page 115 of the transcript you say use written directive. On 127 you say drop the word prescription. Let me say yes, we can easily use written directive rather than prescription.

DR. BRICKNER: In those places where it is applicable, because we have one exception to even written -- telephone referral --

MR. TELFORD: That's correct.

DR. PAYNE: Where it has to be written it's written directive, otherwise it's a directive --

MR. TELFORD: Where you would normally say prescription we would say written directive. Referral is something different. We will get to referral in a minute. Calculated -- you said use calculated administered dose where we said administered dose.

DR. BRICKNER: Absolutely, because that's very important.

MR. TELFORD: That was on page 129, we can do that. For teletherapy, define the location or dose point your way. This was on page 111, and I think I am quoting Dr. Brickner here. Specify dose at the center line of the beam and at the intersection of the beams. In other words,

we would talk about something called location or dose point, and you have to define that.

DR. SMITH: We have to be careful --

MR. TELFORD: We can put an e.g. in there that looks just like this.

DR. SMITH: We are going to be talking about treatment plans that have more than one isocenter and beams. I think intersection of the beams, there may not be one intersection of the beams.

DR. SMITH: Listen to what he just said. Example given along the central axis. He said --

MR. TELFORD: That would be an e.g.

DR. SMITH: The directive is that you will define in your program the point.

DR. SMITH: Okay, I understand.

MR. TELFORD: Something else you told us for teletherapy was include the total dose, number of fractions in the treatment site or whatever we called that. For brachytherapy, you said we should use a pre-plan prior to going to the OR instead of what we called a prescription or what we will call a written directive. We would be after in the pre-plan to know the number of sources and their activities or their combined total strength or something.

DR. PAYNE: I made a comment that instead of activity I think we call could live with -- I think we could

all live with using strength. As we may be switching to air kerma or something like that, we may not be dealing with activity as most people would narrowly define it, namely bacharel units or something.

MR. TELFORD: If you are going to the OR for a brachytherapy procedure --

DR. BRICKNER: You don't know the number of sources.

MR. TELFORD: All right.

DR. BRICKNER: What you have is an intention.

MR. TELFORD: Do you know the number of sources to be taken to the OR?

DR. BRICKNER: To be taken, yes. I hope I come back with all of them that aren't in the body.

MR. TELFORD: Yes.

DR. BRICKNER: Those are my intentions. My intention as far as the patient is concerned is to implant a volume and to achieve some kind of a dose that I have in mind. If I say my intention is to implant the entire prostate I take with me 14 gold seeds. I don't know whether I am going to use eight or 14 because I won't know until I put my hands down in the wound, how big it is, how easy it is to get to, where the nodule is on the gland and how I am going to use the needle. So, I may use anywhere from six to 14 or eight to 14 seeds.

When I come out I can say I used 12. I want a dose of --

MR. TELFORD: That goes in the written directive.

DR. BRICKNER: That then becomes the written directive. My intention going in is to implant the entire prostate gland, period. Is that acceptable to everybody? What you go to do with an implant before you know what you are going to accomplish is to treat a volume, that's about all you know that you are going to do is treat the volume. You know what isotope you are going to use because you took it with you.

You know what isotope you are going to use because you took it with you. You know what technique you are going to use because those are the tools that you took with you. For instance, I either took seeds or ribbons. So, I could state those things. I could use iridium ribbons to implant the breast, but I don't know how many ribbons yet.

DR. PAYNE: You do know the strength, because I have to give them and I might have several choices. I have choices of --

DR. BRICKNER: State the strength I took.

DR. PAYNE: I may have different strengths.

DR. BRICKNER: Except in the common most one of all, you do an application to the cervix. You don't know the strength until you see somebody --

DR. PAYNE: Somebody tells me do you want 15-10-10 and then two 20's or do you want 15-10-10 and two 15's. You don't know that --

DR. BRICKNER: You don't know that until after --

DR. PAYNE: Where is the rectum relative to the --

DR. BRICKNER: My intention is to treat the cervix and not burn the rectum, and I don't know what sources I am going to use until after I see what I have accomplished. I would say --

DR. PAYNE: Sometimes we change them. We would start out with 20's and then look at the computer printout --

DR. BRICKNER: What I am saying your intention is what you are going to treat and what type of implant. That's about all you know.

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

DR. BRICKNER: Yes, sir. Everything about number of sources and --

DR. PAYNE: I guess the question now is, does the pre-plan -- right now I have to admit, our pre-plans are not written. A lot of pre-plans are not written. It appears that we are going to go to written pre-plans.

MR. TELFORD: Let's come back to that, because that's really part of objective two. I am trying to clear up words right now.

DR. SMITH: You know, you don't specify source strength when you talk about cobalt-60 teletherapy. You don't even talk about source strength. In the same way, you don't need to talk about source strength here.

DR. BRICKNER: We are talking about brachytherapy.

DR. SMITH: I know. I am saying -- I know we are talking about brachytherapy. You don't have to specify the source strengths in this situation no more than you would specify the cobalt strength when you are talking about teletherapy.

DR. BRICKNER: There's a difference.

DR. PAYNE: On loading you do.

DR. BRICKNER: There is a difference. This is where you have a potential to screw up by loading the wrong source strength. You don't take the source out of the machine for each patient and put in a different source.

DR. SMITH: I understand that. Specifying source strengths up front is not necessary. I was actually agreeing with you.

DR. BRICKNER: No, not before -- no, you don't specify source strengths in the pre-plan. You can't.

DR. SMITH: That is what I was trying to say. I was agreeing with you.

DR. BRICKNER: You may not even put anything. You may put applicators in --

DR. PAYNE: You have situations where you put dummies in, and you have situations where you put real things in.

DR. BRICKNER: You don't choose your source strength until after you see the implant.

DR. SMITH: That's true, so it shouldn't be up front.

DR. BRICKNER: So, what it is that you know ahead of time when you go the OR is the volume you want to treat and the technique that you are going to use to treat it, whether it is afterloading or seeds. If you take material with you that you are going to use, if there is no option, then you can so state.

In a fair number of our cases we will put empty containers, take x-rays, calculate what will happen with different loads put into those containers, then pick the afterloads.

MR. TELFORD: That's a special --

DR. PAYNE: I guess you could have afterloading procedures versus direct loading. I suppose you could use those terms. In direct loading you do have to take the right stuff. In afterloading, then you usually leave the --

MR. TELFORD: Dummies in, find the location and then you have --

DR. PAYNE: Direct you to put the right stuff in.

DR. BRICKNER: In larger institutions, even keeping inventory of iridium on hand. They may decide ribbon strengths. Do you want to go that far? Do you want to start making subsections and doing all that? I think that's --

DR. SUNTHARALINGAM: Because the variables on page 131 again, I had indicated I was in favor of deleting all that and just saying that the physician, at the time of writing an intention of treatment can only give us total dose, can give us the radioisotope that he wants to use, and the treatment site. Those are the three things which can be put down as a written directive.

MR. TELFORD: Are you talking about the pre-plan or the written directive?

DR. SUNTHARALINGAM: Written directive, going into the pre-plan or whatever it is.

MR. TELFORD: Pre-plan is when you go the OR. Written directive is after you come out of the OR.

DR. SUNTHARALINGAM: No, no. But in the -- before going to the OR, when the physician decides he wants to do a brachytherapy procedure the information he needs is available and gives it to the people in the department that he wants to deliver a certain dose, I want to use this isotope and here's the site.

Then there are variables, depending on the type of

isotope, the type of implant -- whether you do it in the OR or whether you do it afterloading -- not remote afterloading. What you take to the OR or what to take to the patient's room, all of these then become variables depending on how your dose is going to be administered.

In the initial phase, on page 131, there was this question of does one say source trend and combined activity and things like that. I suggest that you delete that section.

MR. TELFORD: You are jumping ahead.

DR. SUNTHARALINGAM: Are we on page 105 then?

MR. TELFORD: No, we were on words.

DR. SUNTHARALINGAM: Words, but --

MR. TELFORD: We were trying to clear up words.

DR. SUNTHARALINGAM: The words are coming in according to what the page is.

DR. DEYE: Why do we need pre-plan?

DR. BRICKNER: Because they ask for a written directive "prescription" for all brachytherapy and we can't give them one that includes anything about sources, either number or strength in certain situations.

DR. DEYE: Therefore, maybe it is --

DR. BRICKNER: Except for the concept of stating ahead of time that you wanted to give 3,000 rads to a prostate.

DR. DEYE: Therefore, it's not germane to regulation possibly by byproduct material license. Maybe it only becomes subject to regulation once the sources are actually loaded into the patient. We don't need to discuss pre-plan. I am suggesting that we might drop the whole concept of pre-plan and leave that up to the physician, which is where it properly belongs, to be thinking about pre-planning.

The physician then goes to the OR and does what he or she needs to do. Once the sources are in the patient it becomes a regulatory concern, and then we start writing wording to deal with that issue. The sources that are in the patient agree with the written directive or documentation that the physician puts into the chart. If the physician comes back from the OR and says I implanted 16 sources in the patient's prostate expecting to deliver a dose of x-rad or gray over such a period of time, it is now the responsibility of the licensee to ensure by all methods possible that that's in fact what occurred; that the source count is correct, that the dose distribution is going to result in the dose rate and total dose that the physician has written, et cetera, et cetera.

It only becomes a regulatory concern once the sources have been applied to the patient. Pre-plan is not appropriate here.

DR. PAYNE: I will disagree in terms of we are doing a lot of prostate implants now. They are being done by a urologist and a radiation oncologist that are not a part of our department, they are from the outside coming into our hospital from the outside. I have to order the seeds. The way it works is, the radiation oncologist at another facility fax's to me the patient's name and how many seeds he wants in the activity. I want him to sign that, because I have to go and order. Then we have another real practical dilemma. I call 3M Company and I say I want some .33 millicurie seeds and I want 50 of them. They look in their inventory and say we don't have any .33. We have some .37. I will take something that is 12 percent out of it. Then I have to say okay, I will call the doctor back. Anyway, we have this process of working out the strength between what 3M has in inventory, what he wants, what is going to work. I want his signature on there because I don't want to be held liable for entering the wrong sources.

I got to order. Then we have three patients that are going to be done that day, and they all have different source strength. I don't want to give the wrong patient the wrong strength. I have to have -- now we even have a more problem. I have like 105 seeds for patient number one. 65 seeds for patient number two, and we put a bunch of them in. There is where you get into the doctor's discretion at

jamming these seeds in. We order 15 more than they know they are going to put in, but they hit bone and do things.

We end up with ten extra seeds in bottle number, so we set it aside and go to the next patient. Now, oops, we can get all of them in and he says I really need some more. Let's take five seeds from bottle one and put them into patient number two. We have had no written directive to do that, but he told me to do that. He's a doctor. I don't think we want take that away from him, his ability to give five seeds that had to --

DR. DEYE: That is my point -- my point is exactly that.

DR. PAYNE: Okay, but I'm saying --

DR. DEYE: All of those matters are administrative matters and should not be regulatory in framework. They should only become part of the regulatory framework once they are in the patient and you have to guarantee the regulatory authority --

DR. PAYNE: I still want to get the right seeds in the right patient.

DR. DEYE: That's an administrative problems. You have to deal with that in your institution and with your ordering.

DR. PAYNE: Okay, so I have --

DR. DEYE: You have to deal with the right seeds

and the right number of seeds in the patient after they are in the patient.

MR. TELFORD: We have a small problem. That's a known cause -- the problem that Dr. Payne is alluding to is a known cause for brachytherapy misadministration.

DR. DEYE: Which problem is that?

MR. TELFORD: The person pulled out the w seeds, took them to the OR and the physician put them in. They put in the wrong seeds, okay. If you want to hear this talk later -

DR. DEYE: I understand that. I know the cases.

MR. TELFORD: The person pulled the wrong seeds out of the drawer --

DR. DEYE: The problem is --

MR. TELFORD: There is more than one strength that was kept in the same drawer.

DR. DEYE: I understand that. The problem is, the administrative details of ordering the sources you deal with in other ways. You deal with those in terms of checking out the receipt, in terms of licensing of the people that deliver, in terms of licensing of those who receive, et cetera.

DR. PAYNE: That's a process in place and --

DR. DEYE: But don't bring that into the therapeutic process. Don't talk about pre-planning, and

don't talk about source strength. Those things are already dealt with in other aspects of the byproduct process.

DR. SUNTHARALINGAM: In many places the physician does not know even to give us that information, because the information is generated some other place. The physician is only saying that I want to deliver this much dose with this isotope. Somebody will go in and do a calculation.

DR. BRICKNER: Somewhere when you walk in with seeds, you and the physicist both need to know what the strength is.

DR. SUNTHARALINGAM: Fine, but not on day one of the area you are trying to sign off. You are now going into --

DR. BRICKNER: Before you pick up the needle --

DR. SUNTHARALINGAM: Yes.

DR. BRICKNER: -- or the implanter, you need to know that you are both talking about the same strength you had in mind when you did the pre-planning.

DR. SUNTHARALINGAM: Yes, that's during the procedure.

DR. DEYE: Define pre-planning.

MR. KLINE: Can I make a comment. I think you might be confusing pre-plan and written directive. Either of those methods is amendable. Either can be changed throughout the process. It appears to me that if you are

going to do a procedure you have to know somewhat if you are going to use so many seeds you are guessing, you are not sure, you have to have somewhat of a reason for going up there. If you come back later and insert a different group of seeds you can amend your written directive. you can change it constantly until it is exactly what you are going to give.

I don't see how that pre-plan is a problem. You have a plan anyway when you go. Your objective is hopefully to implant so many seeds to do so much irradiate a volume based on how it looks when you are in the operating room. It's irrelevant -- that's your initial plan. You can change that pre-plan. I think we are focusing too much on once you make the pre-plan you can't change it. Anything can be amendable.

The final prescription has to be -- the written directive has to reflect what was really give. That is the judgment call of the physician.

DR. SMITH: What are we talking about. What is the basic principle of what we are talking about here, because I have no --

MR. KLINE: A plan by which you know that you are meeting certain objectives as you go up to insert your seeds. In other words you have to have certain things you know before you go. You have to know what isotope you hope

to use --

DR. SMITH: Specific language --

MR. TELFORD: Let are getting completely -- let me suggest that we are done -- we are completely talking about words, which is page three. Let's go back to page one. Let's pick up objective two, where we are talking about brachytherapy.

DR. DEYE: Let's stay with definitions for a minute. When were you going to talk to us about misadministration, since that's a term and you said you had something to fill us in on.

MR. TELFORD: That's under the proposed rule, that's covered under the reporting requirements. That follows the objectives. That follows 35.35.

DR. DEYE: We will come back to definitions later?

MR. TELFORD: We are going to come back to that. That is on your agenda for 11:15 where we are talking about teletherapy and brachytherapy.

DR. DEYE: All right.

MR. TELFORD: Are we all on page one, objective number two, brachytherapy. What we heard was that for brachytherapy you use a pre-plan. Reference page 100, then have the authorized user sign the written directive prior to completion of the plan. In other words, the pre-plan tells you what you are roughly going to do in the OR. It tells

you the number of sources, it tells you their activities so that you know if you are going to implant or use a ten-ten and 20 or two ten's or two 15. You know what to bring. That's the pre-plan.

When you get out of the OR then you do the calculations and you decide how long to leave them in. I assume you are not talking about a remote afterloader here or high dose rate application.

DR. SUNTHARALINGAM: Can we just stop there, if that is your concept and definition of pre-plan, and this is where we ran into a problem last time. Again, there are so many brachytherapy procedures that writing some general statement like this will put all us into difficulties.

DR. BRICKNER: The admission history and physical would be a written thing. Patient is admitted --

DR. SUNTHARALINGAM: See, as I said -- in a pre-plan the physician can give us the intent of the total dose, the isotope to be used and the site. There are many instances where we will -- they will say bring the iodine seeds to the OR and the decision will be made right there in the OR as to -- based on what volume they establish and each department might have a different -- based on their practice how many seeds they want to use.

All those are decisions now made in the OR. Once they are in the pre-planning stages -- the pre-plan will say

bring 50 seeds or bring 30 seeds.

DR. BRICKNER: That's fine, you can amend it. It can be changed in the OR.

DR. SUNTHARALINGAM: No, but there is no need to amend it. All I am saying why put in a fictitious number --

MR. KLINE: In your case it might be fictitious. Let's look at a lot of reported incidents that come to the NRC -- it's not fictitious.

DR. SUNTHARALINGAM: Maybe they need --

MR. KLINE: It is put in and they are wrong. We even have wrong isotopes used, wrong activities and seeds. The pre-plan might help prevent this so that everybody is in synchronization, the orchestra has one conductor. If he wants to change the tune he can stop the orchestra and say we are going to do a different tune.

DR. SUNTHARALINGAM: Now in this rulemaking you are again going back to essentially telling each one, do it this way. You are trying to say --

MR. KLINE: No. There are certain minimum guidelines that you have to follow. We can't just say do it anyway that you want, or else what is the sense in even having a rule.

DR. DEYE: I think what he's saying Suntha is, you can't get a call anymore from the OR saying bring me 50 iridium seeds.

MR. KLINE: You have to have --

DR. DEYE: Unless the doc has written it in the chart somewhere that he called you and asked you to bring 50 iridium seeds to the OR on such and such a strength.

DR. PAYNE: I want that, because I don't have one happy family. I have an unhappy family, and when I have an unhappy family, I want to protect my butt.

DR. SUNTHARALINGAM: We are now going into the --

MR. TELFORD: Dr. Brickner, would you like to try your pre-plan definition one more time?

DR. BRICKNER: I see no problem for the physician to make a statement that he intends to use a brachytherapy modality and a specific isotope to treat a specific volume, to some range of dose. Whether he writes that up on a sheet of paper and signs it and gives it to the good doctor here or whether he states that in his admission history and physical and plan of therapy at the time he admits to the hospital, somewhere in his chart he has said I am going to give a standard cervical application to this lady with cesium 137.

I want to deliver 4,000 rads to point A. If he hasn't said that, then what the hell is he doing?

DR. SUNTHARALINGAM: That part we want to --

DR. BRICKNER: He said that and that's a pre-plan.

MR. CAMPER: Could you then please clarify for the

record minimally -- if we were going to design pre-plan --

DR. BRICKNER: Site.

MR. CAMPER: It should include what, site?

DR. BRICKNER: Site or volume, whichever word rings your bell.

DR. SUNTHARALINGAM: Site, volume, the dose --

DR. BRICKNER: Isotope, method, end.

DR. SUNTHARALINGAM: Did you put on the dose?

DR. PAYNE: Dose, I will contend -- again, I am anecdotal. We do not necessarily fix the dose.

DR. DEYE: He's not saying that.

DR. BRICKNER: It can vary. The dose can --

DR. DEYE: Nobody is saying dose --

MR. TELFORD: This is pre-plan.

DR. DEYE: This is pre-plan. That's not even a question.

DR. BRICKNER: The dose can change according to what you have accomplished. I would say isotope, site and methodology. You know whether you are going to use seeds or iridium ribbons, or you are going to use a --

MR. CAMPER: If we create a definition of pre-plan and it contains minimally those items --

DR. SUNTHARALINGAM: Yes, that's exactly --

MR. CAMPER: That would be palatable.

DR. SUNTHARALINGAM: I might even ask the

physician that I am going to ask again the question, if in their thought process they are taking a decision that this patient requires a brachytherapy treatment, you already in your thought process have at least an approximate range of dose.

DR. BRICKNER: Yes.

DR. SUNTHARALINGAM: You might want to do it with. The intent is to try to say deliver -- I am taking a breast boost -- 2,000 centigrade, that was the intent. Later after the first implant, you might change and say based on what you saw in the implant --

DR. BRICKNER: The best we can do --

DR. SUNTHARALINGAM: The best we can do is I am only going to deliver 1,200 centigrade - -that is a forced implant. So, even accepting some dose information but in terms of the number of sources and what activity of the sources, all that to go into a pre-plan --

DR. BRICKNER: No, we couldn't do that. If it is terribly important we can make a general dose statement.

MR. CAMPER: Is dose range then acceptable?

DR. SUNTHARALINGAM: The 1,500 to 3,500 --

MR. CAMPER: In the pre-plan.

MR. TELFORD: The word range or approximate dose?

DR. BRICKNER: Dose range is good.

DR. SUNTHARALINGAM: It is, again, intent of

treatment. That is what we are after.

DR. BRICKNER: But open to change, depending on what --

DR. SUNTHARALINGAM: Yes, that's right.

MR. TELFORD: After the OR then you sign the written directive which says delivered 1,200.

DR. SUNTHARALINGAM: Yes.

DR. BRICKNER: And then you define, at some point --

DR. SUNTHARALINGAM: That is not --

DR. BRICKNER: That's when you define source strength, number of sources and specific dose.

DR. SMITH: Your intent here -- let's understand your intent. You want people to arrive at the OR room with some idea about what the hell they are going to do when they get there.

MR. CAMPER: That's right, a game plan, exactly.

MR. TSE: Dr. Brickner, I have a question. At some point the physician will be involved in what kind of source strength --

DR. BRICKNER: Yes, sir.

MR. TSE: You need. What is that point? It must be before the administration of the byproduct --

DR. BRICKNER: No -- before the administration, yes. If I have empty applicators in the patient, the

physicist and I will sit with the films and talk and make and decision and I will say yes. When I say yes, that's the source strength that should be put down on paper and signed off.

MR. TSE: Right. The physician will be involved?

DR. BRICKNER: Yes, sir.

MR. TSE: Also, somebody must go to somewhere -- either purchase or order or go to the storage room to pick up those sources.

DR. BRICKNER: That should be done.

MR. TSE: Now, is there any place that possibly a written directive to say I need those sources --

DR. BRICKNER: Yes. Time after time when Suntha and I sit down an hour after surgery and look at the orthogonal films and start arguing, when we finish that discussion or argument and decide on what seeds or ribbons or whatever to use, that would be a perfectly reasonable time to say you should dictate a note stating what your decision is and that should be signed by one or both of you at some point.

MR. TSE: I think that is our intention here.

DR. BRICKNER: Yes, sir, I understand that. I have no trouble with that at all. In our department for instance, if Suntha was working with me I would not go up and put those sources in, because I can get somebody else to

do it for me. He would go up and say put the sources in, and then he would write in the chart what he put into the patient.

I would have already dictated a note saying what we wanted to put in the patient, and he would document what he did put in the patient. When we took it out three days later we would document what we took out. That's just the way we do it.

MR. TSE: Somehow those procedures should be done for every --

DR. BRICKNER: I think so. I think that is perfectly reasonable.

MR. TSE: I think that is our intention with this particular --

DR. BRICKNER: As the pre-plan I am going to say --

DR. SMITH: He's leading you down a road I don't think you want to go down here.

DR. BRICKNER: When I have agreed on a strength which is after the procedure is done for some things, that's when I would document the strength. That is after the surgical procedure.

DR. SMITH: I think he's trying to get you to pull that into your --

MR. TSE: No. What I am saying is that before the

administration of the byproduct material, you need something such that certain people can -- your employees can pick up those sources correctly for the administration.

DR. PAYNE: I truly believe, in terms of your regulatory responsibility and just the facts of the world, I think we have to divide brachytherapy into two sections; namely, the direct application of radiation at the time of the procedure. That has to be dealt with differently from the afterloading situation, whether it is remote or computerized.

You have to have two. You cannot easily make changes in a direct application. With the afterloading procedure you could always make changes. We can always take sources out and we can take them out now, we can take them out tomorrow if we find out we have made a problem, if we had loaded the wrong sources, we can pull them out. We are going to have to divide brachytherapy into two sections, the direct application process and the afterloading process.

MR. TELFORD: Let's follow that thought process for the moment. Dr. Brickner, tell us what you would put into a pre-plan for the direct application.

DR. BRICKNER: Source strength. I would want to -- I think you should state then that I want my seeds to be .5 millicuries. I want the source type -- I don't know that I need to say how many I want to carry to the operating

room, but I want to implant the prostate. I want to do it with gold. This is something that we did for a long time. Do it with gold, and I want all the seeds to be .5.

Once I have said that I have covered myself. That's what I want and he knows what he is supposed to bring. He should understand that I always used at least eight and I like to have 14 on hand. I don't know if that needs to be written down. He knows not to bring one millicurie or five millicurie. I said .5. Or, he brings iridium needles instead of gold seeds, and th n we have a real discussion there and embarrass the nurses.

That meets your disaster criteria, when the guy brings instead of .5 he brings fives. Then you have rectal ulcers and all kinds of horrible things.

MR. TELFORD: We can understand that after implant --

DR. BRICKNER: For direct application.

MR. TELFORD: For direct application, then you would do the calculations and determine how long they would stay in or what total dose would be. Then, you would sign off on the written directive.

DR. BRICKNER: Usually direct application is total -- the permanent implant, usually. Just leave it like he said.

MR. TELFORD: Let's go back to afterloading. What

would you put in the pre-plan for afterloading?

DR. BRICKNER: What I wanted to treat, again, site, methodology -- you probably ought to say I am going to use iridium ribbon needle application. I guess you could say a dose range, that my intentions are to deliver approximately -- you don't need to say it then. What you are really saying is I am going to take needles up and I am going to implant only the left breast and I want a homogeneous dose distribution there.

That's it. You just -- I am going to take needles -- for iridium ribbons I am going to take needles and implant the tumor volume of the left breast, period. You could say what the dose range is going to be, but you may change it later.

MR. TELFORD: Isn't that a direct application?

DR. BRICKNER: No.

DR. PAYNE: I will be the devil's advocate. I will say for the afterloading, why do we need a pre-plan?

DR. SMITH: What if you are talking about high dose rate afterloading brachytherapy --

DR. PAYNE: That has to be separate --

DR. PAYNE: Now you really have a problem with what you just said.

DR. BRICKNER: That's a totally separate thing. I think that's a unique situation that has to be dealt with

separately.

MR. TELFORD: A subset of afterloading.

DR. BRICKNER: Yes. Average afterloading, about all you can expect the doctor to say is that I am going to do t[illegible]east and I am going to do --

MR. TELFORD: Don't you need the written directive prior to really starting the high dose rate remote afterload?

DR. BRICKNER: Yes. We are doing a breast now. Somewhere along the line you and I have a discussion and you have to order ribbons. Does that all need to be written down someplace for them?

DR. SMITH: Call this low dose rate afterloading.

DR. BRICKNER: What they need to know is what did you put in the patient. Did you put in what you intended to put in and does it give the dose that you intended to give. The only time that you need to talk about -- you need to be aware of strength or number of sources is after this hollow tubes are in when we sit down and do the plan and decide how many ribbons to put in the tubes, that has to be documented and the dose calculated.

MR. TSE: That's before the administration of the --

DR. BRICKNER: After the surgery, before the administration. Always before it is stuck into the patient.

That is not strictly true. Sometimes you will say that looks like a 15-10-10 and put it in and we will do the calculations this afternoon and change it if we have to. We are going to do it that way, no matter how you write the regulation because we are not going to have a patient lay around upstairs for four hours immobilized in bed while we wait for the computer to run.

DR. SUNTHARALINGAM: I, again, want to emphasize that there are multiple brachytherapy procedures with multiple radioactive nuclides -- trying to say what should be minimal requirement and irrespective of Dr. Brickner, just as you have your four physicists differing in our opinions over what exactly we might want in there from the physical aspects.

At the moment, unfortunately, Dr. Brickner does not have any therapists sitting around the table to question or say I might disagree. Depending on each type of application what exactly we do and what we don't do and depending on whether it is a small facility, it is going to be very difficult to say this and this. We know the physicians intent, they want to deliver a certain dose, they want to use a certain isotope to a certain site. That is the minimum requirements that they can put down.

Before application of the actual sources, now you can sit down and say we are putting in so many -- the

document has to be there and signed by the physician. We are putting in so many sources of such and such a strength and are treating at such and such a dose rate.

MR. TELFORD: For a certain time.

DR. SUNTHARALINGAM: For a certain time.

MR. TELFORD: That's the written directive.

DR. SUNTHARALINGAM: That is now the written directive, which is just before putting in the source, irrespective of which type of application you are trying to do. Then there is the removal of the sources and whatever procedures of the moment currently one has to follow through NRC. Leaving it general like that -- otherwise we are going to run into problems.

DR. PAYNE: I think your comments earlier were very -- are we working as a team. In other words, is there communication? Somehow you are going to have to write more -- I would hope that you end up with general language, because brachytherapy is going to change. It's a moving target.

We have to be working as a team, the physician, the physicist and any dosimetrist technologists. Somehow your language -- the problem that I see is when we get into language of ten percent of dose, ten percent deviations. That's crazy, because we are going to be constantly amending plans.

MR. TELFORD: Let's come back to that. That is a real interesting point --

DR. PAYNE: I am just being general. I can't disagree that we have to be a team and somehow we have to be communicating. I am just pointing out the pitfalls.

MR. TELFORD: Could you give me some more guidance on the high dose rate afterloading?

DR. BRICKNER: I can't, because I don't have one.

DR. SMITH: Let's don't be that specific. I think Sunthar made a very good point. I think you need to have pre-plan written directive that makes those general. In fact, I think all of us would say that when we go to teach residents brachytherapy it is such a complex issue with types of isotopes, applicators, procedures, high dose rate, that it is impossible to even teach.

How the hell can you cover in this the kind of language if you start getting more specific. You can't possibly cover all the types of procedures and applicators. I think you must do what Sunthar says, have a pre-plan which states what he said and then a written directive for all brachytherapy procedures.

DR. BRICKNER: That would cover high dose rate.

DR. SMITH: It won't cover high dose rates.

DR. BRICKNER: Site, --

MR. TELFORD: Didn't you say about the same thing?

DR. BRICKNER: Site, isotope, dose. High dose rate has to do the same thing.

DR. SMITH: Don't have different language for different kinds of brachytherapy. That is never ending. You will never get to the end of it.

DR. BRICKNER: Again, in high dose rate, what you would do is your written directive would be the calculations of how long the sources stays at each position or whatever it is. I have never seen one of those.

DR. SUNTHARALINGAM: We will wait for some of your reports -- you people tend to think it is many, all relative in terms of numbers. You are using the word many or few. The problems in brachytherapy that you run into is if you have sources long-lived, isotopes, because they are being reused there is a potential for the wrong source being pulled out and put in the wrong patient. Therefore, many people look at it as are we going to reuse some sources which may be short-lived, or do we minimize the potential of error by just adding more cost to medical care by just discarding after one use.

You can take that approach, which some people might say the headaches of keeping an inventory. As part of the physicians and hospital -- they always get seeds iridium .5 millicurie per seed or one millicurie per seed. Order a shipment and that will be the activity. I will keep in

storage, and that is where I run into problems. Those are all the logistics of trying to carry out a brachytherapy program. If the intent is what we are trying to put on paper -- I think we have thrashed this around now enough.

MR. TELFORD: That's a pre-plan. You said for brachytherapy use a pre-plan, and then you said use a written directive prior to completion of the plan. In other words, if this is a temporary --

DR. SUNTHARALINGAM: Reactive isotope --

MR. TELFORD: If this is a temporary and not a permanent -- no, any kind of implant. Before the clock stops and it is most applicable if it is a temporary implant. In other words, completion of the plan that means before the clock stops. The written directive must be signed.

DR. SUNTHARALINGAM: Before the clock stops?

MR. TELFORD: Yes.

DR. SMITH: Before you turn the high dose rate button on you better know --

DR. SUNTHARALINGAM: It wasn't before you put in the source.

DR. SMITH: Before you put them in, not before you take them out.

DR. SUNTHARALINGAM: I thought it should be before you put --

MR. TELFORD: For anything?

DR. BRICKNER: Yes.

MR. KLINE: We are talking the same here, the written directive. It is just a matter what the pre-plan will include. You have to, before application, include this minimum information; number of seeds, source activity per seed --

DR. SMITH: Not the pre-plan.

MR. KLINE: The written directive. You have to have that criteria in order to do dose calculations and follow your written directive.

DR. DEYE: The written directive should be signed before completion of the procedure for afterloaded and before loading up the patient with direct loading procedures. The direct loaded, the written directive needs to be signed before you load the patient.

DR. SUNTHARALINGAM: Then I have a problem.

DR. DEYE: If it's an afterloaded situation it has to be signed before completion of the procedure.

DR. SUNTHARALINGAM: Then I have a problem. Let's take prostate iodine implant as an example. You go into the OR to do the iodine seeds, while you are implanting you are making the decision of how many seeds you are putting in. You don't know when you start. Until they go in there they may do some dimensions and things like that and they know

approximately.

Put down an approximate number and then do it, and then say we finally ended up in the OR putting in 72 seeds. That is what you are essentially saying.

MR. TELFORD: If we said prior to completion of the plan or completion of the procedure.

DR. DEYE: This is a long procedure, you leave them in forever.

DR. SUNTHARALINGAM: Technical procedure.

DR. BRICKNER: There are two situations, but I think we cover them both. The pre-plan states site, intended dose and some range, and isotope that you are going to use. For those interstitial programs under dose, you can say we will use 50 to 150 iodine seeds. You do it. The written directive says I used 74 and the dose will be.

DR. DEYE: When does that get signed?

DR. BRICKNER: As soon as you get the calculations done, which --

MR. TELFORD: How about before you stop?

DR. BRICKNER: Once you have implanted those seeds it doesn't matter anymore, because you ain't going to get them back. Those are permanent implants.

MR. TELFORD: You have --

DR. BRICKNER: After they are implanted, in that case. Now, for all other situations other than permanent

implants, it should be the intentions stated the site; the dose and the isotope. After you have put the tools in place and before you put the isotope in the body, you have decided upon the source strength and the number of sources, agreed on that and signed it off.

You say ahead of time here are the parameters I am going to be working in, 50 to 150 seeds.

MR. KLINE: Can you think of any other situations, the iridium 192 breast implants, anything that is not a permanent seed.

DR. SUNTHARALINGAM: The iodine palladium is being used.

MR. KLINE: The distinction needs to be made between temporary and permanent.

DR. SUNTHARALINGAM: Exactly.

MR. KLINE: And which high dose afterloading device would fall into temporary.

DR. BRICKNER: They would fall into the temporary. They would be covered under Sunthar's discussion, just like any other implant.

DR. SMITH: If we use the concept that we have come up with teletherapy -- we use the concept of calculated prescribed dose. If we used that same concept over here, calculated prescribed dose -- once you have calculated and prescribed the dose, then that is the written directive.

DR. SUNTHARALINGAM: That's right.

DR. SMITH: That applies across the board to all kinds of -- doesn't it, calculated prescribed dose?

DR. DEYE: I think he said --

DR. SUNTHARALINGAM: He said calculated administered dose.

DR. DEYE: What are you doing on the permanent implants; what are you going to require?

MR. KLINE: I was trying to understand what you were talking about as far as the best calculation occurring after the implant is in.

DR. SMITH: The directive can't ever be written until the calculation is made. If you say the calculated administered dose -- in this case -- you have covered it.

MR. TELFORD: You have told us this is for the written directive for brachytherapy. You have told us that for the permanent implant you sign the written directive after the actual loading of the byproduct material in the patient. At some point you want a couple or three days or something --

DR. BRICKNER: Something reasonable.

MR. TELFORD: Something reasonable, is what I would guess.

MR. KLINE: That's the question, what is reasonable time. What would be a reasonable time.

DR. BRICKNER: Three days is plenty of time.

MR. TELFORD: What does the ACR advise?

DR. SMITH: I think you are getting into detail that you simply don't need to get into.

MR. KLINE: They do, if they are going to regulate.

MR. TELFORD: Dr. Smith, we have lawyers to deal with who insist on a time. Three days is a practical and reasonable time.

DR. SUNTHARALINGAM: On this whole concept of permanent implants, there is still even a lot of discussion going on as to does dose have any meaning. There, the dose is going to be written down. For many years people just put total activity, number of seeds times activity. That was what was reported. This dose number is --

DR. BRICKNER: That's still --

DR. SUNTHARALINGAM: Right, so we have to be careful putting into a regulatory requirement that you now specify dose also. I am sitting here thinking about that, because it took quite some time before people decided there and what dose to say.

DR. BRICKNER: That is something that you decide when you write your QA program, what you mean by dose.

DR. SUNTHARALINGAM: What you mean by dose.

DR. BRICKNER: Your dose is your definition,

correct? Dose is definition, and my definition may be different. I may settle for milligram hours equivalent and you may want rads on the surface of the sphere or something.

DR. SUNTHARALINGAM: As long as the NRC staff recognizes that this term dose in permanent implants, it can be interpreted differently, very differently.

MR. TSE: Earlier you mentioned the dose, and I believe we have a problem. Somebody said they want to use hours and therefore they are not going to determine the dose. Therefore, in our proposed rule in the kind of brachytherapy definition we have the dose or activities. We have a choice.

John, I think I hear more the discussion about pre-plan and the written directive. I think that probably we have some concern with the term of what it means. I think a pre-plan, what we are thinking about is the one who writes before the administration of the byproduct material, which originally we called prescription. Based on our discussion under some circumstances, you cannot write that.

We say that pre-plan would be before administration of byproduct material. To base our discussion, I think everybody agrees that you should know what sources you want and what strength you want, and that is why we --

DR. SUNTHARALINGAM: Fine. Just before putting

the sources in that information is available.

MR. TSE: Right. I guess the discussion now looks like we can divide into two different parts. One is for permanent implant which may not even need to write something or write something after the implant. For non-permanent implant, before the administration of the byproduct material, some written directive should be written either including the dose or including the source or source strength. Is that a correct interpretation?

DR. DEYE: That's reasonable.

DR. SUNTHARALINGAM: That's fine.

MR. TELFORD: How are we all holding up? Would you like a break, or should we continue on until lunch?

The other bullet under objective two that I heard was for teletherapy, and how the written directive -- before you start -- not a verbal. We are on page one of directive two. Page two of the summary, objective two, second bullet. It says, please read it this way. For teletherapy, have a written directive before you start and not verbal.

I used that prescription word because it is actually in the transcript. I want to translate it for you now.

DR. BRICKNER: Yes, absolutely.

DR. PAYNE: Then there is an emergency situation qualifier.

MR. TELFORD: Definitely. There is an emergent condition qualifier that we have problems to everything.

DR. BRICKNER: Dr. Bogardus and I told you, many of the errors that we see are verbal communications.

MR. TELFORD: Okay, objective three. I heard three things. The first bullet is take out the word prescription and -- objective three is all about the referral. The second thing that I heard is use a telephone referral as an alternative to a written referral. In other words, you can have a written referral if you like and you can have a telephone referral if you like. If you have a telephone referral, you said get the following information.

Get the patient's name, the requested study, the clinical history, the patient's date of birth and some other I.D. number like social security number, the referring doctor's name and today's date.

DR. DEYE: I assume that clinical history could be extremely brief.

MR. TELFORD: Did I say brief clinical history?

DR. DEYE: No, I am just making sure that we understand that.

DR. BRICKNER: Leave it as it is. Clinical history -- I want the damn study, what do you mean.

DR. SVENNSON: This is only for diagnostic?

MR. TELFORD: Yes, sir. Objective three only

applies to diagnostic studies.

DR. DEYE: I think put the word brief in t[illegible], brief clinical. You are going to have a lot less trouble from the society of nuclear medicine.

MR. TELFORD: Third, you said eliminate the signature requirement.

DR. BRICKNER: Yes.

MR. TELFORD: You have recorded that the referring doctor's name in your log -- that's all you need.

DR. BRICKNER: That's an interesting point with our people. They have quality assurance programs set up with operative manuals on how to do things in the safest and best way, and that writing an individual signature or and individual prescription for diagnostic procedures is an invitation to make mistakes. They thought it was going to disarm their QA program.

MR. TELFORD: You just about convinced me to throw out the signature requirement.

DR. BRICKNER: You have criteria and controls set up on how you do your diagnostic studies --

MR. TELFORD. We think of that as the clinical procedures manual.

DR. BRICKNER: Right.

MR. TELFORD: We also think of the clinical procedures manual as standing orders from the authorized

user. You do the study this way and the other study the other way. If you get gall bladder scan as your referral -- as your requested study, the technologist goes to the clinical procedures manual and follows that.

DR. BRICKNER: Right.

MR. TELFORD: What you want to make sure is that it's this Mr. Jones and not the other one that is supposed to get the gall bladder study, that the correct isotope and right amount gets used for gall bladder.

DR. DEYE: When they said bone scan they really meant nuclear medicine procedure and not a cat scan.

MR. TELFORD: And then they said -- when they said thyroid scan, they didn't mean whole body scan. That's what I heard for objective three. Is there anything that you want to add to that as we are going along here?

DR. BRICKNER: No.

MR. TELFORD: Objective four. You said establish a standard procedure. This is the one that says make sure that people understand. That is this objective, make sure that people involved understand. If you are going to do this, you ought to have a standard procedure that said you tell your folks to ask if there's a question -- any question of all of what to do.

That is, do not begin a treatment if there is any question as to the statement of the written directive or the

intentions of the physician. This would be kind of advice that we would put into the reg guide if we used this objective.

DR. SUNTHARALINGAM: I thought we had a concern or question about how does one ensure. What does it require to ensure. I mean, you are right in your directive to your technologies, you know, how to --

DR. BRICKNER: You cannot ensure. All you can do it say --

DR. SUNTHARALINGAM: You have to ensure. There is a policy in the department that if you ever have a question stop and ask a physician. That, you can implement.

MR. TELFORD: We call that policy a procedure. That procedure would be part of your quality management program.

DR. SUNTHARALINGAM: Yes, so this whole --

MR. TELFORD: You have that procedure, and you are ensuring. If you have it and you make sure that your folks follow it, you are ensuring.

DR. SUNTHARALINGAM: That's why this --

DR. DEYE: You keep getting back to this zero thing. If one technologist makes a mistake --

DR. BRICKNER: Nobody mentioned zero.

DR. DEYE: They do tend to -- you guy sit through some inspections, sir. You sit there and are being told you

are culpable for one event and maybe you will start learning.

DR. BRICKNER: Putting a note on the wall that says when in doubt ask, does that meet your requirement?

MR. TELFORD: Yes.

DR. DEYE: It meets their requirements until a single event occurs. Then you have not ensured it.

DR. SUNTHARALINGAM: How I interpret it --

DR. DEYE: That is what the inspector will tell you.

DR. SUNTHARALINGAM: How I interpret the word assurance --

DR. DEYE: Then, we have a problem.

DR. BRICKNER: Where is the word ensure stated?

DR. DEYE: The very first word says ensure prior to any medical use, that the --

DR. SUNTHARALINGAM: The way I interpret --

MR. TELFORD: Dr. Suntharalingam, we hear you. We share your concerns. We don't want this to be an ongoing ratchet. Let me suggest that we move to the next objective.

DR. SUNTHARALINGAM: You might want to give some thought to the term ensure.

MR. TELFORD: Ultimately, we may want to place our emphasis on something else like making sure that the byproduct material is administered as directed.

DR. BRICKNER: Yes.

MR. TELFORD: Which is a different objective.

DR. SMITH: In these cases what you really mean is, I think, you want to ensure that there is a policy that you have written down in a departmental policy -- people understand things before they take action. Why don't you say ensure that there is a policy --

MR. TELFORD: The other part --

DR. SMITH: You can never ensure the action, John. You can only ask that we have a policy.

MR. TELFORD: That doesn't have to be followed?

DR. SMITH: You can never ensure that the policies are followed, John. It is within your prerogative to ensure that there is a policy.

MR. TELFORD: Let's apply this to the fifth objective.

DR. SUNTHARALINGAM: All right, let's carry on.

MR. TELFORD: I don't mean to -- let's focus on the fifth objective on the ensure business.

MR. CAMPER: Let me make a point -- two points I would make with regard to Dr. Smith's comment. If you look at the language that says that each applicant or licensee under this part shall establish a written whatever to prevent, detect, correct, and so forth. The last sentence says this basic quality assurance program -- as the wording

was before -- must include written policies and procedures to meet the following specific objectives.

It is all about written procedures to achieve these objectives. On the other hand, the other point that I want to make to Dr. Deye is, you are right. Anytime that you make a commitment on a license for example, you cannot ensure that your people are going to do that. That does not keep you from committing that it will occur, that you will attempt to do that. You are right, it does break down.

Sometimes it results in reasonable violations and sometimes it results in not so reasonable violations. It is a well understood regulatory axiom that you cannot prevent people from making mistakes and you cannot prevent them from not making commitments. It is known, you are right. I am just trying to say though, that whether you are doing it under this quality assurance umbrella or whether you are doing it under license commitments, you can never totally ensure that they are going to do everything you tell them to do.

DR. SUNTHARALINGAM: Is it correct to assume that the language in the rule did not have the word ensure, and this is now another interpretation in trying to summarize the objectives?

MR. TELFORD: I think you will find the word ensure at the beginning at each of the objectives. Let me

reinforce what Mr. Camper just said. These are eight good things to do, eight objectives. It says at the very beginning how procedures, policies and procedures to meet these objectives.

We are on objective number five, which is ensure that the byproduct material is administered as directed. On that you told me one way to ensure compliance is to have period review of the charts. Are there any comments on five?

DR. DEYE: It just focuses, again, on this contradiction I suppose that I keep seeing. That is that the review of charts will help to detect, correct and minimize occurrences of deviation between clinical directive and administered byproduct material. It will not ensure that those will never occur.

MR. TELFORD: Your procedures ensure.

DR. DEYE: No, they don't. The procedures don't ensure that. The procedures --

MR. CAMPER: Attempt.

DR. DEYE: -- attempt to minimize, they do not ensure. This word ensure, I would like to see it get back here in our new definition section.

DR. SUNTHARALINGAM: Procedures are there to detect and correct.

DR. DEYE: Yes.

DR. SUNTHARALINGAM: The procedures will attempt to therefore, as a consequence, reduce, minimize -- you can use the word prevent. The intent is there.

DR. SVENNSON: You may want to write a qualifying statement to prevent -- it is really the same category.

DR. DEYE: You can do what you suggested before. The procedures will attempt to ensure compliance with your directive. They attempt to ensure the positive and not the negative. I am trying to ensure the positive; that is, the compliance between the directive and the administered byproduct material. I am not ensuring that it is never going to be the contrary, that the negative won't occur.

MR. TELFORD: If we state number five in a positive fashion --

DR. DEYE: Right.

MR. TELFORD: Ensure that the administration --

DR. BRICKNER: On page two it is, ensure compliance with the written directive.

DR. SUNTHARALINGAM: With the written directive.

DR. SMITH: I think you kind of have a mixed usage of the concept of ensure. Sometimes you have used it appropriately and other times you have it used inappropriately. You are not consistent, John.

MR. TELFORD: Is there another word that I should be using?

DR. DEYE: Yes, I would prefer not to use the word ensure.

DR. BRICKNER: Encourage isn't strong enough.

DR. SMITH: Again, you can't ensure action. I think you might require -- you might require assurance of policies and procedures, but you cannot ensure actions ever. In some of these cases I think you are asking for the assurance that the policies and procedures and other cases you are asking for the assurance of actions which you can never do.

MR. TELFORD: What if we didn't use the word ensure. The lead in sentence says the quality management program must include written policies and procedures to meet the following specific objectives. Number five could be the byproduct material is administered as directed.

DR. BRICKNER: Somehow, ensure keeps bringing us to zero defects to everybody's mind. It is not your problem John, it seems to be that the inspectors have a zero compliance in mind. You are getting the fallout from these people living with inspectors who they feel have zero compliance in mind. You have a bridge down the middle of the table that you didn't build. They can understandably or looking at a future --

MR. TELFORD: If we say it that way --

DR. SMITH: You want to establish some initiative

for doing something that you can't be God, John. You can never ensure something that is not going to happen.

MR. TELFORD: Would that get the idea across?

DR. DEYE: It certainly would, because it would take away any -- yes.

MR. TELFORD: Okay. Are you willing to move to objective six?

DR. DEYE: Yes.

MR. TELFORD: What I heard on objective six which is, by the way, to redundantly identify patient. Use any two methods to redundantly identify the patient. That is, you can use their bracelet, the name on the bracelet, you can ask their name, you can ask them to sign something and look at their signature, you can use their social security number, date of birth, et cetera. Any two, that's what you told me.

DR. BRICKNER: Wonderful.

DR. DEYE: Sounds good to us.

MR. TELFORD: Are we willing to go to objective seven? Replace prescription with written directive. I can say to you that we have done that in our thinking. Are we ready to go to objective eight? Replace treatment planning with treatment plan. This is in particular for teletherapy or something that might be applicable to the high dose rate remote afterloading brachytherapy.

DR. SUNTHARALINGAM: I have, for many years, promoted -- and I haven't seen it much used -- therefore, probably it is not widely accepted, is to turn around and call it plan of treatment. Always there is this confusion when there is treatment plan, people think of it as quantitative isodose distribution, treatment planning or treatment plan. It is a plan of treatment or design of treatment -- that's more --

DR. BRICKNER: I think treatment is good. That clears up -- he is exactly right. Treatment plan frequently brings isodose curves.

DR. SUNTHARALINGAM: Isodose and qualitative. I tried to push this in the community, but for some reason the people are not -- I am saying it again at this table. One day it will sink in.

DR. SMITH: We are promoting in the concept of treatment planning as all those activities that occur between referral of patient and completion of follow up, all those activities.

DR. SUNTHARALINGAM: People say treatment planning computer. The term treatment plan is -- it is some distribution that we are generating. Plan of treatment, I think is better.

MR. TELFORD: Another thing you told me is what you have in objective eight is fine. I think that should be

interpreted as with the proviso of saying treatment plan or plan of treatment. The third thing you told me was use "ensure that brachytherapy and teletherapy treatment plan is in accordance with the written directive and approved by the prescribing or responsible physician." In parenthesis I say by the authorized user because that's what we call that person.

DR. BRICKNER: That's fine. Just as you did before, take out ensure.

DR. SUNTHARALINGAM: Do you people allow authorized user or his designee? Is that allowed?

MR. TELFORD: That is allowed under 35.25 currently in 10 CFR. That defines supervision. If you want to supervises someone else, then you can delegate your authority to them.

DR. SUNTHARALINGAM: The license is issued to the chief of the department.

MR. TELFORD: Keep in mind, we are writing a regulation which would apply to 29 agreement states, and those states, they may want to say no to that. They may want to say -- if we say authorized user, NRC licensees can still use 35.25. Agreement states, they get to decide.

The other thing you told me was on treatment plan, isodose distributions and other calculations in parenthesis.

DR. SUNTHARALINGAM: There, the treatment plan is

this dose calculation or dose distribution or whatever it is.

MR. TELFORD: I think they meant in parenthesis as an example.

DR. SUNTHARALINGAM: An example.

DR. BRICKNER: Yes.

MR. TELFORD: The last thing you told me was to put in a definition for treatment plan or now we are saying plan of treatment. One quick definition was a document or graphic that represents the details of the specific treatment.

DR. DEYE: That is treatment planning, yes.

DR. SUNTHARALINGAM: This can just be a document and you don't have to draw a graphic, a document that represents the details of this specific treatment.

DR. BRICKNER: Without graphic, say it again.

MR. TELFORD: A document that represents the details of the specific treatment. That is what --

DR. BRICKNER: That is a plan of treatment.

MR. TELFORD: Plan of treatment.

DR. SVENNSON: Do you need anything at all if you use the generic term, plan of treatment? Is there a need to define that?

DR. BRICKNER: If they want that definition in for --

DR. SVENNSON: I meant definition.

DR. BRICKNER: That's fine, definition --

DR. SUNTHARALINGAM: The section that they may have definitions they will have to define what is a plan of treatment.

DR. BRICKNER: That's broad enough to cover --

DR. SUNTHARALINGAM: That is to say that the written document that represents the details of the specific --

MR. TELFORD: That completes my summary of what I heard on 35.35. There are some other points that we will bring up as we go through the rest of the agenda so that you can also tell -- the suggestion is that we talk a little bit about paragraph C, which is what we call the audit paragraph and paragraph B.

DR. BRICKNER: Would you like to give me a page number on that?

MR. TELFORD: Page 1449.

MR. CAMPER: I think I would make just a general comment or two about it, and then John can be as specific as he feels comfortable with, with things we are working on currently. I mention this at this point because I think we came away from our last meeting with this group with a lot of very good suggestions in that area as well.

Let me say a couple of general comments then. One

is the use of the term audit is something that we are leaning toward not using, using a term such as program review for example rather than audit. Also, we felt that some of your comments about the nature of quality assurance programs as used under the JCAHO concept was helpful, in that the licensee should have some flexibility to make changes in the program that are designed to maximize the effectiveness of the program.

We have come up with some language that we think will be very clear that the licensee has that kind of flexibility, and that it does not require an amendment to their license.

Another thing that we came away was with the idea that the program review would consider and include the review of X number of cases. We actually go back and look at representative patient studies to see if that was working effectively. We think with those as general comments about some of the things we are looking at there, we think again that will receive a better fanfare amongst your organizations.

I don't know to what degree John feels comfortable with any of the specifics, but these are at least some general thoughts about B in particular, paragraph B-1 and B-2.

DR. BRICKNER: I did not see in B-1 and I am

looking at B-2, anything similar to the statement that we had in your simplified thing here where you said audits will be conducted following the written policy and procedures by qualified personnel who are not involved with the activity being audited. That brought an exception from our people as a 1,000 bed hospital --

MR. CAMPER: Is that the regulatory guide?

DR. BRICKNER: It's not in here. But it was in the other thing we had. If you add that -- an outside expert, you are putting a big burden. No matter how big the institution, anybody that is qualified is in the business.

MR. TELFORD: Feedback. We don't mean outside, we mean that the licensee management can determine that person A is qualified to do what we should now call an annual review rather than an audit. Not a comprehensive audit, but rather, we think of it as an annual program review. Realize that for legal purposes we will have to say for every 12 months. You could think of it as an annual program review.

We will not use language that would imply it has to be an outside firm who has to be hired.

DR. SUNTHARALINGAM: It implies one or more individuals who are not involved with the daily implementation of the program.

MR. TELFORD: Not necessarily. We don't intend that.

DR. SUNTHARALINGAM: Okay. That needs to be made clear.

DR. SMITH: Could it be your departmental quality assurance designee?

DR. SUNTHARALINGAM: I think of a small facility where you only have one radiotherapist and one part-time physicist.

DR. BRICKNER: His review might be that the associate administrator joins the two of them and they go over the program.

MR. TELFORD: For instance, let me just turn the clock forward about a month or two and we are re-writing the reg guide now. We will say something like you should have this program review -- it is a bad idea to review your own work. If you are doing that, have two people do it, such that if person A is reviewing their own work person B is there with him so that it will, in effect, keep them honest.

You set up your own way of doing it, but we will make suggestions in the guide as to what we think would be an acceptable way.

DR. SUNTHARALINGAM: We will come back to that later in terms of answering the question of the impact of a review program, in terms of cost as well as personnel and time. We need to address that. I am not sure whether the NRC has addressed that carefully in terms of what impact it

would have on each type of facility in terms of manpower and man hours and cost.

DR. SMITH: Mr. Telford, I think your concept is compatible also with JCAHO. I, as a medical physics director, can set up certain policies and procedures, but they want to see that I have reviewed those and signed off on them every year to make sure they are being followed. That is kind of the same thing you are talking about, right?

MR. TELFORD: We have in the handout that we gave you last time, we had certain ideas that we were putting down which the language in paragraph B-1 doesn't quite spell out. Let me outline it for you. You have this annual program review. That would include a sample of last year's cases sufficient to represent however many cases you had. If you only had 50 you sample a certain number. If you had 500 you sample a different number.

You look at those. The reason is that it is an independent evaluation to see that the byproduct material was administered as directed. Fine. Now, management or its designee will evaluate the findings of this review. They will determine that the program is sufficient. If they find it is deficient they will promptly make changes.

On the other hand, let's take the optimization idea that I captured on page 64 of the transcript that Dr. Deye brought up and which Mr. Camper has alluded to, what if

we said we think you ought to have the ability to kind of optimize your program. We might talk about effectiveness of the program or efficiency of the program so that if you are finding that -- you have a completely successful program but you need to fine tune it a little bit. This is a performance-based rule. You have the responsibility for making sure that the byproduct material is administered as directed, shouldn't you have the responsibility or latitude to fine tune your program a little bit.

I believe in the previous meeting Dr. Deye was saying JCAHO says if you don't have any problems in that area, maybe you can cut back a little bit. That is an idea we would like to put in that paragraph.

DR. SMITH: With a concept on -- all departments that I am aware of has a weekly chart rounds where they review cases. I don't understand if you do that weekly why your are going to say yearly pick out -- every case is reviewed, not just a sample. It looks like your yearly audit would want to say just indicate that you have made a review of the entire program, that you have looked at incidents and made sure that those incidents were followed up on and corrected.

You don't want to start reviewing cases that were reviewed --

MR. TELFORD: You make a good point, and let me

just reinforce what Dr. Deye said. Let's say that you do monthly reviews.

DR. SMITH: We do weekly.

MR. TELFORD: Or weekly reviews, or quarterly reviews. You stack them up at the end of the year, management looks at that and says we have a program --

DR. SMITH: Wait a minute, he records those weekly reviews is what is acceptable, not that you start reviewing cases again.

MR. TELFORD: Think about time --

DR. PAYNE: The rule says we have to have a documented program review that we can -- we can't just say we did it all and we are okay. You say where does it say that. There will have to be some documentation --

DR. BRICKNER: Let me give you an example, and you tell me if this flies. In our hospital we do not feel that anybody can perform peer review on us because we are so wonderful. So we sit down once a month and we review each other's charts. I review four charts from my two colleagues. We all sit around, we review them, and we have a two page check list. We look for faults, deviations in dose, dumb thought, bad prescriptions, anything that you can think of, failure to get signed permissions.

So, we wind up with six a month and at the end of the year we have 72 charts that have been reviewed by

ourselves because we are the only people we think understand the proper way to prescribe. We now have documented 72 charts as a proper prescription and a proper dose administered. We could then take those reports, hand those to administration and say here's our peer review results. None of the 72 charts was there an error that is applicable to a byproduct.

That might be sufficient, rather than pulling another 20 or 50 charts.

MR. TELFORD: You have done a program review by looking at last year's cases. You just happen to have done it monthly.

DR. BRICKNER: Yes.

MR. TELFORD: There was an evaluation and a finding, management said the program is still sufficient. No changes required, done.

MR. CAMPER: In fact, that is far more effective obviously than doing it at the year.

DR. SMITH: We do our detailed minutes of our weekly program.

MR. CAMPER: Our concern is that --

DR. SMITH: Every single patient is discussed and reviewed.

MR. CAMPER: Our concern is that you --

DR. SMITH: The records of those minutes then

comprise a record that every patient -- you audit that the records were complete and that's what you do.

MR. CAMPER: Our concern from a minimal point of view of the staff is that there be some representative sampling of patient procedures and that it be documented, and that's the bottom line concern. Your way is clearly more effective.

MR. TELFORD: Dr. Smith, the process that you described is slightly different than what Dr. Brickner described. Dr. Brickner said at the end of the month they pull 12 cases and look at them sort of as an independent sample. Regardless of whatever else happened during the month --

DR. SMITH: They are both acceptable, aren't they? He is sampling cases and we are saying we keep documentation that every case was reviewed. You are saying two different ways of doing the same thing.

DR. BRICKNER: Because we do another process, our peer review technologist has a 15 point -- now 21 point screen for quality assurance, and she reviews ten randomly selected charts, brings the results to me as the Chairman of the Department. In addition to that, we have six more charts that we do this peer review on.

So, I can sit down and say that every month 16 charts in my department have been compared to a written

document screen for failure to comply. That, to me, would be sufficient. Not all of those have anything to do with isotopes, but a fair number do.

DR. SUNTHARALINGAM: I am sure there are different methods of review that are currently on -- depending on the type and nature of the facility and institution. Do I get it correct that your intent is more some firm documentation of what review has taken place. Two, that management has participated in this review program or is aware of the review program; is that right?

MR. TELFORD: Management has participated in the decision of a finding that the program is still sufficient.

DR. SUNTHARALINGAM: All right then --

MR. TELFORD: Not necessarily the review.

DR. SUNTHARALINGAM: Later on you will --

DR. SMITH: Management reviewing --

DR. SUNTHARALINGAM: Later on you will define for us the term management.

MR. CAMPER: Management or its designee.

DR. SUNTHARALINGAM: All right, whatever that is.

MR. CAMPER: Typically, that is going to be the radiation safety officer, I would think or the Chairman of the department, one of the two.

DR. SUNTHARALINGAM: We will come back to that problem. That, again, can be very confusing, this term

management. Even if you say radiation safety officer, some of us have problems.

MR. TELFORD: If we say management or its designee, is there any confusion?

DR. SMITH: Keep it general.

DR. BRICKNER: The executive officer of the hospital is management.

MR. TELFORD: Management or its designee.

DR. SUNTHARALINGAM: Which, today correct me -- I mean, we are all doing a lot of chart checks and cross checks and reviews, but it is still done within the department of radiation oncology. Very few people send reports. Now, because of JCAHO requirements, the monthly summary report is sent to some hospital committee.

DR. SMITH: Hospital quality assurance committee.

DR. SUNTHARALINGAM: Management is -- as long as that is clearly defined.

DR. SMITH: I think the words you are suggesting are suggesting are exactly right.

DR. BRICKNER: I like them because it lets you integrate your programs and do all of this with one fatal swish -- fell swoop.

[Laughter.]

MR. TELFORD: Let's say that completes the summary of what we heard then. I hope that convinces you that we

listened.

DR. BRICKNER: I am getting worried now, I am beginning to understand you.

[Laughter.]

MR. TELFORD: We have now covered introduction and the 10:45 item of summary of recommended changes. What would you like to do next?

DR. SUNTHARALINGAM: Maybe if I may make a suggestion -- I don't know how others feel -- since the future of this program it is important for us to spend some time on understanding the need for this rule --

MR. TELFORD: Okay.

DR. SUNTHARALINGAM: -- I don't know if we are thinking of breaking for lunch. You have come prepared, and I think we should spend some time and talk about the need for the rule.

MR. TELFORD: We can do some of these questions.

DR. SUNTHARALINGAM: Some questions maybe --

MR. TELFORD: I think I can do most of these pretty quickly.

DR. BRICKNER: What are we talking about?

MR. TELFORD: We are on the 10:15 item, discussion of questions. The first bullet, purpose of regulatory guide. This is a performance-based rule, meaning it is not a prescriptive rule. We are not telling you exactly how to

do it. We are saying here are the eight good things to do and some other good things to do, and we would really like each licensee to be able to tailor their own program for their own hospital. Thus, it is performance-based. It only says what to do and not how to do it.

Thus, the regulatory guide is a how to document. It will represent one, at least one acceptable way of doing something. It is not the only way. That is its purpose.

DR. SUNTHARALINGAM: You still see a need for it?

MR. TELFORD: Definitely.

DR. SUNTHARALINGAM: Why do you see a need for it? Even the reg guide, but I am trying to find out why.

MR. CAMPER: I would say that the reason that you have a need for a regulatory guide -- think of it not only in the instance of this particular regulation, think of it as part 35. You are familiar with regulatory guide, right.

The need for that regulatory guide is to help all licensees understand a way to minimally implement the requirements of the regulations. The reason for that is really two -fold. Number one is, believe it or not, there are a number of institutions out there who just don't have the sophistication if they are not given that guidance. The second reason is --

DR. SUNTHARALINGAM: But the --

MR. CAMPER: The second reason is, if I may, is

that regulations by their nature are skeletal. If you put every line item, every detail that it takes to fully comply with Part 35, we would be looking at an extremely thick text. What you do is, you develop a regulation and you then develop a supporting regulatory guide to give the licensee a minimal way to meet the expectations of the regulation.

DR. SUNTHARALINGAM: I fully appreciate and understand on the past and needs for guides in the past. For this specific rule and based on past experience of how NRC has come into institutions and interpret it based on what is in the guide as people not meeting certain requirements. There was this concern expressed in writing to you that what we saw in the current version of the guide may lead to more misunderstanding in requirements by inspectors coming in.

I know that last time we said we would change the word from will to should. Even that, I am not sure is going to take care of --

MR. TELFORD: May I?

DR. SUNTHARALINGAM: Yes.

MR. TELFORD: Dr. Suntharalingam, I think you are a little off base. Let me explain. A rule that gets published -- the guide is available, to be used is optional. The next thing that happens is a licensee sends in an application to get a license; that is, to see if their

quality assurance program meets the rule. The purpose of the reg guide is so that the licensee can use it if they like to, if they want to, to write their program.

The NRC reviews the application and says yes, your program is acceptable. That becomes -- your application becomes your set of license conditions. When you get inspected, you get inspected against that set of license conditions. Not the guide, that set of license conditions. It is only appropriate to talk about the conditions that are in your license as far as inspections goes

DR. SUNTHARALINGAM: I am fully aware of that, but even before getting to inspection in getting the license approved or getting the license, the amount of interaction that goes back and forth when a program is sent in -- an NRC staff looks at it and does it meet the requirements in the guide. Then we go back and forth.

DR. DEYE: Really, they look at does it meet the requirement of the regulation.

MR. TELFORD: No, it's regulation.

DR. DEYE: Not guide.

MR. TELFORD: It's not the guide.

DR. SUNTHARALINGAM: Not the guide?

MR. TELFORD: No, sir.

MR. CAMPER: There are instances where people will commit to the use of the Reg Guide, okay. In that case it

becomes an inspectable item.

DR. DEYE: That's right.

MR. CAMPER: There is no question that there is a standard review plan -- everything that we do in licensing a standard review plan is created. From a regulatory guide, that standard review plan will contain a number of items we are looking for in a checklist mode. If the licensee does not address some minimum level of commitment on a particular issue, then a deficiency issue is generated.

Again, it is against the regulation and they are inspected against the regulation, and they are inspected against their commitments. I think where this breaks down sometimes in all candor is, there are times when agreement states in the licensing process will put more emphasis on the regulatory guide than perhaps it should.

I would like to make one point, if I may, about the regulatory guide -- it will have language in it that will indicate that it is a guide and these are considered to be minimally level things. There will be inspection guidance published. Obviously, we have to prepare an inspection guidance against this rule assuming that it becomes a regulation. Then, we will have to develop a standard review plan to license against it.

There is nothing in that process that is going to interfere with the concern that you have.

DR. SUNTHARALINGAM: The reason I gave the point is that just as you said, how you write something and how the agreement states interpret and how when states take this program over and put it into all users of radiation, do we as users face different problems every time.

DR. DEYE: I think we are going to be in worse shape without it. Without a reg guide the average hospital really doesn't know which end is up.

MR. CAMPER: That's correct.

DR. SUNTHARALINGAM: They care about the language --

DR. PAYNE: I will give an example. I am 100 percent for the guide, and I am going to work to the best of my ability to get a good guide. But there is an exact example. My group, another physicist and I provide consultation to a hospital. Prior to the guide, 10.08 -- this goes back to a previous RSO. A previous RSO made a number of commitments and it was difficult to understand all of these.

What happened was, without the guide -- prior to the guide -- a number of commitments were made that are very difficult to live with. The inspector came in and he did his job right. I have to give the inspector credit. He said back in 1979 you committed to this and you haven't changed it. He said you would have been much better off to have

used the guide because you committed something that is a lot more work than you would have done.

We said you are right. He had to do his job, so those were problems. What we did was, we amended the license. We turned around and used the guide. We said let's just get rid of this and let's go according to so and so. So, we have to have a guide. I share your concern is, we want a good guide.

MR. TELFORD: One hundred percent agreement. We want a good guide too.

DR. BRICKNER: Are the instructions for inspections -- you used the term and that's as close as I can recall -- given to the inspectee as well as the inspector?

MR. CAMPER: No. It's an operating document for --

DR. BRICKNER: Wouldn't it be only fair to let Suntha know what the guide given to the inspector so that if he is off base you can say as I understand the way you are to inspect me is this and this, and is that what you are doing. Discuss whether it is appropriate or not.

MR. CAMPER: I understand that anytime there is an inspection and there are violations which are posed, there are certain rights available to the licensee, the hearing process and what have you.

DR. DEYE: I really wouldn't want to see that

document because it's yet one more document that can be interpreted and misinterpreted. It is difficult enough to argue with the inspector over the interpretation of the regulation and my license, and I don't yet want another document that we are both quibbling over. We will just quibble over the regulation.

MR. CAMPER: From a practical standpoint it wouldn't be possible, because some of the protocols or documents that are referred to in the inspection guidance are purely internal documents that the licensee would not recognize or be able to relate to. There are some practical problems.

MR. TELFORD: Can we try the second bullet, contracts. You will find in the copy of the transcript that you have several statements that say no, we have sufficient information. Thank you very much. Please think of these contracts as ongoing information gathering exercises which you will find the NRC doing this year, next year and the following year.

Let me assure you that as I describe the process of rulemaking this morning to you the first thing, that is an ordinary rulemaking that I described to you. What we are doing here is not, by any stretch of the imagination, an ordinary rulemaking. I can personally guarantee you that the amount of work that has gone into this rule so far is an

order of magnitude at least ten times more than any rule that I have ever done. And I have been doing rules for quite a few years now guys. We don't need those contracts.

DR. DEYE: Before you move on, let me back up for just a second to two of them. The Brookhaven contract, you had indicated you might be able to share at least off the record, some summary of what came out of that contract looking at 72 institutions and trying to implement this proposed QA rule. Then the contract with SAIC that relates to a snapshot of what QA is out there today.

I guess if you get rid of the quality assurance terminology here, if we call this a quality management -- I forgot what we used before.

MR. TELFORD: Quality management.

DR. DEYE: Quality management program for something or another -- if you take it out of the quality assurance arena and call it a management program, then I guess I don't care about SAIC. But I would still like to know the record to some extent relative to cost-effectiveness of the 72 Brookhaven institutions.

DR. SUNTHARALINGAM: I have a problem accepting that in some information from at least some of the contracts may not impact on the nature of this rule and the implementation of this rule. Example, I don't want the Commissioners to be mislead that they have requested that a

pilot study be done and that pilot study hopefully also addressed the question of if you implement such and such a program the new requirements describing events, what impact will that have in terms of cost and personnel.

MR. TELFORD: You are off base again.

DR. SUNTHARALINGAM: All right. Tell us, because to me if a pilot study was to be undertaken -- if the Commissioners felt that a pilot study needed to be undertaken as a result of a physician from nuclear medicine coming and telling that I did visit my own department and found this is what it is going to take in terms of time, paperwork and whatever else to do to try to initiate such a QA program --

MR. CAMPER: I am trying to understand your question, if I may. We had that information. That contract in the pilot program has been conducted. We have access to that information right now.

DR. SUNTHARALINGAM: We are asking you to share that information with us if you want to get some positive feedback. You are taking some information that --

DR. DEYE: Let me clarify, Larry. In your NMSS license newsletter of March/June 1990 there's a statement here that in addition to requesting public comment, NRC is conducting a pilot program to assess the benefits and costs of the proposed rule and draft regulatory guide.

You can't ignore -- and I know you are going to say we are getting into reporting requirements and we are not there yet -- you can't ignore the cost of reporting requirements. In point in fact, when the pilot program was run they were not caused or forced or recommended or whatever to use all of the reporting requirements that came forth in the January 16 Federal Register. They didn't have to implement the therapy event and diagnostic event terminology.

I would propose that those new definitions and expanded definition of misadministration impact significantly the cost of the implementation of this program. Therefore, the data from the pilot program might be deficient in that respect. I think that's the heart of what Suntha --

DR. SUNTHARALINGAM: I don't want the Commissioners to feel that a pilot study has been done and information has been gathered --

MR. TELFORD: Let me go in a positive direction here. We first of all agree with your I think intended statement that the proposed reporting requirements are costly. The positive statement that I want to make is that I think I know how to fix those. It is based on ten workshops with our volunteers, it is based on discussions with this group, other groups, agreement states, et cetera.

I hope to get to the point in this discussion where we can outline what we might have in mind as to what might fix that. I am here to talk to you because I already know what the problems are. Additionally, I have a pretty good idea how to fix it. I just want to hear from you that this would be an effective fix, or that you have a better suggestion on how to fix it.

I would like to leap frog over to the bottom line and discuss what to do, how to fix, how to polish, how to amend this proposed rule. We have a whole truckload of information on this proceeding.

DR. DEYE: I think as long as you are indicating that the information relative to cost is not going to be based solely upon the pilot program of 72 institutions nor even primarily upon that study but in fact will hopefully take in a very positive way things that came out of all your meetings such as this -- and we are anxious to hear it -- great.

MR. TELFORD: Let me add to my list the public comments. For example, your letter was quite eye opening as to what you thought the impact would be in your hospital for those reporting requirements. I might add, quite an effective letter. All of those things, each of them are only one part. The pilot program is only one part, the public comment letters are another part, and these

discussions are another part.

When you put it all together, you get a very good picture. The pilot program was supposed to be a real world test of the rule itself, of 35.35. While we were at it, we tried to optimize our time and effort and get as much information as we can. Please, don't think that we are relying solely on the pilot program for cost information.

DR. SMITH: Okay, John, you say that you have put all these various information together and you have a pretty good picture.

MR. TELFORD: Yes, sir. They all look like this.

DR. SMITH: Why don't you tell us what the picture is. I would like to know the bottom line. If you have an impact statement of how this is going to impact the cost of health care including the cost --

MR. TELFORD: That's what I tried to say two minutes ago. I thought the way to do it was to leap frog over to the bottom line and say let's talk about the reporting requirements. Let's talk about these definitions that would define what --

DR. SMITH: That's not what I am requesting.

MR. TELFORD: Hang on just a second. What is an event, what is a misadministration, what do you have to do with those, what are the investigation and reporting requirements that we would associate with an event, with

misadministration.

DR. SMITH: That's not what I asked, John. I am asking you, have you prepared an impact statement which gives the bottom line of the cost of health care of implementing this program which includes all those things which must take place in institutions across this country and include your in-house cost of implementing it. What is this going to cost us in this country in terms of health care, total.

If you have this bottom line, if you have the impact statement, what is it?

MR. TELFORD: I have to translate your language into what I am familiar with. I call that a regulatory impact analysis. We developed one for the proposed rule, it is available and has been available in the Public Document Room since January of this year. Upon examination of the public comments, all of these workshops that I have alluded to, the totality of information gathering, looking at the final version of the final rule, we will go back and amend that regulatory impact analysis if required.

It probably will be required, because in my humble opinion, we will greatly reduce those costs.

DR. SMITH: I guess what I am trying to get you to do, and I don't think you want to do it -- you can't do it -- I gave you in my introductory statement an estimate of

what it could cost in this country not including your cost of implementation. I gave you an estimate which is some $200 and some million. You don't even say to me, Dr. Smith, that is about what we calculated what it is going to cost, you are way off or you are underestimating.

Do you have any idea of whether or not those $200 or some million that I told you that it was going to cost --

MR. TELFORD: Let me say it to you, you are way off. DR. SMITH: Well, then, I am asking you for your numbers. I gave you my estimate, what is your estimate.

MR. TELFORD: Let me suggest to you that it is really not worthwhile to debate yet what the costs will be because we haven't defined what the rule will be.

DR. SMITH: It is incredibly important.

MR. TELFORD: We agree 100 percent that it is totally important.

DR. SMITH: In fact, tremendously important.

MR. TELFORD: The way you can help us is to say look, it is this item right here and point to it, that's the cost driver. Dr. Deye has done that in his public comment letter. I am sure that he will reiterate those comments. What I want to do is try to amend this proposed rule to eliminate those costs to the greatest extent.

Don't you see this is sort of a futile exercise to talk about what will be, because we are not even --

DR. SMITH: I just wanted to understand and have a statement from you as to whether or not you have estimated that cost at this time.

MR. CAMPER: Again, it --

MR. TELFORD: It's in the regulatory impact analysis. It currently is and has been in the public document room since January of this year. Yes, we have estimated that cost. No, I don't agree with your number.

DR. SMITH: What is it?

MR. TELFORD: I don't recall.

MR. CAMPER: Again, point out too, Dr. Smith as he said, once we know what the rule is the regulatory impact analysis has to be re-evaluated.

DR. SMITH: I understand that.

MR. CAMPER: Out of that rule comes the final estimate of cost.

DR. SMITH: I understand that.

DR. DEYE: It sounds like you weren't too far off, because I just heard the number.

MR. TELFORD: It's $4 million.

DR. DEYE: I thought you said $40, I'm sorry.

DR. SMITH: Four million?

MR. TELFORD: Four million.

DR. SMITH: The cost of health care in this country to implement?

MR. TELFORD: With the original.

DR. DEYE: It has to be changed, so that's academic at this point.

MR. TELFORD: I think you have to examine the regulatory impact analysis.

MR. TSE: That's right.

MR. TELFORD: If you want to analyze the way that we have estimated the costs, please do so.

DR. SUNTHARALINGAM: Where can I find that document?

MR. TELFORD: It is in the public document room, Washington, D. C.

MR. TSE: John, in fact, you can let me know and I will be glad to send you a copy.

DR. DEYE: Would you just send every one of us a copy?

MR. TSE: All these cost estimates are outlined in the chart.

DR. SMITH: It seems to me we are talking about different costs, because I am talking about what it will eventually cost health care in this country because of the things that physicians will do in their private practice to -- I think that's going to be pretty tremendous.

MR. TELFORD: Dr. Smith, could we agree that cost is important?

DR. SMITH: Yes.

MR. TELFORD: Could we agree that minimizing cost is important, and could we agree that it is important to talk about how to do that, how to modify the reporting requirements such that we do that.

DR. SMITH: I would also like to understand and have the public understand somebody's estimate at some time, what is the total cost figure on health care in this country for implementing this regulation. I think that needs to be estimated.

DR. DEYE: I think it's fair to say that you have to do that by your mandate from Congress every time that you come forth with a new rulemaking. They have done it, you probably won't agree with their numbers, but to quibble with those at this time is academic. Let's wait to see what they --

DR. SMITH: I would like to have some estimate. Maybe you don't want to share that, how you came about -- what parameters went into that cost estimate.

MR. CAMPER: I think it would be beneficial to you to go back and review the document. The bases for how the numbers were arrived at are described in the document. Again, accept the fact, if you will, that once we get to the conclusion that document becomes modified. That would be my suggestion. We will be happy to make a copy of it for you.

MR. TSE: In fact, we ask in the statement in this document, we ask for public comment on regulatory analysis.

MR. CAMPER: If I may though, I would really like to re-emphasize what John has diligently tried to point out. We think that some of the things that we are looking at on the reporting requirements and related thresholds, and even what we call these things to be very meaningful to you and, frankly, in the long run, could be meaningful in reducing some of these costs. I just wanted to emphasize what he tried to point out in that regard.

DR. DEYE: Some of the things that you have already said this morning that you are taking into serious consideration will affect cost in a downward direction.

MR. CAMPER: We think so.

MR. TELFORD: We are only getting started.

DR. DEYE: You start talking about the reporting can be done in-house rather than up through management, you are talking about not having to bring in outside consultants. When you start mentioning these things, you are bringing this cost down.

MR. TELFORD: I will tell you in terms of objective three the written referral, the minute you go to telephone referral the cost goes down dramatically. You know what the big driver is for cost, Dr. Smith, for a written referral -- it is accounting for time for the

physician to sign that, to review and sign that. There are seven million of those across the country each year, approximately. Nobody knows the real number.

DR. SMITH: That why that $4 million number I heard is so ridiculous. In your original specification of this, if you come up with $4 million for the cost of this, that just blows my mind.

MR. TELFORD: I have a suggestion. Should we break for lunch? Try to do lunch in 45 minutes.

[Whereupon, at 12:15 p.m., the meeting recessed, to reconvene at 1:00 p.m., this same day.]

AFTERNOON SESSION

[1:10 p.m.]

MR. TELFORD: Let's go back on the record. Let me suggest that we now look at the item that we had at 9:15, which is discuss the need for the rule. Before we do that, let me say to you that the copies of the transcripts are yours because you are participants of the meeting. You need those in order to carry on with this workshop. Please do not duplicate those and please do not give them to anybody else until such time as you know that we have put it in the PDR, and then it will be available for the public.

I felt that you couldn't meaningfully and effectively participate in this meeting unless you had a copy of that. I am quoting certain pages, and I want you to be able to test me and see if it's really right.

DR. BRICKNER: What's the PDR?

MR. TELFORD: Public Document Room. It's 2120 L Street N.W., Washington, D.C.

The need for the rule. What I have is a collection of misadministration, and I will also say unusual occurrences that I would like to go through with you. What I really want to show you is the details of what went wrong where. These are real cases, they are reported. Most of these you will find in these reports, Report to Congress on Abnormal Occurrences. The NRC is required to report these

quarterly to Congress. We have copies for you of seven of the most recent reports that we have given to Congress.

I have one here in my left hand which is a draft report for this quarter which you don't have, which I have some cases that I have drawn from that. I am going to give you these because I want you to be able to reference something and look back at it and make sure that I am not making these up. I will go through these pretty quickly.

I have put these up in three groups. The first group is nuclear medicine. The second group is brachytherapy, and the third group is teletherapy. I want you to understand what we see nationally.

[Slide.]

This is one of the oldest ones that I have from May of 1988. It happened in Houston, Texas. This patient was given 30 microcuries of I-131 instead of 30 millicuries. It is a very easy switch to make and lot of people do it. What was the cause? Well, the order was verbal, the technologist was confused as to what was required for that study, and when they got it back they did not check the dose in the dose calibrator because in the State of Texas, an agreement State, a dose calibrator is not required.

It was assayed in front of a gamma camera and the results were more or less ignored. The patient got 30,000 rads to the thyroid. What they did to prevent recurrence

is, they now have new procedures to require that the nuclear physician order all therapy doses of radiopharmaceuticals, and they changed their clinical procedures manual to make sure that the technologists know what is supposed to be used for what studies.

[Slide.]

This is March of 1989, New England Medical Center in Boston. The patient received the wrong radiopharmaceutical and the wrong dose. The patient was supposed to get one millicurie of I-123 but instead got five millicuries of I-131. The wrong radiopharmaceutical, the wrong dose. What is the cause? We have a staff endocrinologist that mistakingly requested an I-131 uptake in scan. They have a person they call a floor administrator which transcribes this into a computer. That person misunderstood the wording of the endocrinologist and though okay, we want 131 whole body scan. The consequence was 5,000 rads to the thyroid.

The actions taken. These actions taken are actions suggested by the licensee. If it is an NRC licensee, we merely go and say you have a problem and how do you want to fix it. These are suggested actions by the licensee. This is not anything that we required or don't force on them. Therefore, you will see a wide variety of different things that are not exactly uniform.

Now at this hospital they revised the requisition form to include the patient's name, the type of study and the isotope. They require approval of all I-131 use by the chief nuclear medicine technologist, and they will have additional training for the radiology residents, the endocrinologists and the technologist.

[Slide.]

This is May of 1989, Minneapolis, Minnesota. We have a patient receiving three millicurie doses of I-131 instead of 300 microcuries of I-123 -- sound familiar?

DR. PAYNE: That's my hospital, by the way.

MR. TELFORD: What is the cause? It was incorrectly recorded as thyroid I-131 CAPS instead of thyroid scan. Secondly, the technologist, seeing I-131 CAPS assumed whole body scan and did not check the reference to clinical history or the diagnosis for thyroid nodule. Third, there were inadequate procedures to ensure that the directions are writing and that doses are verified, and that the technologist check diagnosis or clinical history before administering.

The consequence is that we have 3,000 rads to the thyroid, and this one ran over to two pages. The actions taken to prevent reoccurrence, the licensee now has prior approval by an authorized user for I-131 administration. They have written prescriptions for I-131 use, they have a

nuclear medicine technologist review the diagnosis and the reason for giving I-131 to a patient to ensure that the isotope matches.

[Slide.]

October, 1989, Rochester, Minnesota. This dose was an I-131, and was ten times too large. The cause is the referring physician checked the wrong box. He should have checked microcuries but checked the box for millicurie. The nuclear medicine physician approved the procedure but didn't notice the incorrect dose.

The consequence, 1,000 rads to the thyroid. Actions taken to prevent recurrence, we have the nuclear medicine physician is now required to review the request and the patient's chart and the nuclear medicine physician to approve the request and write in the prescribed dose on the chart. The pharmacy there is only allowed to dispense quantities of iodine greater than 20 microcuries if the authorized or nuclear medicine physician has properly completed a form including that information.

[Slide]

Now we have November, 1989. This has become a fairly famous case. This is Phoenix, Arizona. This patient received the wrong radiopharmaceutical and the wrong dose. Again, the patient was supposed to get 100 microcuries of I-123 and instead got 1) millicuries of 131. The causes were

many. The radiopharmaceutical order was by phone. The dose was not measured in the dose calibrator. Miscommunication between two technologists where one said give this dose to this lady and assumed that the other technologist has checked it in the dose calibrator but actually had not. There was no comparison of the I-131 label with the physician's request.

Probable consequences, thyroid destroyed. What is the action taken? First of all the state got into the act. This is an agreement state. It suspended use of I-131 and later revised that order to say if you will show us how you will prevent reoccurrence, we will let you use up to a certain amount, up to 100 microcuries. After that, they have allowed them beyond that. The hospital has totally amended its procedure.

DR. DEYE: Since that probably requires hospitalization, did the technologist not even -- did they just administer the capsule right there in the nuclear medicine department?

MR. TELFORD: They sure did.

DR. DEYE: They let that patient go home?

MR. TELFORD: Yes, they did, and the members of the family got dosed. Yes, they did.

[Slide.]

November of 1989, Kuakini Medical Center,

Honolulu. We have the wrong patient received 10 millicuries of I-131. The cause, the technologist called Patient B but another patient, Patient A responded and took the I-131 dose. Patient A was supposed to get 20 millicuries of technetium. Another cause was that there was inadequate procedural controls and inadequate control of activities.

The probable consequence, we have the wrong patient receiving a dose with no benefit. Actions taken to prevent recurrence, they now have one technologist that handles all aspects of I-131 and give that person responsibility for correctly identifying a patient. Secondly, they will have the technologist, physician and that patient concurrently sign the therapy worksheet prior to, and will have additional training for all technologists.

DR. PAYNE: I might add, this is going to become more of a problem, this type of thing. In the Twin Cities we have a large population of Asians, particularly Mong. A lot of then don't speak English and you say something and they all pop up. We have had trouble, because we don't know which one is the patient. There is this family -- two sisters and something like that, but they don't speak English. You have to get an interpreter and it's not that easy.

You are under fire and somebody nods yes, and the next thing you know --

[Slide.]

MR. TELFORD: May of 1990, Overlook Hospital in New Jersey. Here we have an outpatient given the wrong radiopharmaceutical and the wrong dose. We have 1.4 millicuries of I-131 instead of I-123. The cause, the person in the nuclear medicine department misunderstood the request. There is an I-131 scan. They use a written referral, but the referral didn't get to the department until after the study was completed. The patient came in as an out-patient and it just didn't get there.

The department's referral verification procedures were inadequate and they didn't have any. The consequence, that patient's thyroid gets 1,820 rads according to a medical consultant that we asked. The actions taken were that the licensee now requires a written referral in the department prior to any iodine administrations.

[Slide.]

This is June 5 of this year, Mercy Medical Center, St. Joseph, Michigan. This patient was referred for a diagnostic evaluation for an enlarged thyroid. The patient received 4.3 millicuries of I-131 instead of the 50 to 100 microcuries. What was the cause? The department's procedure manual listed the wrong amount. The dosage was not reviewed by an authorized user prior to adminstration.

Probable consequence, the patient's thyroid got

about 4,300 rads which, according to our medical consultant, gives them a 10 percent change of hypothyroidism in the next five years. The action taken, they will now have a written prescription from an authorized user prior to administration. This is an I-131 procedure. They will have two technologists who will independently verify the prescribed dosage, check the dosage in the dose calibrator, and two signatures required on all documents involving anything to do with I-131.

This runs over with a little post-script here. The department's clinical procedures manual was corrected to ensure that it has the proper dose for substernal thyroid scan.

[Slide.]

June, 1990. I call this an unusual occurrence by current definitions. This was at Tripler Army Medical Center, Honolulu. Here we have the mother of an eight pound infant given 4.89 millicuries of I-131 for a whole body scan. The patient had a previous thyroid disease. The infant received a large dose of I-131 through the mother's milk. The cause, they didn't ask the mother if she was breast feeding even though it's on their checklist.

The consequence, 30,000 rads to the infant's thyroid, destroyed. Actions taken, they now have a procedure which I call redundant, so that they have the

receptionist go through the checklist, have the technologist ask the receptionist if they went through the checklist and then repeat it. And then, they have an authorized user check it. They have a sign off by all three of these. The Army invented that.

[Slide.]

July, 1990, North County Hospital, Newport, Vermont. Here we have a diagnostic dose of I-131 containing 15 microcuries that was administered to a pregnant patient. Again, I call this an unusual occurrence because the technologist failed to ask the patient if she was pregnant. The consequence, in this case, they were lucky. They estimated that there were 2.25 millirads to the whole fetal body and not thyroid dose because the fetus was through to be just a couple of weeks old. If it had been 12 weeks old or more it would have gotten a much larger dose.

The actions taken, the licensee is now asked to respond to a notice of violation that we gave them for failure to instruct technologist to ask female patients if they were pregnant. They are going to have to fix that problem.

[Slide.]

July, 1990 at North Detroit General Hospital, Detroit, Michigan. The nature of this occurrence was that they have a temporary technologist. This technologist was

very inventive. He took films from patients for the last two years and said you want a scan on Mr. Jones, okay I will reach back here in the file and grab an old film. I will change the names and the dates and there's your scan.

In most cases the licensee was unable to determine if the patient actually got the radiopharmaceutical. There were several causes here, but basically failure of the licensee to have adequate supervision and breakdown in management control. The consequences, it is almost a sure case that some of these patients received a radiation exposure with no benefit whatsoever.

The action taken, they are going to strengthen their screening procedures for prospective employees. They have intensified their training, and they are going to require ongoing supervision and review work of new employees. There were 29 of these that were bogus. One of them was supervised very closely and it came out right. The guy did everything he was supposed to.

[Slide.]

August of 1990, Copley Hospital, Vermont. This patient was given the wrong dosage, 112 microcuries of I-131 instead of the 10 microcuries intended. Several causes. The I-131 capsules were ordered, five capsules of 100 microcuries each instead of five capsules with a total of 100 microcuries. Another technologist assayed this dose and

had a reading of 11.2 instead of the correct reading of 112.

The consequence, the patient's thyroid gets 100 rads. The actions taken, they are going to retrain the technologists on the procedures for assaying doses. They require that only one technologist do both the ordering and the administering.

[Slide.]

Nuclear Medicine. November, 1990, West Shore Hospital, Manistee, Michigan. The patient received 171 millicuries of technetium instead of the intended eight millicuries specified in the procedures manual. Several causes. Licensee failure to properly train and supervise the inexperienced technologists. Here we have an x-ray technologist with two weeks of training previous to February. The person had exactly two procedures they had handled since then. That's the total of their experience.

This person was on weekend call all by themselves. The technologist improperly prepared the radiopharmaceutical use the generator, and second misread the dose calibrator. You will find this write up to go on to say that the supervisor was at home coaching this person over the phone.

Consequence, we have the gall bladder and large intestine receiving 36 and 26 rads respectively. The actions taken, more training for new employees, required meetings are held and required tests are performed. Added

oversight by the nuclear medicine program by management, and the RSO -- by the way, they dismissed the x-ray technologist.

[Slide.]

Switch gears.

DR. SUNTHARALINGAM: Stop there for a minute and I will have a discussion on nuclear medicine.

MR. TELFORD: Yes.

DR. SUNTHARALINGAM: All the information that you have given -- I am sure you are sitting here saying why did you -- these are all horrible mistakes. I think it might also be appropriate to go on record, how many cases have been reported over how many procedures have been performed. I think it is also appropriate to ask the question when trying to enforce or implement a new rule if there is a small percentage of bad workers, should the rest of the community be penalized in terms of additional measures on documentation procedures.

I mean, we all want to minimize. Again, this whole question of I don't know if these were samples or actual total number.

MR. TELFORD: Let me say again, most of these came from these reports to Congress of abnormal occurrences. For instance, nuclear medicine diagnostic misadministration are about 400 per year.

DR. SUNTHARALINGAM: Four hundred?

MR. TELFORD: But there something like 60 percent are wrong radiopharmaceutical.

DR. SUNTHARALINGAM: Four hundred per year --

MR. TELFORD: Twelve percent are wrong patient.

DR. SMITH: But those are the types of things -- see, this is a wonderful example John, a wonderful example of the classes and types of things that can go wrong. You probably have no idea how, if a colleague of ours gave this kind of information through -- anecdotal information to justify a clinical trial or something, how we have come down on him.

This is not a justification for a national study. These are wonderful examples of the kinds of things that can go wrong. We are asking you, why is this national program necessary? This is no evidence whatsoever why a national program --

MR. TELFORD: Will you be willing to wait until my last two slides?

DR. SUNTHARALINGAM: Yeah, but you still give me an answer of 400 events, but you didn't -- from your perspective, how many nuclear medicine procedures are done across the United States.

MR. TELFORD: Let me bring up one more point which was made in a public comment letter. The point was that --

it is begging the question of how many are reported. Are all of them reported, all misadministration reported? The writer made reference to the patterns of care study. If I understand the point correctly, even close to correct, the writer was saying look at the patterns of care study. Look at the hospitals, the clinics that have properly staffed, properly equipped.

The better staffed and better equipped you are, your cure rate goes up. Apply that logic to misadministration. The basic question is, do you think the hospitals in the outback of Michigan in the middle of some remote area that are not as well staffed and not as well equipped, do you really think they are even detecting misadministration much less reporting them?

DR. SMITH: Guidelines for staffing and equipment. That is different than writing a regulation for quality assurance, John. Guidelines for staffing and equipment are very appropriate. Those aren't the same thing as regulations.

MR. TELFORD: Let me do these one at a time, please. I am addressing a point that Dr. Suntharalingam made here. If you want to talk about rate on the agenda here, it had a point that the data is very fuzzy. Fuzzy, meaning I am not going to tell you that I believe that all misadministration are being reported. That's the numerator.

Secondly, I don't know the denominator. I don't know how many administrations are given each year.

DR. SUNTHARALINGAM: Does the NRC have a feeling for that number?

MR. TELFORD: Feelings are really dangerous. You see, what is the precision with which you know that number; is it plus or minus ten percent or plus or minus 100 percent as opposed to plus or minus 1,000 percent.

DR. SMITH: That is why that we are concerned, is that you haven't done those studies to find out how many incidents per administrations in the country to justify the regulations you are proposing.

MR. TELFORD: Could I ask you to hold that argument until you have seen my final two slides?

DR. SMITH: Sure.

DR. SUNTHARALINGAM: Let's proceed.

MR. TELFORD: The other thing that you wanted to discuss about nuclear medicine before we move on?

DR. BRICKNER: It seems like everything is associated with iodine.

MR. TELFORD: That's a good point. There is a lot of iodine cases, there are a lot of wrong patient and wrong radiopharmaceutical cases. That is three things that you can pick up on right away.

[Slide.]

January of 1989, New Haven, Connecticut. The nature of this event was the technologist entered the wrong decay factor, 267 to 128 and put that into the computer. The cause, the technologist misread the number and there was no overcheck procedure to check that number. Probable consequence, we got 1,000 rads instead of 500 rads for treatment fractions.

The action take to prevent reoccurrence was that they now have a new overcheck procedure to check those input numbers.

DR. SUNTHARALINGAM: Was there an isotope involved.

MS. PICCONE: High dose rate.

MR. TELFORD: High dose rate.

[Slide.]

MR. TELFORD: This is January, 1989, Kansas City, Missouri. We have two cesium sources of strength 25 and five were administered instead of 25 and 20. The current requirement is both over and under. The cause here, we had one storage drawer containing two different source strengths. The consequence, we have a 56 percent underdose.

The action taken, the licensee is now going to arrange the sources so that each drawer contains only one source strength.

[Slide.]

February of 1990, Ball Memorial Hospital, Muncie, Indiana. Here we have a patient who is administered an iridium implant via catheter. The iridium ribbon was inserted and the afterloading catheter left there for 25 hours. Upon removal, they discovered that it didn't go down to the end of the catheter. It only went 17 centimeters down through the intended 45 centimeters down. The cause, they think the patient's vomiting caused a kink in the catheter during insertion which prevented it from traveling to the end of the catheter.

The consequence is that you get 1,500 rads to the patient's pharynx. The actions taken, they will now use a portable x-ray immediately after the implant to confirm that positioning.

[Slide.]

Here we have February and March of 1990, Madison, Wisconsin. We have two patients here. One received a 27 percent higher dose than prescribed, and the other received a treatment to an unintended point. The cause, we have incorrect data in the treatment planning computer for a high dose rate afterloading device. The data from planning computer was then transferred to the treatment system.

You get wrong information in and you get wrong information out. The consequence, the first patient gets 4,120 rads to the vaginal wall instead of the intended 3240.

The other one received 400 rads to the wrong treatment site.

The actions taken, they will now develop a quality assurance program because apparently they didn't have one, including verification of key steps and calculations by a second qualified individual. Most extensive training for personnel, and written treatment procedures. Again, these are actions taken at the option of the licensee. They proposed these.

[Slide.]

March, 1990, New York. This patient received an unintended therapy dose to the face. We have a ribbon containing 25 seeds of iridium 192. It became dislodged during the night and the nurse noticed the dislodged ribbon, curled it up and taped it the patient's hair and it stayed there for three hours approximately. The left side of the patient's face received a dose of over 1,000 rads. The eyes and scalp received dose of 280 rads and 357 rads respectively.

The action taken, they are going to review the contents of the nurses brachytherapy training course, they are going to have additional training. They are going to have pictures or a sketch of the patient's treatment chart so that they can see what configuration is supposed to be in and they are going to not use untrained nurses working with brachytherapy patients.

[Slide.]

April of 1990, Yuma Regional Medical Center, Yuma, Arizona. This patient received a higher than prescribed therapeutic dose to the tumor site. What happened here is that you had upon insertion, they think the -- attempted removal, five seeds came loose from the ribbon and stayed in the tumor. The consequence is that you have 107 times the prescribed dose to the tumor site.

This is an agreement state, so we have the agreement state reporting the problem to the U.S. Department -- this physician, by the way, left the State of Arizona but reported that in the future he would only use the rigid tungsten instead of a flexible catheter.

[Slide.]

March and May of 1990, St. Mary Medical Center in Gary and Hobart, Indiana. We have a third facility in Porter Valparaiso, Indiana. The NRC in this case received allegations that an authorized user didn't evaluate the treatment plans prior to treatment, and there was no way of telling if the patient got the prescribed dose or not. Upon inspection it was determined that the medical records have not been maintained to evaluate whether the procedures had been administered as prescribed in the plan.

We have one of the inspectors from Region III had told us about this case previously. It turned out that this

authorized user "determined the dose to the patient by rule of thumb." The cause here was that none of the three facilities had maintained adequate records of either the plans or the prescriptions. The licensee management had not ensured that established procedures were followed. The RSC and RSO did not know when the treatments were taking place or when the sources were ordered.

Consequence is we issued order to suspend brachytherapy activities at these three facilities, and directed independent evaluations of all cases since May of 1986.

[Slide.]

Another page here. The licensee has submitted quality assurance procedures for brachytherapy. Those are under review. St. Mary's facility has requested a hearing before the Atomic Safety and Licensing Board. The authorized user, I believe, requested a review by the ACR of his procedures.

[Slide.]

Teletherapy, to switch gears. This happened over a 13 month period in 1987 and 1988. This is in Cumberland, Maryland, which is an agreement state. We have a 13 month period in which 33 patients received the wrong teletherapy dose, greater than 110 percent of the prescribed dose. The cause here was that they changed the cobalt source but then

forgot to tell the computer about it. The computer was dosing patients as if it was in the old lower source.

The consequence is different in each of the 33 patients. Now they have the licensee has instituted overcheck procedures to prevent recurrence of this type of event. Also, they have changed some personnel.

DR. BRICKNER: They are lucky that was only 110 percent. That could have been three or 400 percent just as easily.

MR. TELFORD: Yes.

[Slide.]

January of 1989, Minneapolis. This patient received 250 rads to the left femur instead of the right femur. The patient was scheduled for both treatments at 250 rads each to the right thigh. The simulator technologist marked the wrong thigh and the therapy physician reviewed and approved the incorrect set up. The patient was given the dose. Upon review of the simulator checklist after the treatment, the therapy technologist discovered the error. This was after the fact. The therapy technologist did not receive -- should have received the checklist before the treatment.

The consequence is licensee determined that the unintended dose could possibly cause bone marrow suppression in the left femur. That is the licensee. The action taken,

they are going to provide additional guidance to both the simulator and the therapy technologist for the position on teletherapy administration procedures.

DR. PAYNE: I reported this, and I will take the physician -- it was a screw up, and I will bet you there are few of these that don't get reported. This is a metastatic disease, et cetera, but it's a screw up.

MR. TELFORD: Secondly, the licensee is going to inform the therapy technologist that the completed simulation checklist must be reviewed prior to set up, and they are going to establish QA procedures involving dosimetry checks by three independent reviewers, chart checks by independent reviewers, and a written prescription by physician.

DR. PAYNE: We have two incidents from my hospital already.

DR. BRICKNER: You are honest, but you are not doing a very good job.

[Laughter.]

[Slide.]

MR. TELFORD: March of 1989, Augusta, Maine. The patient was administered an unintended dose of 100 rads to the brain instead of the floor of the mouth. The causes, we have names, physical appearances and treatment planning pictures in two elderly patients, pretty much the same. The

patient requiring treatment to lower palate was administered the brain dose instead of the other patient -- wrong patient.

The consequence, 100 rads to the brain. The action taken, the licensee has procedures now which require each patient's identity verified by a photograph or positive identification by a second person.

[Slide.]

March of 1989, Indianapolis, Indiana. This patient was administered nine fractions of 300 rads each to the wrong hip. The cause, the written prescription was not given to the simulator technologist. The simulator technologist put the person in a prone position and marked the right hip instead of the usual supine position and marked the other hip. The resident oncologist did not discover the mistake until the patient's chart was reviewed after the treatment was completed.

The consequence, we get 2,700 rads to the wrong hip. Actions taken to prevent the recurrence, we have precautionary steps have been taken before beginning treatment. We will have a separate review by a physicist who will have chart review at least once a week. They will have additional training for the radiation oncology staff.

DR. BRICKNER: Anybody who hasn't done that once in their career hasn't treated any patients.

MR. TELFORD: That's testimonial.

DR. BRICKNER: I still remember mine back at Walter Reed 30 years ago. We treated this side and turned him over and treated the opposite side, because they looked the same.

[Slide.]

MR. TELFORD: July of 1989, Massachusetts. The wrong patient was given a 250 rad dose to the spine. The cause, the wrong patient responded and the technologist failed to confirm the identity even with an available photograph. The technologist failed to recognize the absence of tattoos and used freckles to set up the patient. Consequence, 150 rads to the spine.

Action taken, they have each patient's identity will be verified by photograph and in questionable cases we have a physician verify the need for identification prior to initiation of treatment. We will have the physician verify the patient in questionable cases.

[Slide.]

February of 1990, Cleveland, Ohio. The patient received a dose that was 50 percent greater than what was prescribed. The cause, the physician stopped the treatments. The technologist failed to see the notice of stopped treatment in the patient's chart. The licensee didn't have a clear mechanism for documenting these changes.

Consequence, we get 278 rads to the spine. Actions taken, establish a clear mechanism for identifying or documenting changes in the prescriptions, and they will conduct annual in-service training.

[Slide.]

February of 1990, Wasnington, D. C. Wrong patient was administered a teletherapy dose to the lung. What is the cause? The radiation and therapy technologist called the patient's name and the wrong patient, Patient B responded. The technologist did not confirm the identification with either the wrist band or the name on the hospital chart. The wrong patient gets 4,500 rads to the lung.

Actions taken, counseling of the technologist. Will reinstruct all the therapy technologists in the proper method of patient identification, and will discuss the incident as part of a staff meeting. Additional emphasis on patient identification --

DR. SUNTHARALINGAM: Forty-five rads or 4,500? You read it at 4,500 and it was 45. Was it just one treatment?

MR. TELFORD: Yes. I believe it's the same treatment.

[Slide.]

February of 1990, Danville, Pennsylvania. The

patient received four additional fractions through the spinal field, resulting in 4,200 rads instead of 3,000 rads. The cause, neither the staff technologist nor his student saw the words treatment completed in the patient's chart. The consequence, you get 1,200 extra rads to the spine.

Actions taken, they will have both technologist and the student will initial the daily record individually, independently, to reflect that each of the patient's charts -- they are going to use a stamp with a large block letters "complete" instead of relying on a handwritten note.

[Slide.]

March of 1990, Muskogee, Oklahoma. The patient received 2,160 rads to the wrong treatment site, the right side of the neck instead of the left. The cause, the treatment was simulated in a prone position to the spine. The failure to record independent chart reviews, failure to review the patient's -- the physician's prescription after the patient's treatment was simulated. Consequence, an extra 2,160 rads to the wrong side of the neck.

Actions taken, they are going to alter the treatment chart to include the prescription, making it readily acceptable for review during the course of treatment. They are going to provide a more detailed review of the treatment plan by the dosimetrist and physicist, including verification of the treatment field. There will

be more to follow after the RSO completes his review.

[Slide.]

March of 1990, Newport News, Virginia. The wrong patient administered a teletherapy dose to the midline of the brain. The therapy technologist called for a patient by surname and the technologist did not properly identify the patient prior to the treatment by using the photograph that was affixed to the patient's chart. Consequence of 296 rads to the brain.

Actions taken, now they are going to require the use of the photograph should be kept with the therapy set up sheet for each patient. They will use skin markings to identify the treatment area, and they will have training of the therapy staff in proper patient identification.

[Slide.]

March of 1990, Saginaw, Michigan. We have a therapeutic dose to an unintended treatment site. The causes, we have following normal treatment -- failure to follow normal treatment procedures that require the technologist to review the patient's chart, failure to examine the simulator x-ray film that shows the treatment area, and failure to obtain verification of the treatment site by the technologist prior to initiating treatment. This place seems to have pretty good procedures, they just weren't followed.

The consequence is that you get 250 rads to the wrong portion of the spine. The licensee's actions included training to the technologist on following the correct treatment procedures, quality assurance measure including verification of the set up by a second individual.

[Slide.]

This is June of 1990, Cleveland, Ohio. This patient with lung cancer was erroneously given 178 rads to the brain instead of 200 rads to the chest. The technologist here did not look at the treatment documents and set up sheet and treatment field pictures. Although the technologist previously treated this patient, the technologist just assumed that the brain was to be treated that day. The licensee says no adverse medical effects.

The actions taken, they will have verification of the treatment set up by a second technologist using set up documentation and secondly, they will have training for all technologists on verification procedures.

I have gone through nuclear medicine, brachytherapy and teletherapy. These are misadministration. These are cases that have happened largely in 1989 and 1990, as you can see by the dates.

[Slide.]

What we are doing currently is currently in 10 CFR we establish six types of mistakes which we call

misadministration. Those are reported to the NRC. As of April 1 of this year, agreement states now have to report misadministration. Heretofore, not true. Our job is to ensure adequate safety to the public, including patients.

These reports are going to Congress. If you will look at these reports and you open one, right in the front you will see the kinds of things that get reported. I am looking at Volume 12, number one, January to March of 1989. Two incidents here are related to nuclear power plants followed by three nuclear therapy, two nuclear therapy misadministration and a medical diagnostic misadministration.

When you look through these, you will find that these types of misadministration reports do not have the appearance of being something that is just barely appearing. In terms of the overall responsibility that the NRC has, they look like a large fraction of what is occurring.

DR. SUNTHARALINGAM: Why does it look like that?

DR. BRICKNER: Where do you get that evidence, John?

MR. TELFORD: Look at the table of contents for each one of those and decide for yourself.

DR. DEYE: That's the way the document is laid out. That doesn't truly represent --

DR. SUNTHARALINGAM: I reported to Congress --

MR. TELFORD: Whether they are in that report or not, the point that I am trying to make I think still holds true. That is, all we require currently is that these be reported. We don't ask anybody to try not to have them happen. I subrit to you, how could I say that I am doing my job unless I say something about quality management for licensees and say gee, I think it's a good idea to try and prevent these. I can't just say report them.

I can't go to Congress and say I am doing my job, no way.

DR. DEYE: I would agree with that. I would just agree that it is part of the total package. You don't ask somebody to report an occurrence that you haven't asked them to avoid, which is the last way that you stated it rather than the first way.

MR. TELFORD: I stand corrected.

DR. DEYE: It's just another way to say it, but I think it's the more defensible way.

MR. TELFORD: When we look at the misadministration that we just went through, what I see is inattention to detail. I see inattention to following procedures or no procedures existing. I see inadequate supervision or no supervision whatsoever. To me, I would say we need to require something more than merely reporting these mistakes.

DR. DEYE: Could I add a fourth one there? I think you could also see if you look into a number of these occurrences inadequately trained people. Supervision alone won't do it. You have to have people who are adequately trained in the first place to do the job.

MR. TELFORD: I agree with you. Notice, a lot of these actions taken by licensees, additional training.

DR. DEYE: Yes. The licensee's picked up on it. I think you might want to consider that in your --

MR. TELFORD: Okay, I will add that.

MR. CAMPER: That is an interesting point, Jim, not so much only in this context but a concern that some of us have is we keep hearing that there is a shortage of personnel. Yet, we don't see a committed reduction of the number of therapy or imaging procedures being performed. The question then that goes begging is, who is handling --

DR. DEYE: That's exactly right.

MR. CAMPER: I think most of sitting here now know who is handling the materials and what is happening out there. I think that there is a growing body of evidence that training and experience is a factor in misadministration and, for that matter, is a factor in some of the overall violations that occur. It is something that we are going to be looking at lot more in the future into what is going on.

MR. TELFORD: On that point, look at the April to June 1990 report on pages eight and nine, particularly on page nine the first paragraph, last sentence. The inspection also identified a concern about -- this is the NRC inspection -- concern about staff shortages that may virtually affect the licensee's radiation therapy program. The NRC requested the hospital's response to this concern.

Number five, what we really have going on here if you look at it is, we have a teletherapy problem occurring at one hospital. The inspector goes in and says okay, you have problem here and what are you going to do. Then we have a brachytherapy problem that occurs at a different hospital. The inspector goes in and says we have a problem here, and what are you going to do. Then we have a nuclear medicine problem at yet a third hospital. There are 6,000 facilities out there, 4,000 agreement state and 2,000 NRC facilities -- not licensees but facilities.

You know what we could do? We could iterate around this chain of 6,000 licensees a lot of times --

DR. SUNTHARALINGAM: But John --

MR. TELFORD: What I think we need is a national solution rather than solving the problem one time every time that it occurs as it occurs throughout the country.

DR. SUNTHARALINGAM: John, you are having difficulty convincing some of us by taking these incidents

that have been reported and trying to justify the need for a national program. We all accept -- the question that you are addressing and has been pointed out are standards of practice in medicine. We are talking about medicine.

MR. TELFORD: Excuse me --

DR. SUNTHARALINGAM: The medical community is addressing standards of practice.

MR. TELFORD: How is patient identification -- how is wrong radiopharmaceutical, how is that related to medicine?

DR. SUNTHARALINGAM: That is all the standards of practice. In surgery -- I am sure you go through the medical literature and there are documents written about sometimes the wrong patient has been called into the OR. Sometimes the left leg has been amputated instead of the right leg. These are procedures, okay. These are standards of practice, whether they be in surgery or any other.

These are, again, isolated small number of incidents. You are, again, addressing this question that we have 6,000 licensees and are taking incidents that have been reported, and simply trying to convince the community that there are a lot of these incidents and therefore we have to have a national program. If one percent of the facilities are making these occurrences, the 99 percent of the facilities should also go through all the required

procedures that you are outlining and add to the workload that already we assume is unmanageable because of a shortage of personnel.

DR. DEYE: We haven't seen yet what this is going to look like. We started off even this morning and the 19th of November saying that we all agree that there is need for national commitment to quality control.

DR. SUNTHARALINGAM: Right, but we didn't agree regarding regulatory rules.

DR. DEYE: That's right. That's what we did not agree on.

DR. SUNTHARALINGAM: That's the difference. There is a difference between enforcing through regulation a program --

DR. PAYNE: But we do agree that we have to have the right patient, we have to follow the right written directive --

DR. SUNTHARALINGAM: That is true.

DR. PAYNE: Why not just say we are going to do it and regulate it.

DR. DEYE: I know what you are saying, Suntha, but I don't -- it may be begging the question to say the NRC is going to regulate this area. The probability is not the issue here, it's to get a program that is livable.

DR. SMITH: Let's ask something for the record.

John, do you have an estimate based on a valid study of the incidents -- that means the number of whatever you want to call it, incidents per procedures in this country for either brachytherapy, teletherapy or nuclear medicine procedures; what are the numbers that you are using to justify this vast amount of regulation that you are doing?

MR. TELFORD: Let me say again, the reason that I am showing case histories of misadministration is so that you can understand the details, you can understand what is going wrong. You can understand that we have people who aren't following directions. We have no procedures at all, we have no supervision, we have inadequate training. When you look at the recurrence of the patient that got I-131 instead of I-123, the wrong patient and the wrong radiopharmaceutical.

DR. SMITH: Just a second, John --

MR. TELFORD: I am getting there, hang on. You look at all of this and say what is my job. It is very simple, you should just say you should have a quality assurance program to prevent these kinds of mistakes. When you go talk to licensees you find out that 90 percent of them already have a quality assurance program for one reason or another, and they are already trying to do this. It's just that no licensee wants any regulation, no new rules, and I can understand that.

In this case, I can't do my job without it. I would submit to you that regardless of the rate, that it is required.

DR. SUNTHARALINGAM: John, is it right to go on record that you don't have the number that we are asking for.

DR. SMITH: It's true that you do not have --

DR. SUNTHARALINGAM: That is all we are trying to find out, and you can deal with all the reasoning why you need the program. So that it goes on record and the Commissioner are also aware, that there is no hard data on the rate of occurrence; is that true or not true?

MR. TELFORD: Well, we keep records of the number of misadministration both in diagnostic areas and in therapy areas. There are about 400 per year in diagnostics.

DR. SMITH: What is the rate of incidents, John? We are asking you, do have a number that you can quote as to the rate of incidents?

MR. TELFORD: I don't. I don't have a firm number. I know --

DR. SMITH: The number of incidents per administration.

MR. TELFORD: I know roughly that there are seven million diagnostic cases per year.

DR. SMITH: You have 400 incidents out of seven

million? Is that what you are saying, that is your rate of incidents, 400 incidents out of seven million administrations?

MR. TELFORD: I don't attach very much precision to that, because I can't say that they are all being reported.

DR. SMITH: That's the number that you have, 400 out of seven million?

DR. SUNTHARALINGAM: You estimated that there are seven million procedures.

MR. TELFORD: Given all the inadequacies in that rate, that is the best we have.

DR. SMITH: You are basing then the need for this study on the basis of that incidents?

MR. TELFORD: No. I think you missed the point totally.

MR. CAMPER: There is a very serious fallacy in some of the logic in some of the questions I hear being asked. You are asking questions like you are doing this only because there is a very -- you are doing this in spite of the fact that there is only a very small rate of occurrence and, therefore, it's not justified.

DR. SMITH: We are trying to understand the basis of what you are doing.

MR. CAMPER: The problem with that logic is that

you could apply the same kind of questions to the nuclear power industry. We could say look, in all the hours of operation and in all of the watts of power created a particular system fails only "X" percent of the time. The power industry would say to you, yes, but look, it occurs once or twice but we produce thousands upon thousands or hundreds of thousands of watts of power and what have you.

The problem with using that kind of argument is that it doesn't negate the fact that the Nuclear Regulatory Commission doesn't want these things to occur. You would argue that the frequency is small and, th. efore, it is acceptable. The Commission would say no, it is not acceptable. We don't want it to occur.

DR. SMITH: You guys agreed with us this morning and it's on .ecord, that there is no way that any of us can prevent occurrences.

MR. CAMPER: We understand that.

DR. SMITH: There's no way.

MR. CAMPER: We understand that.

DR. SMITH: Because of any Commission or anything else.

MR. CAMPER: We understand, but that does not remove from the Commission its responsibility to take steps to prevent these things from happening. It is charged with protecting the public health and safety. It cannot -- it

believes that it cannot sit by and simply say report these things to us only and have you say to us okay, we are reporting them -- we all agree that the data is fuzzy, we are not sure of the numbers. The Commission is not comfortable in saying report it to us only any longer. There is a problem here that we want to do something about.

You also have to look at it, what does it have available to do about it? It can send out information notices, it can inspect, it can pass rules and do different things. What it does is, it looks at things available to it and says we have tried certain things and now need to take a different course.

DR. SUNTHARALINGAM: I think to save time, we understand your position. I think each of us is also free to use our judgment and go back to our respective organizations and write to the Commissioners how we feel about the need for this program. We have the freedom to do that.

MR. CAMPER: You can certainly do that.

DR. DEYE: What you really ought to do -- on the previous slide to this -- ask yourself the question of do you really object if there are regulations that address 3-A, 3-B, 3-C and 3-D which I added D. We all agree that those things exist. We all agree that the numbers are very, very small, and let's not talk numbers.

Would you really object if there are regulations that require the field to address 3-A through appended D, and I think that's where we are headed.

DR. SUNTHARALINGAM: The point that some of us are trying to make is that there are many programs in existence. As soon as you say you shall do this, you shall document this and you need to keep this and we will inspect you, these are the things which immediately says that you are now trying to enforce this. People are doing this program.

MR. CAMPER: The problem though is, when the regulatory agency has the responsibility to do that --

DR. SUNTHARALINGAM: No, but --

MR. CAMPER: It is going to take steps to regulate a community --

DR. SUNTHARALINGAM: I have a feeling that some of us have and therefore, it is an educational process that the Regulatory agency might be overextending into areas and interpreting far too much into what is going on.

MR. CAMPER: I think that there will always be those that say that in any case.

DR. SUNTHARALINGAM: Therefore, I think that -- we want to get those hard facts of where those are coming from.

MR. CAMPER: Let me just say this then, to try to address I think what your real concern is. The need for this rule as the Commission sees it at this point in time is

not being driven purely by the rate of frequency of occurrence.

DR. SMITH: That's what we want to establish, because obviously that is a valid question and not --

MR. CAMPER: I don't disagree.

DR. SMITH: Now we have established that.

MR. TELFORD: We have sufficiently establish that this rule is not driven by the rate of --

DR. SMITH: Unfortunately, you have established --

MR. TELFORD: Dr. Suntharalingam, it is unfortunate that high rates of accidents or bad surgeries or whatever in other areas, just because some other area has a high rate of making mistakes, that is not a basis for saying that the rate not ought to apply here.

DR. SUNTHARALINGAM: I didn't say high rate, I said there are a lot of mistakes made in every branch of medicine and every discipline, even in the slides that you prepared they had typographical errors. That is human nature.

MR. TELFORD: That is not an admissible argument.

MR. KLINE: The significance is another point. Also, John, you might want to bring up independent numbers if you look at trends. If you are trying to follow that concept the JCAHO incorporates, you look for the trends and problem areas and focus on them. Over this past year have

we had twice as many, have we had misadministration --

MR. TELFORD: In 1989 we had 11 and in 1990 we had 12, and this year so far, we have had 20.

MR. KLINE: In addressing that --

DR. PAYNE: That could be reporting too, so I don't agree with those --

MR. TELFORD: One other question, do you think that any of these are not true?

DR. SUNTHARALINGAM: It is true, but --

MR. TELFORD: In 3-A, 3-B or 3-C or D, do you think any of those are not true?

DR. SUNTHARALINGAM: They are all true. They have been happening in a few facilities. But now, for those facilities that have already good programs, asking them now to over extend and bring in the radiation safety officer into the process and bringing administration into the process, asking them to document this, asking them to have an audit, all of these are over extension.

MR. CAMPER: Don't you think though, in those facilities where this has happened, do you think that some representative from their institution would not have set up a meeting like this and said in our institutions there were no problems, it is happening elsewhere. That implies that it can't happen in those places where it hasn't occurred.

DR. SUNTHARALINGAM: It's like anything else.

When we are trying to address that small percentage --

MR. CAMPER: That's true.

DR. SUNTHARALINGAM: And establish that a larger percentage will have to be accommodating. The question is where do you draw this balance.

MR. TELFORD: My own problem with what you just said is that you brought up topics which are really not valid. You said bringing in administration, bringing in the RSO. You are talking against the proposed rule. We are here to fix each of those deficiencies. I don't think any of those are admissible as being arguments against what the final rule would look like.

DR. SMITH: How would you address the reality though, that in the community there is an enormous activity from various professional organizations -- the ACR, people like the JCAHO, the ACMP, The American College of Medical Physics, the American Association of Medical Physics -- we are all doing an enormous amount of work in quality assurance. We recognize these problems.

We think that we probably have the mechanisms and also the knowledge, the technical expertise and everything to put in place quality assurance programs and to make sure that everyone has one. I think that we are making enormous strides in the community. I doubt that when you take the number of incidents you are talking about which are

extraordinarily small, and the large amount of activity in the community to solve its own problems, I really question what is going on here.

MR. TELFORD: I was going along with you there 100 percent, but I got this one hangup. This is my job. You tell me how I can work with these associations to do my job and I will do it.

DR. SUNTHARALINGAM: Some of us feel that you people are over emphasizing and trying to stretch that first phrase which is your job to ensure adequate safety to the public. That is included in the original regulation regarding radiation safety, radiation protection activities. Now you people are coming in and saying you want to use that first item because your job is to ensure adequate safety of the public including patients --

MR. CAMPER: We can only tell you that our Office of General Council says we are on firm ground.

DR. SUNTHARALINGAM: We recognize that, but it is an educational process of trying to convince people that -- is it over extending, are the Commissioners over reacting to incidents that have happened. We have also heard -- this can be off the record -- as to why this rule is being pushed forward by the Commissioners.

MR. TELFORD: These are the reasons.

DR. SUNTHARALINGAM: I said off the record. There

is information -- again, off the record -- as to why the Commissioners are asking you from the office to say come with this rule.

MR. CAMPER: I am not aware of that.

MR. TELFORD: I don't follow you. There is one thing that you are implying, is that somehow this is something new. If you look at Part 35 in the entire area, it has been around for some years now. This job here has been around here for some years in Part 35.

DR. BRICKNER: This is not the forum in which we are going to settle the Commission's job.

DR. SMITH: We have things on the record now that I want to get into the record.

DR. SUNTHARALINGAM: The Commissioner's are aware of the --

DR. SMITH: They really don't have the rate of incidents and the study has not been made.

MR. TELFORD: My final point here. What I think we need is for each licensee to have quality assurance or quality management program, whatever you would like to call it, to ensure that byproduct material is administered as directed; that all licensees have at least a minimum program which should be designed to prevent, detect the cause of mistakes.

The rule requirement that I think we need is to

have a quality assurance or quality management program as we were saying. The eight things that we list to do are the good things. This is a performance-based effort, so each licensee would be free to tailor it to their own hospital or clinic.

DR. DEYE: What else do we want to cover on the agenda today before we get back to philosophical issues?

DR. BRICKNER: Have we covered reporting requirements, events, misadministration or another term for it?

MR. CAMPER: No.

DR. BRICKNER: That might be nice to tough on, the essence of problems. To me, that's a large piece of the things that disturb many of us.

MR. CAMPER: This is the 11:15 item on the agenda, right?

DR. SUNTHARALINGAM: Some of these other questions -- did we miss anything on the 10:15 items?

MR. TELFORD: Whatever you would like to do next is fine with me.

DR. PAYNE: The role of the RSO, maybe we haven't covered. It does, in my opinion, put more responsibility on the RSO.

MR. TELFORD: How and where? Meaning the proposed rule and --

DR. SUNTHARALINGAM: Not in the proposed rule. We all know what the role of an RSO is. Now we are questioning the role of the RSO to implement this rule.

MR. TELFORD: Could you point to something? Are you talking about 35.35, are you talking about 35.33, 35.34.

DR. DEYE: I think you are talking about 35.34, isn't that the reporting requirements?

MR. TELFORD: I think he's talking about 35.33 and 35.34, where you investigate events. That is the place where we name the RSO.

DR. DEYE: Can you start putting RSO or their designee in a lot of places? I think one of the problems that we have is that RSO's in big institutions are highly specialized and may well know nothing about teletherapy. I would rather have them delegate the responsibility for the investigation to me -- I would rather almost see the RSO's title changed to RSM, Radiation Safety Manager. They are only expected to collate information and not necessarily understand it, just like administrators often don't understand everything that comes up to them but they have the responsibility of delegating --

DR. SUNTHARALINGAM: Since I put that question on the agenda and I was asked to re-emphasize by the group that I am representing which is the College of Medical Physics, one of the concerns we sent in writing during the public

comment period was -- I will read it again, just so that you people understand.

We are very concerned about the failure to address the issue of technical and administrative qualifications of personnel needed to administer or oversee such a program, which is this new rule. The increased role of the radiation safety officer requires this individual to be more familiar with clinical matters. Most radiation safety officers are not directly involved in radiation oncology, and they are only qualified to address radiation protection and safety matters.

Hence, requiring them to investigate, audit and report to management events in radiation therapy would be a difficult task.

MR. TELFORD: Whom would you like to do that?

DR. SUNTHARALINGAM: It would probably be more practical and efficient if the radiation oncology physicist who in some institutions might be the RSO, is asked to serve the role of management.

MR. TELFORD: That is for teletherapy incidents.

DR. SUNTHARALINGAM: Teletherapy and brachytherapy. See, we are all running into these problems in our different institutions. The nature and qualifications of who is brought in to administer a radiation safety program -- you are spending three days

explaining to this individual --

MR. CAMPER: Let me ask you a question, if I may. Where in the proposed rule -- can you be specific about where you see this being a problem? For example if we, in 35.35 use language as we indicated this morning the licensee, management or his designee -- where was this

MR. TELFORD: I believe it is on page 1448, 35.33 paragraph C, where we say the radiation safety officer shall promptly investigate, et cetera. If we didn't say RSO there, what if we allowed the licensee to designate the person -- the licensee management or designee could name that person.

DR. SMITH: I think to be consistent, that would be the best way.

DR. BRICKNER: That may be he[illegible], and you may have two or three people. The therapeutic physicist may do his --

DR. SUNTHARALINGAM: On page 1143 I think is that the same things you have. 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, and notify licensee management to take corrective action.

MR. TELFORD: Right.

MR. CAMPER: Right, but I am saying if we use the language that we have mentioned, the licensee management or

its designee throughout the document for consistency, does that work? Does that help?

DR. SUNTHARALINGAM: Oh, yes.

DR. SMITH: As a matter of fact, that ruling has to be better because we don't even have a hospital radiation safety officer, we have a university radiation safety officer who knows nothing about hospital procedures.

MR. TELFORD: Okay. We fixed that, right?

DR. SUNTHARALINGAM: Yes.

MR. TELFORD: Let's hang on to events here for a minute.

DR. DEYE: You might require though, that the hospital indicate in their QA program who their designees are for the various categories of reporting. I don't think it should be just left ambiguous for the event to occur and then you designate somebody.

MR. CAMPER: That's a good point. It should be that should be an item within our standard review plan.

DR. DEYE: I think it should be reviewed prior to events occurring, because sometimes who you appoint is unfortunately tainted by the nature of the event and it should have been determined ahead of time for the various categories of reporting.

MR. CAMPER: That's a good point.

MR. TELFORD: While we are on 35.33, events, what

if the events -- what if no report were required for events? What if these matters -- you just make a record and talk about the event at the RSC meeting or the quality management meeting, whatever you have.

DR. DEYE: I think that's --

MR. TELFORD: Let the --

DR. DEYE: It allows me to integrate it into a program that I already have to perform for JCAHO and ACR. I can integrate it very nicely into those programs if you say it that way.

DR. BRICKNER: You can document in your minutes that problems related to source selection or whatever were discussed and a policy formulated if you do.

MR. TELFORD: That way the inspector could look at the minutes and find out. Events are an internal matter.

DR. BRICKNER: Yes.

DR. SUNTHARALINGAM: Now you are making a distinction between reporting to NRC whether reporting internally. There is still some reporting internally.

MR. TELFORD: I didn't say that. I said the event would be discussed at the RSC meeting or the quality management meeting. The report or the record is the minutes.

DR. BRICKNER: We will still have documentation that these were --

DR. SUNTHARALINGAM: Events will be discussed at the institution level.

MR. TELFORD: We haven't defined event yet.

DR. SUNTHARALINGAM: Again, I don't want to get into radiation safety committees.

MR. TELFORD: I gave you a choice. Would you like me to give more choices?

DR. SUNTHARALINGAM: If you leave it as events will be discussed within the institution --

MR. TELFORD: By the department or the RSC or quality management committee, something like that.

DR. SUNTHARALINGAM: That's right.

DR. BRICKNER: You have that now. Diagnostic events requiring a record or report -- it doesn't say requiring a report.

MR. TELFORD: Scratch the report.

DR. SUNTHARALINGAM: No reporting.

MR. TELFORD: You already have some mechanism of discussing these things. You already have -- some institutions don't have an RSC. In that case, it has to be department management or something like that. We are making a distinction between those things that are to be handled internally and those things that are reported to the NRC.

DR. BRICKNER: In 35.34 regarding therapy, it would be therapy events requiring a record, period. No oral

report to licensee management.

DR. DEYE: He's not saying that yet. We are only talking about -- did you say event or misadministration.

DR. BRICKNER: Event.

DR. DEYE: I guess he's saying that.

MR. TELFORD: Events require a record.

DR. PAYNE: Serious events.

MR. TELFORD: Are you with me?

DR. BRICKNER: The 35.34 then regarding -- we presently see therapy -- events requiring a record or report to licensee management, that would be changed to read therapy events requiring a record, period.

MR. TELFORD: Notice --

DR. BRICKNER: Is that what you are proposing?

MR. TELFORD: A record, and the events to be discussed at some applicable meeting like the RSC quality management --

DR. BRICKNER: How are you going to phrase that? To be something recorded and addressed appropriately.

MR. TELFORD: Recorded in the minutes. Notice that 33 has two parts. It has an A part which are events and a B part which are misadministration. The A part the events, those are the ones that I am talking about. They should be handled internally.

DR. BRICKNER: Okay.

MR. TELFORD: B, or misadministration, that's the word we are using currently, those ge. reported to NRC.

DR. BRICKNER: Yes.

DR. DEYE: Were you going to tell us something new about misadministration terminology? We talked about this morning and you said wait until later, and it's now later.

DR. BRICKNER: Did you want to say something more about events before you --

MR. TELFORD: Events, like the A paragraph?

DR. BRICKNER: Yes, did you have something else you wanted to say. He's pushing you to get to that.

MR. TELFORD: He wants to go to B.

DR. BRICKNER: Misadministration, yes. Is there anything else we should know about events, except that we can report them in the minutes and handle them internally. We can record them in minutes as a satisfactory method of documenting what we have addressed. Am I not stating it correctly?

MR. CAMPER: You are correct.

MR. TELFORD: The business about the RSO investigating --

DR. BRICKNER: All of that --

MR. TELFORD: Our latest thinking is to take all of that out, and just have the events --

DR. BRICKNER: There's a significant cost

reduction.

DR. DEYE: Yes, it is. I think that is a very good step in the right direction.

MR. TELFORD: Even if we require misadministration or whatever we call them to be reported to the NRC, if the number is truly small -- one out of every 10,000 cases -- how do you make a big deal out of the cost there?

DR. BRICKNER: No problem.

MR. TELFORD: Misadministration. We have had discussions among ourselves as to what to call these. It could be that the staff could propose that we not use the M word, that we call these things something like events and reportable events. We should really get into the discussion of what we are going to call the event and what is the threshold that makes something an event, and what is the threshold that makes something a misadministration.

We quickly went through some of that in the November meeting. In truth, I need a little more logic as to why we were throwing out those thresholds. Conceptually we are amenable to calling it something else. Frankly, I am not sure how far I can get with it. To me, it is something -- here is an event that occurred. This ought to be handled internally to the licensee. Here is something that is reportable.

DR. DEYE: I like reportable event. I think that

is good terminology.

DR. PAYNE: In the power industry, is that -- there is just indications for reports. You just have a stratification. Of course, then you go off -- it used to be monetary problems and contamination problems and things, and I think now it is --

MR. CAMPER: There are categories of reportable --

DR. PAYNE: We could refer to that. We could hang some hats on that.

MR. CAMPER: Generally speaking amongst the team, the rule writing team, there is a feeling that trying to pursue the idea of reportable events is the way to go. One of our reasons for that is the logic that you were just mentioning. That is, the concept of reportable events and categories of reportable events exist elsewhere in the Commission.

We would not make the argument that the M word is an unfavorable term to the regulated community. We would argue that to be consistent with other reporting requirements throughout the agency and if indeed we get the information that we are looking for, I am not so certain that we are concerned with what we call it.

DR. BRICKNER: We would appreciate that, because our motivations as you say might not be acceptable to the Commission. The legal aspects of it --

DR. SUNTHARALINGAM: I think the last meeting I made the suggestion and they are in the minutes -- it probably has come up in phraseology somewhere else. That is, to think in terms of an event as a deviation from intended treatment. The threshold of the deviation is what then becomes a reportable event. As long as we define -- we are now getting away from an error or misadministration. It is a deviation from intended treatment.

DR. BRICKNER: I like events and reportable events. We are looking at --

DR. SUNTHARALINGAM: That is where -- define what an event is because --

DR. BRICKNER: It certainly is hard to finish a sentence here. We are looking at a distribution of things that happened that we didn't want to happen, and some of them are extremely minor and some of them are extremely major. We are saying at this level we have to tell somebody. Below this, we will take care of our own house. All these are events, but at some place they become reportable. That should make infinitely good sense to the Commission or any other body.

MR. TELFORD: Another argument that we might make in favor of using that terminology is that if you think as Dr. Suntharalingam was thinking, we really have an unintended deviation here if you are talking about 4,000

rads instead of 2,000 rads. You might want to call that an unintended deviation.

But something else which is equally reportable might be wrong patient, wrong site. That is not an unintended deviation. That begs for a different category. If you have a term that covers everything --

DR. SUNTHARALINGAM: It's still a deviation from intended treatment. The treatment was intended for Patient and they deviated and gave the treatment to patient B.

MR. CAMPER: One thing I think would be very important to us -- I will throw out a couple of things and then come back to I think what is really the essence of John's concern at this point about thresholds. There are certain things that we see as misadministration, reportable events, whatever, things like the wrong patient, the wrong radiopharmaceutical, the wrong --

DR. BRICKNER: The wrong site.

MR. CAMPER: The wrong site. We are concerned about ancillary events, if you will, which occurred at Tripler when a embryo fetus receives exposure or a nursing infant receives exposure. Those things we see as reportable events and misadministration or whatever.

The tough area through is these threshold events and these -- teletherapy, brachytherapy and even in the diagnostic area on the one where you are talking about two

times the dose intended or two rem to a given organ, those kind of things. That is the tough area. In looking at the transcript of our last meeting we felt that there was a lot of good dialogue that we really did pour over rather seriously.

I think to the extent possible we can go through briefly and talk about those thresholds and get any specific inputs you might have at this stage of the game now that all of this has transpired. It would be very helpful to us. I think the team would agree that this is the tough thing to wrestle with, the threshold.

DR. BRICKNER: Can I address that for a minute, because not everybody was still there when we got to this point. What we attempted to do from this side of the table was to say that you have a series of events, some of these you are going to have as what we now call reportable events. The significance of that is that you are -- if we are still going to do this, require notification of the patient, notification of the referring physician. Therefore, several people at the table felt that those should be reserved for things which carried a significant threat to the patient's welfare, not just something dumb but something dumb that had a risk attached to it with some possibility of injury to the patient.

We felt that such a thing, for instance a

diagnostic isotope dose of 50 percent more than intended had no risk to the patient at all in the diagnostic setting. What we have seen up here today as events that were reported was 100 times or 1,000 times. We felt for instance that a 50 percent overdosage on an isotope diagnostic study shouldn't bother to be reported but 100 times, 50 times, some level, you might be getting to a biologically significant dose.

Similarly, we felt that an individual fraction being 20 percent too high probably has never a biological significance to the patient, whereas a fraction being twice what it was intended may. For instance, if you give 600 instead of 300 that may -- it's kind of iffy -- but that may have a biological effect.

We attempted to establish some threshold to have biological threat to the patient because along with the reporting was notification of the patient. You shouldn't be notifying them about every little thing that happened that had no significance to them biologically. That was our rationale.

DR. SUNTHARALINGAM: But as long as we recognize that there is still insufficient data to arrive at these meaningful threshold values --

DR. BRICKNER: Yes, sir.

DR. SUNTHARALINGAM: -- and as long as we

recognize that the number is thrown in in a hurry, when the initial rule came into existence was based on, again, some advice of the Committee coming up with a number with the current requirements. Now you are making a change to the current requirements in a new rule -- you might be changing.

All of us fought the battle when the current requirements were coming into existence. NRC reasoning was look we have an Advisory Committee or we call on our consultants and they gave us these numbers, period.

DR. BRICKNER: We are having the opportunity to do it and evaluate it.

M . CAMPER: In that regard, while we are not at great liberty to discuss the specifics of it now because there is a contract process going on -- I really can't talk about organizations or what have you by name -- I can tell you that we have a great deal of interest in having certain organizations take a look at what might be worthwhile biological indicators and the idea of hanging some of these threshold values with those significant indicators.

If we are able to do what we are trying to do, we think that the types of organizations that we are looking at to provide input would be met with a considerable amount of respect.

DR. SMITH: Are you going to contract to them, or are you just going to --

MR. CAMPER: We are exploring the possibility of it, but we can't be certain of it.

MR. TELFORD: Let me suggest that what we are really talking about is the item at 11:15, the roundtable discussion of proposed reporting requirements to be continued from before. Let me suggest that we should concentrate on 35.34 at page 1448 A and B.

We have before you a proposed paragraph A. These are events, not reportable outside but we took at cut at what those ought to be. The first is a therapeutic use without both prescription and prior review of the patient's case by an authorized user. Second, we need therapeutic use without daily recording of the dose or dosage given. The third is a teletherapy administration that is different by 20 percent or the administered dose is 20 percent different from the prescribed dose. The fourth is any use not authorized by your license. Maybe you just use a new brachytherapy source but it's not on your license yet.

Let's discuss events, and let me tell you about a little recent thinking as to what we would still capture in our thoughts as events. Any therapy administration without a written directive -- this is a new list.

DR. BRICKNER: New list, all over.

MR. TELFORD: Clean piece of paper, alternative list. Any administration without a written directive, any

administration without recording daily. Teletherapy, administration where you have the weekly cumulative is 20 percent greater than what was directed or not authorized by your license.

Are those things worth worrying about internally to your hospital?

DR. DEYE: Let's say that they are reasonable monitors to begin with, not meant to be mutually exclusive or all inclusive. Sure, those four seem --

MR. TELFORD: This is the minimum list.

DR. DEYE: Reasonable. It's a list that one could come up with another list of four things that would be probably just as good. As long as it is understood that they are four descent monitors within the context of how we describe therapy event, I would certainly say yes.

MR. TELFORD: Should any of these be replaced by any one that you are thinking about or added to?

DR. SUNTHARALINGAM: In our current thinking -- maybe you will get to that later on -- if you are going to encompass everything as events and then subdivide into what is reportable, then you will now continue with additional --

MR. TELFORD: Yes.

DR. DEYE: These are just the non-reportable.

MR. TELFORD: These are the non-reportable.

DR. SUNTHARALINGAM: These are non-reportable.

MR. TELFORD: You have to understand that paragraph A, the action words will be greatly modified, no more RSO, no more investigation. This is something that the licensee, management or its designee would determine which person would go and look at these events --

DR. BRICKNER: Administer some -- at some meeting they were handled.

MR. TELFORD: Yes. Discussed at the RSC meeting or in a quality management meeting. Or, if you only have two partners and that's your private therapy practice, the partners sit down and talk about it and make a record of the minutes of the meeting so that the inspector can look at the minutes and determine if the appropriate thing is done, if anything is done, or if it needn't be done.

DR. BRICKNER: I find that very acceptable.

MR. TELFORD: Let's move to the B paragraph. We could talk about these as being reportable events. These reports go to the NRC.

DR. BRICKNER: Are we still retaining a letter to the patient as part of reportable event?

MR. TELFORD: Keep in mind there is what I might call a safety valve, and that you can go to the referring physician or the primary care physician and make a medical determination of whether or not telling this patient could cause more harm than good. That determination is made, then

you don't have to tell the patient.

By the way, that is currently in 10 CFR.

DR. PAYNE: I am not a physician, but if I were a physician I would try and keep that.

DR. SUNTHARALINGAM: The emphasis can be placed on review of the referring physician and decision taken regarding reporting to patient. I think the emphasis can be placed on reviewing with referring physician.

DR. BRICKNER: You give them two options. You give them two options, and you do whatever you want. Most of the wise people in the world will go and talk to the referring physician. Now we are going to talk about what are the reportable events.

MR. TELFORD: Clean piece of paper, new sheet. I think we talked about the B events before here, the reportable events. We call them misadministration. The latest thinking that we would like to still capture as reportable events is when you have the wrong patient, the wrong radiopharmaceutical, or the wrong route.

DR. BRICKNER: Or the wrong site.

MR. TELFORD: That sounds an awful lot like radiopharmaceutical therapy. Let's go to teletherapy or brachytherapy. You have the wrong patient, the wrong seal source or the wrong site.

DR. BRICKNER: If you treat the left leg instead

of the right leg even if it's just one fraction, it is reportable.

MR. TELFORD: Yes.

DR. SUNTHARALINGAM: Supposing it is a one fraction error detected, the left leg was treated instead of the right leg 200 rads, what is the thought in reporting that to NRC? We were going to establish threshold value, but here you are saying even if you do it once it becomes reportable to NRC.

MR. TELFORD: At what point would you refer it?

DR. SUNTHARALINGAM: Let's ask the physician.

MR. TELFORD: Two treatments, three fractions, 100 rads.

DR. BRICKNER: If you were going to have some limiting factor what you would start talking about is at some percentage of the intended total dose or at a dose which has a biological danger to it, I think you can probably just go ahead and leave it as it is. You treat the wrong place -- I don't know. I don't know what kind of limit to put on it.

DR. SMITH: Because there was no intended dose there in the first place. Some things I think you should never tolerate. Some things you will tolerate some but other things you will --

DR. BRICKNER: Usually the patient knows what you

do.

DR. SMITH: You just shouldn't damn well be doing that, doing the wrong patient and the wrong site and those things. I agree, I think they should be there.

DR. DEYE: Let me complicate it just a tad and say what if you only treated have the site, in other words you set up your central axis on the lateral border tattoo instead of the central axis tattoo, so half your field was correct and half it was outside. Is it a reportable event or not?

DR. BRICKNER: That is a quality judgment the physician responsible for the department will have to make. You can extrapolate the --

DR. PAYNE: To me, wrong site means really wrong, like wrong side. Now, wrong site could be -- you have some custom block --

MR. TELFORD: We mean that's the site and you missed it, all of it.

DR. PAYNE: Okay. What if you hit part of it?

DR. DEYE: That's clear --

MR. TELFORD: The reason I am willing to say that is that we will capture the other ones someplace else. Now you are going to get -- if you overdose another site and now you might have some other catch.

DR. DEYE: If the wrong site means I missed all of

the intended site -- I understand that.

DR. BRICKNER: Remember the patient who came in to have the lung treated and the technician treated the head; that is the wrong site.

DR. DEYE: I don't know what to do with this other patient. I just know they are not in this group yet. We will find out where they are.

DR. BRICKNER: Ask the Chairman of the department what to do.

DR. DEYE: Right. He said call the NRC.

DR. BRICKNER: You asked the wrong man then.

DR. PAYNE: I think when we get into the guidebook, what does it mean, I am sure we will talk about that.

MR. TELFORD: I think we will pick it up in a minute.

DR. PAYNE: All right, then we will keep going.

MR. KLINE: Let's touch more on that, because we don't want to have a misunderstanding as to what the wrong site is. I think it's impossible to write a broad interpretation whether or not you were this close to the site, this far off or this far off, what the site is. I think in your case I think you were trying to point to the fact if what if you have an overlapping field, what if you have half the field that on the site and half that is off,

what if you have fields that are connected one beside the other but one field was not the right field. They both should have been in that one field.

They are pretty much reviewed case by case. It is almost impossible at times to say that meets a criteria or that doesn't. We would have to get very proscriptive to do that. I would submit that if I were a licensee, I would submit that information to the NRC and let them review it and critique it, and then determine whether or not --

DR. DEYE: You wouldn't do that if you were a licensee because why subject yourself to culpability if you don't have to.

MR. KLINE: If you don't know, I would assume that you would --

DR. DEYE: No, it's like dealing with the IRS. I mean, be quite frank. You are not going to report things -- you are going to wait for the IRS to find the issue. Very much, that is what we are dealing with here.

MR. KLINE: If you can do that, but --

DR. DEYE: I'm afraid that what you promote with this is, you promote ambiguity and imprecision in prescriptions. Instead of right lung the physician writes the prescription to the lung. Now, if I treat right or left I haven't treated the wrong site, have I?

MR. KLINE: If that's the way the physician

designates he wants to treat that area. The whole point of it is not to get around mistakes by writing in these ambiguous statements. That is not the intent here.

DR. DEYE: I know it's not your intent. I am only telling you that you can't lose site of who you are. You are a regulatory body.

MR. TELFORD: I think we will pick that up --

DR. DEYE: With legal authority and --

DR. SUNTHARALINGAM: Here again, based on the incidents reported and so on, we are trying to identify significant deviations that are now reportable to NRC. From what we have seen, the wrong anatomic site or left side was his left side or was his foot. It is not near close proximity to the target area.

DR. DEYE: Let's go ahead, but I think you are going to -- the good actors will be reported and the bad actors will get ambiguous --

DR. SUNTHARALINGAM: Wrong patient, wrong source, wrong site.

DR. BRICKNER: Those are the statutory reportable events.

MR. TELFORD: Wrong patient, wrong radiopharmaceutical, wrong route. Wrong patient, wrong seal source, wrong treatment site.

DR. SMITH: The way you wrote this here though, it

seems to me that you haven't covered the case where the written directive is wrong. You have covered cases where you don't follow the written directive --

DR. BRICKNER: That is not his privilege to tell me my prescription was wrong.

MR. TELFORD: Even if it's wrong. The department of health in your state may not be happy --

DR. BRICKNER: That's not his problem. If I tell you to treat the left leg and it's the right leg, that's not his problem. If you accidentally treat the correct leg for the patient's benefit, you may have to report it.

[Laughter.]

It's not the NRC's responsibility to supervise my medical judgment.

MR. TELFORD: Shall I move on?

DR. BRICKNER: Yes.

MR. TELFORD: Radiopharmaceutical therapy. Are you with me, Dr. Smith? Radiopharmaceutical therapy. I am interpreting that this group is much more interested in therapy than diagnostics. So, we are strictly here in the old 35.34 and in the B category here of reportable events. Radiopharmaceutical therapy, the administered dose differs from the dose in the written directive or dosage by more than 20 percent.

We are considering saying and it exceeds rem dose

for either so many rems effective dose equivalent or so many rem for a list of organs, different dose per organ. That is the work that Mr. Camper was alluding to that we would like --

DR. BRICKNER: That's exactly what we talked about last time and concluded that it should be somehow corresponding to some --

MR. TELFORD: Yes.

DR. BRICKNER: Measured event.

MR. TELFORD: In our position we can't just use the words it has clinical significance or causes harm to the patient. Because there are 6,000 licensee facilities out there we get 6,000 interpretations or maybe 7,001 interpretations --

DR. BRICKNER: That's exactly what we meant. Whatever number you put down though has to be related. IT can't be just arbitrary, it has to relate to a biological endpoint.

MR. CAMPER: We are exploring that.

MR. TELFORD: In teletherapy and brachytherapy, I will come back and ask you experts for a little help here.

DR. SUNTHARALINGAM: This is still addressing more than -- there is nothing to say --

MR. TELFORD: Difference, plus or minus.

DR. SUNTHARALINGAM: That's where I have a little

problem of how we can get a biological relationship and where patient safety come into your reasoning. You hear people talking about a low dose being prescribed.

MR. TELFORD: If we write it that it differs by 20 percent and it exceeds a certain rem dose, then I don't know that it excludes the lower ones.

DR. BRICKNER: And, exceeds rem dose -- low dose is out.

DR. DEYE: You will have to come back later and fill in the rem dose.

MR. TELFORD: Who says I can't write that by March?

DR. DEYE: You think you will have that?

DR. BRICKNER: You will have that by then?

MR. CAMPER: We are exploring that possibility.

DR. SUNTHARALINGAM: If you put a rem dose why not say greater than.

MR. TELFORD: Okay, we will think about that.

MR. CAMPER: That might work, yes.

DR. SMITH: You had an example that you showed us. Remember that you had a spinal cord dose that was supposed to be 28 I think and it turned out to be 33.

MR. CAMPER: Right.

DR. SMITH: That is still way below tolerance, way below tolerance. So you wonder, let's be careful about

requiring --

MR. TELFORD: Okay, let's get to teletherapy.

DR. SUNTHARALINGAM: Let's move on.

DR. BRICKNER: Have you finished isotopic therapy?

MR. CAMPER: No. You are still exploring the old 35.34 item B-5 John, is that correct?

MR. TELFORD: What I am really doing is giving our latest thinking on reportable events therapy.

DR. BRICKNER: We are through with isotopic therapy?

MR. TELFORD: Radiopharmaceutical therapy.

MR. CAMPER: Well, I do have a question about what was the old 35.34 B-5, the 20 percent.

DR. SUNTHARALINGAM: No, that's brachytherapy. Did we do brachytherapy?

MR. CAMPER: That's fine. We will do that when we come to that.

MR. TELFORD: We are not there yet.

MR. CAMPER: Okay, got you.

MR. TELFORD: We are up to teletherapy. Teletherapy calculated administered weekly cumulative, 40 percent greater than the weekly prescribed -- I think we can say prescribed dose because that comes from the written directive. And exceeds a certain number of rads.

DR. BRICKNER: Forty percent, you say?

MR. TELFORD: Forty percent and exceeds a certain number of rads. Now, --

DR. DEYE: This was calculated, administered?

MR. TELFORD: Just think of it as --

DR. DEYE: Weekly?

MR. TELFORD: Weekly accumulated, administered, 40 percent greater than prescribed. But because this is a reportable event, we would like it to have some significance. We say and exceeds a certain number of rads.

DR. DEYE: It was calculated administered.

MR. TELFORD: Yes, calculated.

DR. PAYNE: We cannot measure every single administered radiation dose. You know that, I know that, the record knows that.

DR. SUNTHARALINGAM: Again, for clarification, this is exceeds.

MR. TELFORD: Exceeds.

DR. SUNTHARALINGAM: Not --

MR. TELFORD: For the ease of talking, let me talk about it in terms of weekly, accumulative, administered, exceeds prescribed by 40 percent and exceeds 100 rads, 200 rads?

DR. DEYE: It depends on the organ.

MR. TELFORD: What is the worst case?

DR. BRICKNER: Worst case is probably the lens of

the eye or total body marrow dose to.

MR. TELFORD: Take the case of the lens of the eye.

DR. BRICKNER: It takes about 750 or so to get a cataract, so if you exceeded the dose by 200 or 300 you are probably going to be in the ballpark of developing a cataract.

MR. TELFORD: How about hemi-body?

DR. BRICKNER: That gets very tricky, because you intentionally go right to the edge. For instance, you go right up to within a very small increment of what runs a risk of a fatal --

DR. SUNTHARALINGAM: That's a single treatment.

DR. BRICKNER: That's a single treatment.

DR. SUNTHARALINGAM: That's a single treatment.

DR. BRICKNER: That is a very special circumstance.

MR. TELFORD: We capture that in total. Let's postpone that question until we get to --

DR. SUNTHARALINGAM: Even here we are saying 40 percent of prescribed which is your target dose. Now we are looking at exceeds doses and --

MR. TELFORD: And exceeds --

DR. SUNTHARALINGAM: Exceeds it within the target or the critical structures.

MR. TELFORD: The Delta exceeds this rem dose.

DR. SUNTHARALINGAM: Yes, but it exceeds the dose you are talking about is still from the prescribed target, is what I am saying. Supposing I am treating a target and you want to give 200 rads per day. Weekly is --

MR. TELFORD: We are not worried about the target.

DR. SUNTHARALINGAM: He immediately gives an example of lens of the eye. The lens of the eye is not the target.

MR. TELFORD: That's right.

DR. SUNTHARALINGAM: Therefore, you are -- are we trying to say that we are keeping track of the dose to the lens of the eye and if that exceeds by a certain amount --

MR. TELFORD: No. We are saying that if it were only over by 50 rads, regardless of where you delivered the 50 rads to the body you could probably cause no harm. If we could find a number like that and we could say that's a threshold that you also have to exceed.

DR. SVENNSON: Doubling the fraction -- you mentioned doubling the fraction. That would mean --

DR. BRICKNER: If you were giving say 300 rads a day to the brain and you gave 300 to each side, that would make you nervous. If it happened one time it isn't going to hurt anything. If it happened two or three times, or if it happened all week --

MR. TELFORD: Is that 300 rads to the midline?

DR. SUNTHARALINGAM: Yes.

DR. BRICKNER: If that happened all week, instead of having 1,500 you would have 3,000 in one week.

MR. TELFORD: This is cumulative, weekly cumulative.

DR. BRICKNER: Yes.

DR. SVENNSON: That would be a reportable event.

DR. BRICKNER: If it happened all five fractions.

MR. TELFORD: That would be like 60 extra from each side five times.

DR. BRICKNER: No. What you intended to do --

DR. FLYNN: Instead of 300 midline, 150, 150, 150 if they gave 300, 300, 300.

DR. BRICKNER: It just doubles the dose for the whole week. That could get you in trouble.

DR. FLYNN: Do you really need to cover that at all, because every therapy dose is going to be one, 15 to 200 fraction --

DR. BRICKNER: No.

MR. TELFORD: Aren't there some that are 50?

DR. BRICKNER: There are some that are ten.

MR. TELFORD: How often?

DR. BRICKNER: Rare. Nearly always it's 150 --

DR. FLYNN: Forty percent per week, otherwise you

are going to make the reporting requirements tough. People are going to have to calculate --

DR. SMITH: Why do you have to have the exceeds some miracle dose.

DR. FLYNN: What don't you --

MR. TELFORD: Our purpose is to make sue that it meets something.

DR. SMITH: But that doesn't solve that problem.

DR. BRICKNER: Three hundred rads.

MR. CAMPER: Which problem are you referring to?

DR. SMITH: You could put a number there and it could have no biological significance whatsoever.

MR. TELFORD: Wait a minute. Dr. Brickner just gave us a number of 300 rads. Is the example of the brain, is that what you are --

DR. BRICKNER: No. I am just giving you a number that probably could mean something if you gave it to the wrong place. For instance, if you irradiated the testicles with 300 rads and didn't mean to, that could have some at least transient effect. If you radiated the lens of the eye with an extra 300 rads that you didn't intend to give, that could conceivably lead to cataracts in ten years.

DR. PAYNE: If you gave 300 to my right toe --

DR. BRICKNER: You could that for once a week for the rest of your life and it wouldn't hurt anything. In

fact, my wart might go away. I would say it's 300 or maybe higher, but I would say at least 300. I think 300 is ultimately safe. Some guy will come along and think of a case that I didn't think of and say I'm crazy.

DR. SUNTHARALINGAM: That statement is going to lead to a lot of ambiguity.

DR. SMITH: It is, enormous.

MR. TELFORD: What are you gentlemen thinking of?

DR. SUNTHARALINGAM: At the moment I think the percent of prescribed dose --

DR. FLYNN: I think 40 percent is fine, just leave it there.

DR. SUNTHARALINGAM: Leave it at the 40 percent level.

MR. CAMPER: That's interesting.

MR. TELFORD: I am really curious. Why do you say that?

DR. SUNTHARALINGAM: Now we are getting into areas which may be outside the treatment volume also. This intent here was more to detect and report calculated administered weekly doses.

MR. TELFORD: Of course, but if you intended to hit this cup and a vital organ is in the shine through area, that is where the consequence happens. Of course it is organs not in the treatment volume.

DR. DEYE: That is part of the treatment. We can't just treat --

DR. SMITH: Treatment volume is everything --

MR. TELFORD: True.

DR. DEYE: Therefore, we don't consider what you are suggesting here as relating to those normal tissues that were included in the treatment volume. That is not to be confused with tumor volume.

DR. BRICKNER: If you treat the cervix, cancer is in the cervix. We are treating the whole pelvis, so we are worried about the rectum and bladder. We are cognizant of it, we plan the doses appropriately. What you want to know in this case is, what excessive dose would have an adverse effect on those. We agreed that if you had an administration that was 40 percent higher than you intended you probably have to tell somebody about it because that's -- how many rads would hurt them. A couple hundred, 300 wouldn't mean a tinkers damn to those organs.

Next to that, six inches away is the small bowel. We can't start talking about all the rest of the body. It's not going to be in the field.

DR. SUNTHARALINGAM: Also, when we are keeping track of cumulative doses there may be the target and certain points of clinical interest to the physician. If you only made a 40 percent error in your target dose, then

the 40 percent is going to be carried to other points of interest also. Supposing the rectum and bladder was in the irradiated field, and the physician said I want to carry your target dose but also wanted to record on the chart the rectal dose and bladder dose.

You give 200 rads to the target and the bladders is going at 150, and the rectum is at 160 you record that. Now that there's a accumulate error of 40 percent in your target dose it is going to be carried to the other points.

DR. BRICKNER: Everything else also.

DR. SUNTHARALINGAM: Everything else also. Just saying that it exceeds a number of rads and not defining rads to where --

DR. SMITH: Putting a number of rads is very risky.

DR. FLYNN: In your introduction to your proposed rule back on January 16th, there is 100,000 patients a year that get cobalt-60 treatment and I agree with that. I think that's a good number because probably about 500,000 get teletherapy treatment per year in general today.

Take those 100,000 patients. The average number of treatments that have been calculated by various groups as being approximately on average now about 20 treatments per patient. Some get 15, 16 and some maybe 25 or 30. On average, 20 treatments per patient. The average number of

fields per patient averages extremely close to two. We did this in Massachusetts, average to two.

That's 40 fields per patient times 100,000 patients, about four million fields. I would say that 99 percent of those fields the dose is 150 rads or greater. There is probably a few cases where it's 50 rads. Most of these patients are being treated for various problems where they are getting 150 rads per day or 180 rads per day, 200 rads per day very commonly and 300 rads per day or 350 rads per day.

The percentage probably covers it pretty well. If it's a 1,000 rads per week or 1,500 rads per week, 40 percent is a fairly significant dose. The percentage itself probably covers the seriousness of what might be reportable. Very few patients get ten rads per day to anything that I know.

MR. CAMPER: That's interesting, because in wresting with this this past week we were asking ourselves the same question; rads to what.

DR. BRICKNER: Let's just not discuss rads. It's interesting that if you take those 100,000 treatments at two ports apiece at 20 treatments average over eight years, you come up with 32 million ports were treated. The reports that happen in cobalt were 35. That's just about one in one million ports treated. That's a pretty damn good track

record.

Even if only one out of 100 were reported, it is still a pretty good track record. That's one out of 100,000 rather than -- we are not doing bad. Let's just leave it at 40 percent reportable for weekly cumulative.

MR. TELFORD: Weekly cumulative 40 percent greater.

DR. BRICKNER: Greater, yes.

MR. TELFORD: Total teletherapy administered dose, calculated administered dose differing by 20 percent than what is prescribed. Help me out there.

DR. DEYE: As compared now to what?

MR. TELFORD: Prescribed.

DR. DEYE: Prescribed or final prescribed?

MR. TELFORD: Final.

DR. DEYE: You left the word final out of your original January 16th, so you are thinking of putting that back in. It was in the original from way back when.

MR. TELFORD: Does it matter because you can amend the written directive.

DR. DEYE: You didn't allow that in the January 16th.

MR. TELFORD: We certainly tried to.

DR. DEYE: It doesn't come through that way.

MR. TELFORD: Maybe it's --

DR. DEYE: Even in some of the examples that were

handed out --

DR. BRICKNER: Could we have it as written directive as amended, if amended.

DR. DEYE: If the physician is told that his lung cancer patient got 6,600 rad to his lung instead of 5,800 and he sailed right on through he says great, I will change my prescription to 6,600 --

MR. TELFORD: You have to do it before the fact.

DR. DEYE: That's my problem. It should be allowed. It was allowed on the old misadministration. If the patient survives 6,600 rad -- you really want to say that.

DR. BRICKNER: That gets -- you are going to deliver 5,000 rads.

DR. DEYE: Don't you treat the tolerance?

DR. BRICKNER: I determine tolerance, but what I know from the literature and experience is -- I don't treat --

DR. DEYE: IF the patient got through the 6,600 rads just fine instead of the 5,800 wouldn't you be happy with that.

DR. BRICKNER: I would be happy that he got through it fine, but I would be damned angry at my staff because he got 6,600.

DR. DEYE: Would you want it reported to the

referring physician?

DR. BRICKNER: I think that's perfectly legitimate, yes.

DR. FLYNN: I think also because we see patients every week as a standard, if someone is exceedingly ill who is 90 years old we have at our discretion to modify what the total prescription is going to be on a weekly basis at least. And then, as long as we have done that before it is finalized -- we can't modify it a year later.

DR. SMITH: How about changing prescriptions after the fact --

MR. TELFORD: Only before.

DR. BRICKNER: If you get to 4,000 rads and you are having no tumor regression, and you want to say I am going to push this to the limit and go to 7,000 write it down and do it.

DR. DEYE: I understand all that. I can only tell you that the physicians that I have discussed this with feel that they should not have to report that event to the NRC, the referring physician and to the patient's possible --

DR. SUNTHARALINGAM: There is a difference between changing the prescription and requiring somebody to report. I think there may be instances where, because of some deviation that the final dose is different from the intended dose. Then the physician is using the judgment based on the

performance of the patient -- patient received 6,500 instead of 6,000.

Now the question that I think is being debated is, when does it become reportable --

DR. DEYE: And what is the biological significance.

DR. SUNTHARALINGAM: And the significance. This is this threshold thing. Forget -- everybody agrees that you shouldn't be changing your prescription after the fact.

MR. TELFORD: Let's use an example. The patient is supposed to get 6,000 rads in total. If we allow 20 percent, that's 7,200 rads --

DR. DEYE: Are you changing the number to 20?

MR. TELFORD: This is on the table as a matter of discussion, differs by 20 percent. That allows 7,200 instead of 6,000.

DR. BRICKNER: You have exceeded the 7,200 when you meant to do 6,000 and you have screwed up.

MR. TELFORD: Wait a minute.

DR. DEYE: You don't mind reporting this and making it a --

MR. TELFORD: The point that I need help with is, if this patient -- is this patient supposed to get 6,000 but got 7,200 -- make it 7,199 -- can we argue that it is of no biological significance.

DR. DEYE: Not on that one, but go to my Hodgkins case. This is very real. There is a lot of discrepancy in the community today about what to give a Hodgkins patient.

MR. TELFORD: Yes, but that's a debatable kind of --

DR. DEYE: You want to debate, and let me give you a debate.

MR. TELFORD: Wait a minute. I don't want a debate. I want help here.

DR. DEYE: I am trying to help you, because I am trying to say that 20 percent without allowing the prescription change is much too restrictive, given the realities of radiation oncology. It doesn't recognize the non-significance of 1,000 extra rad in the case of Hodgkins. From 6,000 to 7,200 would be too much.

MR. TELFORD: Why didn't your physician prescribe 4,000 to begin with.

DR. DEYE: Let Dr. Brickner explain that. Why is there so much confusion in the therapy community today?

MR. TELFORD: If the y treat 4,000 that's what they should give.

DR. DEYE: Some disease you don't have to treat the tolerance. Some disease you try to minimize the side effects and you believe that you probably have a cancer societal dose if you get to 3,000, though that is debatable

in the literature. Other doctors say no. I have been in this field for 30 years, and by God Hodgkins needs 4,000 rad and that's what I treat --

DR. FLYNN: Some of these people are getting extremely aggressive chemotherapy and people are backing off on the Hodgkins disease dose. I don't think you can get into the medical judgments because you can't monitor that.

DR. BRICKNER: The question is, if you miss your intentions by more than 20 percent have you demonstrated a serious reportable problem in your management of dosimetry.

DR. SUNTHARALINGAM: But we are trying to approach this threshold with some biological --

DR. BRICKNER: Then you might want to add as was suggested earlier, provided that dose exceeds 1,000 rad. Twenty percent of the total dose --

MR. TELFORD: Here is my question for you. If 6,000 is prescribed and 7,199 was given, can we claim no biological significance?

DR. BRICKNER: No.

DR. SMITH: It depends on the case. Every case is different.

MR. TELFORD: Therefore, is 20 percent too high?

DR. BRICKNER: You have to have one number that you are going to put out. Unless you are going to say here's a list of 500 conditions --

MR. TELFORD: Could we say ten percent and it exceeds 500 rads?

DR. SUNTHARALINGAM: Let's leave it at 20 percent.

MR. TELFORD: That may not work, because that overdose may be of biological significance.

DR. DEYE: My feeling -- this is exactly why I brought this point up, and I wish I could speak with the physicians in more detail on the side. I think it is very important that you recognize that it is an individual decision, the biological significance of X rad overdose at the completion of prescription, at the completion of treatment.

The only way to know the biological significance of that is for the person who is responsible for the medical care of that patient to make that determination. It is made individually from disease to disease, patient to patient. That's why I say final prescribed. I know it is not good practice to be changing one's prescription after the fact. Just as you change your prescription during treatment because of the progress of the patient and because of their lack of morbidity, you might well change your prescription at the completion of treatment knowing that you have done that patient a service for a morbid disease and they survived that fine.

Now, sometimes you don't want that liability. You

would say heck no I am not going to change that prescription. That is a biologically significant dose and I prescribed the correct dose and you gave the wrong dose, this is a misadministration and we are going to have to report it as that.

On the other hand, you may say this went just fine. It may not have been what I intended to prescribe -- it isn't what I prescribed -- given the fact that the patient got through it, I don't believe it did this patient any harm whatsoever. It may have actually eradicated more disease cells another order of magnitude, and I am comfortable with that.

DR. BRICKNER: Yes, and nine months later the patient has a transverse myelitis.

DR. DEYE: Well, that was your decision when you changed the prescription. There was nothing that says you have to change the prescription. You had the medical judgment of whether you wanted to change the prescription or not.

DR. SUNTHARALINGAM: Let me just add one piece of information that might help again. In national clinical trials where there are protocols people have to follow and then there's a prescribed dose. There is this calculated administered dose. In the national studies we say that if it is outside ten percent it is a minor deviation. If it is

outside 20 percent we say it is a major deviation.

DR. BRICKNER: They may not be valuable cases.

DR. SUNTHARALINGAM: Therefore, anything that is outside 20 percent initially --

MR. CAMPER: Strictly a percentage, correct.

DR. SUNTHARALINGAM: It is thrown out of evaluation of the protocols. Statisticians have looked at whether there is a significance of adding those patients into the study and deleting those patients in the study, and to my knowledge think there is only one study where that showed some impact to those patients.

MR. TELFORD: Significance with respect to what?

DR. SUNTHARALINGAM: Outcome of the study. Whatever that protocol was trying to establish. Twenty percent seems to be a criteria that has been -- that is currently in use in terms of national protocol studies as a major deviation. I would think referring to 20 percent.

MR. TELFORD: What do we do if it is a questionable case, do we refer it to our medical consultant and find out on a case by case basis that this may mean something?

DR. FLYNN: Medical Advisory Report. The ACMUI should be practicing clinical people and not retired people. I think they should be people who can review these cases -- I am serious -- review these cases and make a

recommendation.

DR. BRICKNER: If you make it less than 20, then you are going to have -- the minimum has to be 1,000 rads.

MR. CAMPER: Would you, for the record, state that 20 percent number is part of what standard? Would you state that again?

DR. SUNTHARALINGAM: These are for national protocol studies which are institutional or multi-institutional. Most radiotherapy protocol studies have a criteria to analyze their data.

MR. TELFORD: Sponsored by who?

DR. SUNTHARALINGAM: No, it is supported by the National Cancer Institute. NCI funds these studies.

DR. BRICKNER: Less than ten percent is acceptable, over ten percent is minor break in protocol, over 20 percent is major break in protocol, and may not be called an --

MR. CAMPER: I like the idea that the 20 percent from our vantage point can be tied to some other standard that seems to be accepted.

MR. TELFORD: The applicability here is a little bit weak. It is rather abstract and you ought to know whether or not the case was successful. In this case, you are talking about overexposure, and we have to guard against risk or actual harm to the patient. On the one hand I feel

a little bit nervous about the 20 percent, that indeed you could have some cases that are 1,200 rads over and might cause some harm. You don't know unless you look at --

DR. FLYNN: What I am saying is that if there is only five cases a year or ten a year, you could refer these to your medical advisory committee on a case by case -- on your discretion.

MR. TELFORD: We are talking about reportable things here. We only discover these upon inspection which, for large hospitals, is once a year. We could go and collect these and refer them --

DR. FLYNN: You would discover them as an event because they would have to be --

DR. BRICKNER: You could call it 20 percent or 1,000 rads or more -- over 1,000 rads, either one. One Hundred thousand rads, there's not a whole lot -- normally you treat from four to six weeks 1,000 rad either way.

MR. TELFORD: Twenty percent or exceeds 1,000.

DR. BRICKNER: Yes.

DR. PAYNE: Or, or and?

MR. TELFORD: Or.

DR. DEYE: You take 20 percent of any dose as reportable, of any prescribed dose?

MR. TELFORD: Of how much?

DR. DEYE: I think with the or, 20 percent of any

prescribed dose is going to be a reportable event.

MR. TELFORD: Yes.

DR. SUNTHARALINGAM: Supposing the prescribed dose was only 3,000 and 20 percent is less than the --

MR. CAMPER: Right.

DR. SUNTHARALINGAM: That becomes reportable.

MR. KLINE: How are people living with the current definition, the plus or minus 10 percent. You are mentioning your Hodgkins cases. How are people dealing with it?

DR. DEYE: I have seen physicians change the prescription. You may not like to hear that --

MR. KLINE: No.

DR. DEYE: But they would rather not be reporting this to the public document room downtown.

MR. TELFORD: Just don't tell me the name.

DR. DEYE: I won't. I have been into mental institutions. There is a difference between -- we are not dealing with an NCI protocol here. We are dealing with a legal, culpable responsible action here.

DR. SMITH: Let's turn this around. Do you really think that there should be language which permits physicians to change their final prescription merely on the basis of getting out of reporting it?

DR. DEYE: Yes. If they want to take that

responsibility. If they want to prescribe 10,000 --

DR. SMITH: Believe me, they will take it if you give it to them. They shouldn't be able to do that, change a prescription.

DR. DEYE: We have not had any --

DR. SMITH: That's a different argument.

DR. DEYE: If they want to take that upon -- it is their medical decision.

DR. SMITH: We are talking about --

DR. BRICKNER: The purpose of the program is to find people that don't have control of their treatment. The treatment is out of their control. When you miss by 20 percent you wonder do you have control or what the hell is going on in your department.

DR. SVENNSON: That happens too many times.

DR. SUNTHARALINGAM: Differing by 20 percent period, it seems to me more acceptable than even adding anything about dose.

DR. BRICKNER: Over 1,000 rads.

DR. SUNTHARALINGAM: And over --

MR. TELFORD: Total course of therapy.

DR. SUNTHARALINGAM: Total course of therapy.

DR. PAYNE: Almost all of the time it will be over 1,000 rads. That is sort of redundant.

MR. TELFORD: He gave a case of 3,000 as a total.

DR. SUNTHARALINGAM: As 3,000 total, that's only 600.

DR. DEYE: But you are going to report it.

MR. CAMPER: The general consensus, is the general feeling that it would be percentage only, 20 percent if you will, or should it be tied to some rad.

DR. DEYE: Does that show that your program is out of control Ted, if somebody gets two additional fractions?

DR. BRICKNER: I think so.

DR. DEYE: Then you should not want to --

MR. TELFORD: He said or.

DR. DEYE: What if they got one additional fraction, is your program out of control?

DR. BRICKNER: That is not reportable.

DR. DEYE: I am only suggesting --

MR. CAMPER: It is an incident.

DR. DEYE: How many fractions does it take for your program to be out of control?

DR. BRICKNER: Twenty percent.

DR. DEYE: Twenty percent.

DR. SUNTHARALINGAM: That's right.

DR. BRICKNER: If I go down to treat 400 rads of fraction five fractions over the spinal cord and they treat six fractions, we have a problem. If they treat seven fractions, we got a serious problem.

MR. TELFORD: How much is each fraction?

DR. BRICKNER: Four hundred rads a day.

DR. SUNTHARALINGAM: Is it four hundred times five and somebody gave four hundred times six.

MR. TELFORD: Your two fractions is 800. That is approaching 1,000.

DR. BRICKNER: Then I really begin to get worried. I am not going to argue about the and/or because I think if you are off 20 percent you are off. All the problems of reporting and you have to talk to the referring physician and say here is what the regulations are, but they only have 300 rads. It isn't going to hurt anybody.

DR. DEYE: Most referring physicians are not going to take that responsibility.

DR. BRICKNER: That's true.

MR. CAMPER: We are really hearing 20 percent.

DR. SUNTHARALINGAM: Twenty percent is certainly an improvement from the ten percent.

MR. TELFORD: Twenty percent, or exceeds 1,000 rads.

MR. CAMPER: I get the sense that we are not hearing exceeds the 1,000.

MR. TELFORD: You can't argue that, gentlemen. If we are going to say -- we can't make that case. You have to be able to tell me that 1,200 rads doesn't mean anything.

DR. DEYE: I can't tell you that in all cases.

MR. TELFORD: Then we have to say or exceeds 1,000 rads or exceeds X-rads. We have to capture those things that are --

DR. BRICKNER: I think that is reasonable.

MR. TELFORD: I have to go before the Commission with a straight face and say that I believe this.

DR. PAYNE: I want to add one slight complication.

MR. TELFORD: Or.

DR. PAYNE: It does pertain to this a little bit. We have a situation where I know of a physician that writes in his prescription his written directive goes 5,000 to 6,500 as tolerated. Off we go and somehow there is a communication problem. So, we go beyond 5,500. Maybe we are supposed to talk to him, but he has written down there 5,500 to 6,500 as tolerated.

We somehow get to 6,500 and he said oops, I told you 5,500 and we want you to stop. You give him 1,000 more and it's written there. I guess he says you are wrong and we say you should have told us and we go back and forth. Your comment, Dr. Brickner.

DR. BRICKNER: I think you have a physician that needs to have a serious talking to.

DR. PAYNE: A better written directive.

DR. SUNTHARALINGAM: It's more like --

DR. BRICKNER: You have a perfect excuse. You

don't ever have to report anything because he has given you such a big range in there that when you get to 6,500, if you do 20 percent more and get up to 8,000 you would have to report -- God, I hope so. I don't think that's a proper prescription, 5,500 to 6,500 as tolerated.

DR. PAYNE: Interesting.

DR. BRICKNER: You wanted my opinion and I think that's a lousy prescription, that's what I think. That is not what we are addressing here.

MR. TELFORD: Let's move to something really hard.

DR. BRICKNER: All right.

DR. DEYE: What did you come away from this with? Or, is what you said?

MR. TELFORD: By 20 percent or exceeds 1,000 rads.

DR. SUNTHARALINGAM: You are still emphasizing differs by.

MR. TELFORD: Total.

DR. SUNTHARALINGAM: Now my concern again is, what happens if it is less.

MR. TELFORD: I may have a small logical problem there.

DR. BRICKNER: If the physician says therapy discontinued due to the patient's clinical course, that takes care of it.

MR. CAMPER: You just altered the written

directive.

DR. SUNTHARALINGAM: If an error is made --

MR. TELFORD: Prior to --

DR. SUNTHARALINGAM: If an error is made and at the end of treatment you have found that you have given the patient a lower dose than you intended --

DR. BRICKNER: You can never take it away once you give it.

DR. SUNTHARALINGAM: Right.

DR. SMITH: This should be more than.

DR. SUNTHARALINGAM: That is what I am asking.

DR. BRICKNER: You can make the case for 20 percent error is 20 percent error. You right biologically -- you have perhaps taken away from them the possibility of --

MR. TELFORD: Please, the reporter says one at a time.

[Laughter.]

MR. TELFORD: Shall we move to brachytherapy or further comment on teletherapy?

DR. DEYE: I think this is really still a can of worms. Let's just pursue the less than for a minute. If an institution gave 30 percent less than prescribed --

MR. TELFORD: Due to what?

DR. SUNTHARALINGAM: An error.

DR. DEYE: Due to an error, and you find this out a month after the patient is moved to Timbuktu. Is that a sloppy program and therefore should be reported to the NRC as a reportable event, even though they gave less radiation than was prescribed and the biological significance of that is questionable.

DR. BRICKNER: They may have allowed a recurrence that wasn't necessary to allow.

DR. FLYNN: I think the key difference is during the weekly cumulative dose. If there is a problem with a patient not being able to tolerate the treatment and the machine malfunctions and you don't give the 1,000 that week and you give 700. At least by the time that patient has completed the course of treatment hopefully you have made up the difference.

Once the treatment is over, you can make the case that instead of using the word exceeds as you use in the weekly cumulative dose at total dose you can use the word differ. It think that is legitimate. Once that patient is gone, you may cause that patient to die of his cancer because you under-treated the patient.

DR. DEYE: What if the patient disappeared from the face of the earth for three or four weeks in the middle of the course of treatment and went off to Mexico for Laetrile treatments.

DR. FLYNN: You document that. That's patient non-compliance. That is not your problem.

MR. TSE: This is not a mistake made by the licensee. DR. BRICKNER: This is to detect and correct errors. DR. DEYE: What is the exact wording? I thought that it was less than intended?

DR. BRICKNER: Therapy discontinued, due to patient's absence. Change in prescription I guess.

MR. TELFORD: That's not a mistake that you made.

DR. DEYE: I guess I am not hearing the wording correctly. I thought the wording was just that if there was a deviation from the intended prescription by 20 percent or --

DR. SUNTHARALINGAM: A calculated administered total dose defers by the prescribed dose.

MR. TSE: The seal source -- teletherapy administration from a seal source such that errors in the source calibration at the time of exposure due to geometry and other errors resulted in --

DR. DEYE: Except that, I thought we were getting rid of the word errors.

MR. TSE: We might use different words, but the concept is still there.

MR. TELFORD: In other words, those things that you have control over and you would normally manipulate in

the course of treatment, like geometry, time, et cetera. If the patient disappears, the patient disappears. You just --

DR. SMITH: This is the last day we have to do this. I think we have covered this ground. Are there other topics that we have to come back to?

MR. TELFORD: Let's move to brachytherapy.

DR. BRICKNER: Yes, because I am leaving in one hour.

MR. TELFORD: We thought we needed to capture any brachytherapy administration with a source that is leaking or inadvertently not removed. Any brachytherapy administration where the administered dose differs from the prescribed dose by some percent. Now, during the last November discussion we talked about looking at that two ways. One was a difference in dose, and the other way of looking at it in terms of activity or time.

In terms of talking about it in terms of a percentage of the prescribed dose, you are alluding to the fact that it may be difficult to calculate that dose. What I wanted to ask you was it more meaningful to talk about it in terms of percent of dose or in terms of percent of activity and percent time? Think about --

DR. BRICKNER: That depends on really how the physician wrote the documents defining what he intended to do. If he has said I want to give 3,500 milligram hours,

then it would be percent milligram hours. If he has said I want to give 4,000 rads to point A, then it would be some percent of the dose at point A. I think you have to go with the prescription and say what is the variation to the prescription using the same units of definition the prescription used.

DR. SMITH: Just say the difference in the quantity that is prescribed by the physician in his direction. Quantity, however he has written down, whether it is prescribed dose or milligram hours or just hours. The moment you say quantity, whatever he has described, that quantity --

DR. BRICKNER: I frequently will write in the chart plan 70 hour applications. And then you want to talk about the percentage of the time that I have written down I intend to have all that in there. My mistake will be did I Take it out on time.

DR. DEYE: Is it fair to apply the same percentage to each of those various terms? They certainly will, because your rads per hour is not one per hour.

DR. BRICKNER: If you cut the time in half, can you do anything other than cut the dose in half?

DR. DEYE: I understand, but if you are talking the precision of how well you know that number, the milligram hours is much easier to know it seems to me than

the dose to point A. DR. BRICKNER: Then use milligram hours.

DR. DEYE: Is that not promoting imprecise prescriptions?

DR. SMITH: You are really splitting some fine hairs, John.

DR. DEYE: Okay.

DR. SMITH: We are looking for some guidelines here, I think.

DR. DEYE: But they are used as enforcement -- I keep think we are losing sight of where we are going to see these things again.

DR. FLYNN: Why don't you go back in the proposed rule in January 16th, the six most serious reported brachytherapy situations where the wrong sources, six occasions. The wrong number of sources, one occasion, and the wrong site implanted one occasion. Those are the most serious ones in terms of -- if the source fell out of applicator, I mean, some of these may not result in a high dose to the patient. If those were the serious situations that were reported to date in an eight year period, perhaps those are the ones that should be covered.

DR. BRICKNER: I think they are trying to catch the wrong source by difference in dose, aren't you?

DR. SUNTHARALINGAM: Wrong patient, wrong source,

wrong site.

DR. BRICKNER: You already caught the wrong isotope.

DR. DEYE: You have caught the wrong patient.

DR. BRICKNER: Wrong isotope, that's not the wrong strength.

MR. TELFORD: Correct, Dr. Brickner.

DR. BRICKNER: Where are you going to capture the fact that you put 25 milligrams in instead of five milligrams?

DR. SMITH: They are pointing out that the wrong source is covered above, Ted. We are now talking about the source strength and other things.

DR. BRICKNER: A blank sheet is what John said, we are writing the rules over.

MR. TSE: Actually this morning we were discussing permanent implant versus non-permanent implant. Would that have something to do with this prescription or maybe high dose rate afterloading machine? How do you talk about minimum hours of --

MR. TELFORD: The high dose rate, you are talking about dose. High dose to a point.

MR. TSE: Therefore, maybe it is different characteristic that you want to use to describe certain different types of brachytherapy. I wonder whether you can

make a suggestion on each of those cases.

DR. SMITH: That's why I said however he prescribes his written directive, whatever quantity he uses -- quantity will differ in different situations and different physicians --whatever he uses to quantify the treatment that, I think, is what you -- you say use the word quantity because sometimes it will be dose and sometimes it will be time, sometimes it will be --

MR. TELFORD: We talked about dose for brachytherapy. In parenthesis we said or time and source strength is what we should have said. You are talking about it both ways but conceptually we thought of it as dose.

DR. SMITH: It all ends up being dose, but it may be hard to quantify.

DR. SUNTHARALINGAM: Again, total calculated administered treatment defers from prescribed treatment --

MR. TELFORD: Prescribed dose.

DR. SUNTHARALINGAM: Again, prescribed treatment. Rad, suppose you have --

DR. SMITH: Absorbed dose has a very specific physical definition, so once you use the word dose we automatically think about that it is energy per unit mass. You have to be careful when you say dose, because it has a very definite definition.

DR. FLYNN: In treatment it is either dose or

activity --

MR. TELFORD: Quality of radioactivity delivered or something?

DR. SUNTHARALINGAM: Total calculated administered treatment and then in parenthesis you can say example dose, time source trend. It defers from --

DR. SMITH: Other prescriptive parameters. I didn't even think of that.

DR. SUNTHARALINGAM: But now when you lump all these together, can you come up with the same percentage number?

MR. TELFORD: We are still thinking of energy delivered per unit mass conceptually here.

DR. SMITH: They all end up in some energy per unit mass.

MR. TELFORD: Let's pick either a typical case or a worst case brachytherapy procedure and what is the total dose, and what effect would ten percent have over or 20 percent over?

DR. BRICKNER: In most brachytherapy the variation in the volume treated is horrendous. The variation of total dose is going to be pretty acceptable. You may go from 100 units in one place to five units in another place in the same implant. Therefore, ten percent is meaningless, because all you would have to do is move a millimeter --

MR. TELFORD: What is the ten percent in rads?

DR. BRICKNER: It depends.

MR. TELFORD: Pick an example.

DR. SUNTHARALINGAM: A breast implant boost might be 2,000 rads, and ten percent means 200. What you are asking is that if a physician has said, based on all the calculations delivered to such and such a dose rate line, 2,000 rads.

How could an error be made. Either the wrong activity sources were used or the patient was left in -- the sources were left in for a longer or shorter period of time. Or, someone found out a computer glitch in the calculation.

MR. TELFORD: Resulting in an extra 200 rads.

DR. SUNTHARALINGAM: Resulting in a difference to dose in that same prescribed volume or the line where they put the prescription. Now we are trying to address this ten percent significant, 20 percent significant, 50 percent significant.

DR. SMITH: Since brachytherapy usually or almost always a boost you can tolerate more difference in a boost than you can in the total treatment.

DR. SUNTHARALINGAM: That's exactly right.

DR. SMITH: I think we need to at least think about that. This is not the total treatment that we are talking about. It is only a boost of the total treatment.

Often only 30 percent of the total treatment --

DR. BRICKNER: Even in the --

DR. SMITH: We should start out with that premise, and at least say it can be a greater error than we did for the definitive total dose.

DR. SVENNSON: The other problem that you have is that very often these implants, they don't have a very strong anatomic relation. In other words, there is no tumor volume, so there is no particular point they are being prescribed to. It makes more sense to make these regulations in terms of the source strength, total activity or not so much dose.

DR. BRICKNER: That's a good point.

DR. SVENNSON: Very often you just don't have a clear definition of exactly what --

DR. SMITH: Once you are talking about dose -- you talk about a point that the dose is prescribed to. Separately they don't make a lot of --

DR. SVENNSON: Right. A lot of times you do prescribe dose and often you prescribe it in relation to the implant itself but not to the anatomy.

DR. SMITH: You are making a very good point. Maybe the total certain percentage error in the total source strength.

MR. TELFORD: Your example of 2,000 rads to the

breast, 200 extra rads is meaningless, no biological effect.

DR. BRICKNER: Yes.

MR. TELFORD: Four hundred rads, is that a biological effect?

DR. DEYE: I think you have to get away from rads. I think you have to talk about an error in the strength and in the time.

MR. TELFORD: I don't disagree with that. Conceptually, help me out here. Even if we talk about activity and time, it relates to dose. If I can relate to dose, I can relate back to activity and time.

DR. FLYNN: I think conceptually Dr. Brickner had the key. In the worst possible scenario -- let's say cancer of the cervix -- maybe half of the dose is given by implant. With breast it may only be one-third or one-fourth. Take the worst possible case, let's say cervix. Half of a treatment is given by implant.

Therefore, if on the teletherapy what conceptions you said 20 percent of the total dose was too much, maybe 40 percent would make more-- if you had to use a percentage which I don't agree with -- maybe 40 percent would make more sense for brachytherapy because only half of the dose is typically given by a brachytherapy.

You could --

MR. TELFORD: What is the total dose here for the

cervix?

DR. FLYNN: Well, 2,000 rads to point A and one implant.

DR. BRICKNER: Point A, you want to get about 8,000 rads. You get about 4,000 rads from the implant. So, a 40 percent --

MR. TELFORD: Four thousand rads from the implant.

DR. SMITH: With 40 percent of that is 1,600.

DR. FLYNN: Sixteen hundred is what percentage of the total 8,000? Twenty percent.

MR. TELFORD: Forty percent of half, so --

DR. FLYNN: Forty percent of the brachytherapy dose turns out to be 20 percent of the total --

MR. TELFORD: The key question is, what is the extra 1,600 rads mean?

DR. BRICKNER: It means that there is a sloping curve of complications, and that curve starts at about 6,000 rads. That curve gets very significant at 10,000 rads and it's a curve in between. Any incremental increase in dose moves you on the curve.

The question is, at the range where you are 8,000 versus 9,000 or 7,000 versus 8,000, is a 1,000 rads significant. It's getting there, it's close.

DR. SMITH: What we are telling you is that this number of 40 percent is entirely compatible with the 20

percent we had for the total dose in brachytherapy.

MR. TELFORD: No problem with that. He's on to a good point here. You are saying it's 6,000 -- you probably have no problem and at 10,000 you have a problem.

DR. BRICKNER: Yes. The difference between 6, 000 and 7,000 probably doesn't exist.

MR. TELFORD: If you are prescribing four and you give an extra 40 percent which is an extra 1,600, you are now at 7,600. You are not to ten yet.

DR. FLYNN: Actually in this area for cervix, there is some published data, 8,000 versus 9,500. There was some increase in the complications when they gave 9,500 to point A intentionally now. This is not an error, they intentionally did that. I think that that's 40 percent of the brachytherapy dose, but only --

DR. BRICKNER: They planned on eight but gave 96, which is your 40 percent error. You have, according to Carlos' numbers, moved into a higher complication rate.

DR. FLYNN: It is conceptually compatible with your teletherapy limit of 20 percent.

DR. BRICKNER: Should you reduce it to 35, 30 -- I don't know. Forty would certainly be a reasonable number.

MR. TELFORD: The 40 is the threshold of having a biological effect.

DR. SMITH: You can measure the biological effect

at that number is what they are telling you.

DR. DEYE: We are into that whole area of radiobiology here. There is no good science in radiobiology. We don't understand the cause effect relationship of the biological effects of the radiation dose that we give. There is no one who can give you a theory that takes you right on through that process yet.

Therefore, all we have is these curves and the curves are dose-dependent, they are dose rate dependent, they are site specific. You right volumes on this, so you can --

DR. BRICKNER: Forty percent I think ought to be reported.

MR. TELFORD: I need to structure a logical argument that goes something like the following. Let's consider the worst case example, the cervix. Let's consider that the typical dose is 4,000. Let's say that it is 40 percent over.

I need to be able to say that is the beginning of the measurable effect.

DR. DEYE: I know, that's what you --

MR. TELFORD: That is the threshold.

DR. DEYE: I know you want to be able to say to the Commission, but I think we are giving you tools that are going to serve you and us incorrectly in the future. A

little bit of knowledge is a dangerous thing, and I think we are playing with fire.

MR. TELFORD: The choice is, is 40 percent too high or too low.

DR. DEYE: It depends upon the site. You can't give that --

DR. SMITH: We are trying to give them some guidance -- some general guidelines.

DR. DEYE: He has to tell the Commission that it has biological significance. You want him to say that, go ahead.

DR. FLYNN: It may be the best number to use if any number, that is the point.

MR. TELFORD: I tell you what, would one of you gentlemen like to come and take that spot?

DR. DEYE: No, but we could suggest some people. None of us are radiobiologists. You need a very good radiobiologist to have that --

DR. BRICKNER: If you would contact people who have written extensively on the subject like Carlos, I will call and talk to him.

MR. CAMPER: Dr. Deye, is it safe right now to say that we have 20 percent -- is it reasonable to say that a movement to 40 percent makes more sense? Is it approaching something other than what could clearly be viewed as an

arbitrary number?

DR. DEYE: Yes.

MR. TELFORD: In other words, if we took 20 percent to the Commission I would expect that half of you would be willing to go to the Commission and testify against me and say that at least -- say 20 percent is just not --

DR. BRICKNER: For brachytherapy you are right.

MR. TELFORD: If I said 40 percent to the Commission, you would say well, you are barely getting there.

DR. BRICKNER: Yes, more reasonable.

MR. TELFORD: It doesn't mean anything, but in some cases it may.

DR. DEYE: That's true.

DR. SUNTHARALINGAM: There is still some concern expressed in the past and they will now write this table, do we really want to hang onto dose in brachytherapy?

MR. TELFORD: I think we need to put --

DR. PAYNE: I would hope that you would be willing to put qualifiers on dose. Dose just does not mean -- dose is not totally centigrade, i.e., high energy. Excuse me. Dose is energy but dose doesn't mean centigrade and period, nothing else will do.

MR. TELFORD: Couldn't we say dose and then explain that dose could be measured or quantified in a

couple of different ways and then list those ways.

DR. SMITH: As specified by the doctor's directive. Whatever he uses.

MR. TELFORD: These are examples of ways that --

MR. TSE: Excuse me. Let me ask a question here for the two physicians. Time, I think you mentioned time. Time, unless the physician prescribes a time, otherwise is based on certain calculation from the physicist or dosimetrist. If the calculation is wrong then the time is wrong.

How much percent you like to see where you start worrying if you -- 30 percent. So you have two days, 48 hours and nothing to worry until you have how much --

DR. SVENNSON: No. Reportable is different from worry.

DR. FLYNN: We would definitely worry.

DR. SMITH: You obviously worry when you have an incident -- a reportable incident. Obviously you are worrying at that level or it wouldn't be called an incident.

MR. TSE: I don't mean worry. I mean, does QA have some problem, a maybe more important problem that should NRC know.

DR. SUNTHARALINGAM: Let's take a concrete example. An implant is done, the physician knows that certain activity source were intended. A calculation is

done, a dose distribution is shown to the physician. The physician goes over the dose distribution that the physicist or dosimetrist and signs off on a dose rate and a treatment time.

Sources are implanted into the patient. Twenty-four hours later somebody detects and error by some process, someone found out either the wrong source was implanted or in the calculation some glitch occurred and wasn't caught. Now it is taken back to the physician.

The question arises, at what point in terms of quantitative aspects of the error do you want this reported to the NRC? That error could have been due to a miscalculation, it could have been due to the wrong source term either being used or being used in the calculation. The physician has prescribed a time based on the total dose he wanted to deliver and the dose rate he chose to go with.

Either way you look at it there's a -- if it's a 40 percent error and the 40 percent in terms of the total administered treatment -- I still like to use the word treatment. The treatment could have been in terms of time, it could have - if it's related to dose. Or, if it is a wrong source strength being used -- finally counted dose.

You can still state it as 40 percent resulting from wrong source strength, wrong determination of time of treatment, you can put in examples of that.

DR. SMITH: There is a linear relationship between all those variables so it doesn't make any difference when you are talking about any of those, because they are directly proportional.

MR. TSE: I understand that. The question though is, some people would say if you are going to take off 50 hours of implant and going to miss 40 percent of that 50 hours -- less than 40 percent is still not reportable to NRC?

MR. KLINE: What he is saying is, if you have like a 48 hour administration, 40 percent is 19 hours approximately. So, you are going to say you are off by 19 hours from what you originally prescribed to have taken out. If you get the source strength -- say your 40 percent off your source strength. You can see a vast difference.

DR. SMITH: What you have to say to that again, proportion of the total treatment represents -- remember, that may seem like a lot in that one treatment but of the entire treatment --

MR. KLINE: You are talking about if it is complemented by this external --

DR. SMITH: I just told you, almost always is.

MR. KLINE: It is very difficult for us to do any of those two and add them as a cumulative in order to develop this rule.

DR. SMITH: That is how we use brachytherapy though in practice. It rarely is used as a single modality.

MR. KLINE: As a single modality treatment, I understand that. Then you get into a problem of quantitating again total doses from both avenues of treatment. Then, it gets very complicated as how you quantitate --

DR. SMITH: We told you 50 percent of the treatment was a good number because I think probably most of it is less and some of it is higher. Probably 50 percent -- it is right down the middle of the road.

MR. KLINE: The combination --

DR. BRICKNER: You could say both treatments, 40 percent of the brachytherapy dose or exceeds -- if it exceeds 20 percent of the total dose it is reportable on that basis. If it exceeds 40 percent of the brachytherapy it is reportable on that basis. If you did a brachytherapy treatment alone as your only modality -- rare -- we used to do it a lot but it's rare now. Let's say you do a floor of the mouth implant and that's the only treatment you are going to do, and that's going to be in for three days.

If you miss that by more than 20 percent it is reportable, because that is the total dose. We just decided a few minutes ago under teletherapy 20 percent -- we are talking about brachytherapy.

DR. SMITH: In those rare cases that you do use it as a single modality you are covered --

DR. BRICKNER: What you could say is that 20 percent of the brachytherapy dose or 20 percent of the total dose administered to the patient.

MR. KLINE: Would that be just including cobalt 60 because often in a majority of cases --

DR. BRICKNER: That's true.

DR. DEYE: I really think that we are mixing issues. I think we have allowed ourselves to be drawn from what represents a sloppy reportable program to what represents biological harm to the patient. The latter is not doable by this group of people in two days or two weeks. The former probably is, and I think if we just talk about what is reportable -- that's why you don't like 19 hours out of 48 because that sounds like that should be reportable. That is probably a sloppy program.

I think we ought to get back to what events are significant from a descent QA reportable perspective rather than what is biologically significant.

DR. SMITH: Do you think you can separate those two?

DR. DEYE: I think we have to, whether we like it or not.

DR. BRICKNER: If you want to talk about what is

reportable from a QA program, you are talking about significantly less than 40 percent.

DR. DEYE: That's true.

DR. BRICKNER: We are back to 20 percent, I would say. Remember, we have events still in this category as well. We have to look at anything where we are off by how much -- what is the threshold for a not reportable event?

MR. TSE: That's ten --

DR. BRICKNER: That's teletherapy.

DR. SUNTHARALINGAM: In brachytherapy we don't have anything.

DR. BRICKNER: Should we have events and reportable events like we do on --

MR. TELFORD: We could have ten percent on event and 20 percent on reportable event.

DR. SMITH: On brachytherapy?

MR. TELFORD: Yes.

DR. BRICKNER: By the nature of the beast, do you want to notch it up a little bit, like 15 to 20 percent.

DR. SMITH. We are losing ground here.

MR. TELFORD Dr. Deye says it depends on how we approach this. If we approach this from the point of view of quality management, then ten percent is probably something that -- you missed the time. It's 48 hours, and it was done 4.8 hours late. It is probably something you

want to look into. That's an event. Nine hours, if it exceeds nine hours, that is 20 percent. That is something that probably ought to be reported if you just talk about the management of your program.

DR. BRICKNER: Yes, do it.

DR. SUNTHARALINGAM: We go back to the reports that you people have received so far point to much more significant errors which is wrong activity, source strength or in one case I think decay factor was used which changed it by something like 50 percent or something like that.

So, you are still looking at errors that were much larger than this 20 percent that we are talking about.

DR. BRICKNER: Catch all --

DR. SUNTHARALINGAM: An event can catch all those, but a reportable event --

MR. TELFORD: It would still catch all of those.

DR. BRICKNER: If a reportable event is just what we just talked about, ten for an event and 20 for a reportable event would catch all of them.

DR. SUNTHARALINGAM: Twenty may be too restrictive.

MR. TELFORD: It may be, but if you are running a program and you left it in -- a 48 hour implant and you left it in an extra nine hours, how do you feel about that?

DR. FLYNN: The time is an obvious thing that is

very obvious --

DR. BRICKNER: Easy for the --

DR. FLYNN: If it has to do with a lot of isodose curves that are very close together over a very tiny volume and the resident and the staff physician have marked off a millimeter isodose line, that's a much less serious situation than being off by nine hours.

DR. SUNTHARALINGAM: That's why dose shouldn't be used. If you say wrong activity or wrong time, those two everybody can understand and put a figure on. As soon as you talk about dose, even though they are related --

MR. KLINE: What tolerance is it that you feel is a reasonable and reportable one on strength and time for activity involved?

DR. BRICKNER: Twenty percent on time for sure. What about strength.

DR. DEYE: Same thing.

DR. SUNTHARALINGAM: Which means that you are down to 20 percent of dose.

MR. TELFORD: I guess you are.

DR. PAYNE: We are avoiding the semantics of the dose problem, the dose --

DR. SUNTHARALINGAM: The --

MR. KLINE: When you talk about 20 percent of strength, are you talking about 20 percent because of --

let's say you used the wrong value, say ten milligram --

DR. BRICKNER: I can give you two examples --

MR. KLINE: not misloading of the source.

DR. BRICKNER: Anything that gives you -- the patient doesn't give a damn how you got the wrong source in there.

MR. KLINE: Let's say you have the total activity but the configurations are different, where you can move the sources around. That means the strength total is always the same, but you could have the wrong configuration.

DR. BRICKNER: We would not be reporting that.

MR. KLINE: Then you have wrong configurations but same total -- you could have 40-10-10 prescribed but actually put 10-10-40 and that wouldn't be reportable.

DR. BRICKNER: That's possible.

DR. PAYNE: The written directive was very clear, if you had a little diagram -- 40-20-10, 10-20-20 and we did it the other way around, then we have missed it.

DR. SMITH: Well then, that's the wrong strength isn't it, because even though --

DR. PAYNE: It's the wrong strength. We missed the written directive.

MR. KLINE: What if we said wrong configuration or wrong strength --

DR. PAYNE: No, I think you are okay just -- we

didn't follow -- if the written directive --

MR. KLINE: Except for --

DR. PAYNE: If we do we are okay, and if we don't we report.

DR. BRICKNER: We are not going to make the perfect document for the rest of the time on earth. Let's start out with something we can handle. When we start talking about configurations --

MR. CAMPER: Ten percent.

DR. PAYNE: Just say strength and time, and then in the guidebook you are going to have good examples.

MR. TELFORD: Dr. Brickner, give me an example, please.

DR. BRICKNER: You could just use the word strength. Then in your explanations you could include an example that Ed referred to where the dose for the sources were reversed and say although the total strength is correct such a change in configuration might lead to biological damage and could well be considered a reportable event. Then, if it's a minor thing, a ten and a 15 were reversed, forget it.

If a 20 and a five were reversed in a way that would hurt the rectum in a cervix patient, you are going to have to trust these people. These aren't a bunch of crooks that you are out to catch at the bank, contrary to popular

opinion. They are trying to help people, and if they screw up a lot of times they are going to say maybe we ought to report this and this is not too slick.

Give them an example and explain reversed positions could be considered a reportable event, to use your good judgment. You understand what we are trying to do with this regulation.

MR. TELFORD: I would like to suggest that we devote the remaining time to the regulatory guide. Let's see what we can do on the guide. Let's take a five minute break first.

[Brief recess.]

MR. TELFORD: In the time remaining I would like to go through the regulatory guide. Let me suggest that we kind of go through this by section. What I am looking for here is examples of things to put in here, and references or examples would do nicely.

The first section is really kind of just the organization of the program. The words that we have been saying like management or its designee. In item 1.1, I think you can look for that. In 1.2, you could assume that we are going to have program reviews, and we would allow the management or its designee to define the folks that are going to do this program review. I don't think that would particularly give you any problem.

DR. SUNTHARALINGAM: But we are to accept the fact that you will be changing some of the terminology and the wording. Also, this thing about qualified personnel who are not involved with the activity being audited. Those things will change.

MR. TELFORD: Look for words that would say something like we think it's a bad idea if you are auditing your own -- for reviewing your own work. If you are going to review your own work, then it may be a good idea to work with another member for this program review. We think they ought to be qualified people, but we will let the management decide who those people are that are qualified, management or its designee, that is.

Let's go to section two, if you are willing, the regulatory guide. Page four of the guide. Let's see, if you are in -- that's page four of the handout. The things that we said before about written directive for the referral process, we could assume that they would be here. Asking for clarification in 2.2.

DR. SUNTHARALINGAM: Does that have to be documented, that is our question. At 2.2, again, we are back to this -- earlier on you said I am just asking --

MR. TELFORD: The only thing that has to be documented are those procedures that would address the objectives in the QA rule. What is in the guide are just

good things to do or how to address those things. In other words, things you might want to consider doing in order to meet the objective of the rule. In 2.2 and 2.3 we would attempt to capture the advice that you have given us in these two meetings. I read some of that advice to you this morning as part of my summary as feedback.

Can we move to section three.

DR. SUNTHARALINGAM: Let's stop at 2.4. Again, before medical use the person administering the byproduct material shall verify that the medical use is an accordance. That is all fine, but does one have to show evidence that there is documented indication that it has taken place?

MR. TELFORD: Let's put it this way. This is very close to the objective we have now, which is to say the byproduct material is administered as prescribed. Before or prior to administration the person administering the byproduct material should verify that what they are about to do is in accordance with the written directive. This is a good thing to you.

We need a procedure somewhere that addresses that objective, but you don't have to document each case.

DR. PAYNE: That's what I mean, there won't be any documentation.

DR. SUNTHARALINGAM: But I don't want inspectors to come around and say show me a signature on every patient.

DR. PAYNE: No, but they are going to do exactly what they are doing right now. They will walk right up to your technologist and say when you treat a patient how do you know what you are doing. They better have good answers.

DR. SUNTHARALINGAM: How do you verify?

DR. PAYNE: I read the chart. I follow the written directive, that's all I have to say. IF they say that, I think we can defend it.

DR. BRICKNER: Follow the written directive and the procedural manual.

DR. SUNTHARALINGAM: Let's proceed.

MR. TELFORD: Section three. Here we are really talking about radiopharmaceutical therapy and diagnostic procedures involving more than 30 microcuries. Think of this as radiopharmaceutical therapy. This section here would follow the applicable objectives in the rule. For therapy you want a written directive of what you would do before you administer that.

DR. DEYE: You said diagnostic greater than 30 microcuries. That is of any isotope, or just of the iodine.

MR. TELFORD: Just of those two and sodium iodine.

DR. FLYNN: Do I understand correctly for therapeutic administration a written directive for therapeutic administration not necessarily to be a verbal communication. I think --

MR. TELFORD: For the therapy you need a written directive or, if it involves greater than 30 microcuries of I-125 or I-131. For diagnostic cases we would have a referral process where we would define what an acceptable referral could be, a written referral or telephone referral.

If it includes certain information which we listed --things like patient's name, physician name, requested study, the clinical history, the date and some other identification of the patient like social security number. I think I have a handout --

DR. FLYNN: I think all that is reasonable. I think the reason was that in your preamble you said seven million diagnostic procedures a year and 30,000 therapeutic procedures a year. There are far fewer therapeutic procedures. The example that you gave of incidents that have been reported, quite a few of them involve people giving millicuries when they meant to give microcuries.

If it requires a written prescription for a therapeutic administration every technician should know that as soon as the word millicuries comes up for iodine that's a therapeutic administration and requires a written prescription. They wouldn't make errors in dose by a factor of 1,000 because they could never give such a dose without a written prescription so the error wouldn't be made hopefully.

It wouldn't be based on a phone call. They can't give a millicurie dose on a phone call of any time because that's a therapeutic administration.

MR. CAMPER: We hear you loud and clear, and we hope that you are correct.

DR. SVENNSON: What is the acceptable error in therapeutic use of radiopharmaceuticals?

MR. TELFORD: You mean the event?

DR. SVENNSON: Yes. Did we address that before?

MR. TELFORD: Yes, we did.

DR. SUNTHARALINGAM: By more than 20 percent.

MR. TELFORD: Reportable event is 20 percent for radiopharmaceutical therapy.

DR. SVENNSON: That is in the amount of radioactivity administered. That is a tough one though, because the whole process of getting to the point where you administer it has a great deal of uncertainty. You start with the generator, you label the antibodies or whatever you use --

MR. TELFORD: This is therapy.

DR. SVENNSON: I understand. It is a whole process to get to the point where you administer it, and I don't know how well people know exactly what is in that syringe when they actually administer the dose.

MR. TELFORD: Dose calibrator.

DR. SVENNSON: Do they always use that? At what stage?

DR. SUNTHARALINGAM: Are you raising the question of monoclonal antibody --

DR. SVENNSON: Yes, for example.

MR. TELFORD: Research right now --

DR. SVENNSON: Clinical protocols.

MR. TELFORD: I don't think there are any PLA's that are on the market yet, right?

DR. SVENNSON: No, but they are clinical protocols.

DR. PAYNE: That's a different situation. That is not FDA approved.

MR. TELFORD: That is not FDA approved yet. Once it is, it will fall under these rules.

DR. SVENNSON: The byproduct on these protocols do not fall under these rules?

MR. TELFORD: That's an investigational use because you are not treating patients yet.

DR. SVENNSON: Under a protocol. I understand that, I just don't know exactly --

MR. TELFORD: They are not yet applicable under Part 35.

DR. SVENNSON: I see, okay.

MR. TSE: IND is. R and D is.

DR. PAYNE: I still don't see a problem. You should know what you are doing, activity-wise.

DR. SVENNSON: The 20 percent is what I am concerned about.

DR. SMITH: We covered this -- actually, if you say calculated administered dose we know -- if there is some uncertainty in your statement of dose, that is beside the point we are trying to reach here. There are always uncertainties in our statement of dose. If you say calculated administered dose, I think we are covered. We covered that last time.

MR. TELFORD: That has to be under an IND.

MR. TSE: That is. That is included in Part 35.

MR. TELFORD: There are no PLA's on the market yet. When they come on the market they will probably be subject to this restriction, that threshold.

Section four, here we are looking for some guidance on --

DR. DEYE: Wait. You turned to four already, I thought we were on three. On 3.5 after administering a radiopharmaceutical a qualified person under the supervision make, date, sign written record. Will record the agreement or lack thereof.

MR. TELFORD: Let me put it this way, we have three things we are trying to cover there. We really mean

any two. In other words, if you have therapy here so you have a written directive. You have a dose in the written directive. If you record the dose given that's enough. You don't have to record agreement -- we will get to that.

DR. DEYE: All right.

MR. TELFORD: Section four --

DR. BRICKNER: Four point two you are going to change the prescription to written directive.

MR. TELFORD: In 4.2, this is prior to going to the OR.

DR. BRICKNER: Tentative plan or something.

MR. TELFORD: This is preplan.

DR. BRICKNER: Four point five, after implanting either the brachytherapy sources or dummy or simulated sources radiographs will be made.

MR. TSE: I have a question. Is there certain circumstances radiographs are not made?

DR. BRICKNER: Yes.

MR. TELFORD: We might want to say ordinarily.

MR. TSE: What do you use to locate the position of the source?

DR. FLYNN: You mean the fixed geometry template. With 200 seeds to the point where it is impossible for the physicist to give the three dimensional location of each seed which is overlapping with the other seed on an x-ray

film. It is based on fixed geometry calculation.

DR. SMITH: If you are using a plaque or something you don't use x-rays.

DR. DEYE: Right. Or, the other case is the very simplified case of a single source in the vagina. You may put in a wang applicator and it is just placed locally up in the room of the patient without taking perpendicular radiographs. You have a standard wang applicator that you are using.

DR. BRICKNER: Four point eight.

MR. TELFORD: On 4.3, if we want to verit, check on the sources, the source strengths or the loading sequence, what would you say is the best way to do th

DR. SUNTHARALINGAM: Aga n, you are caught in this 4.3, distinguishing what might be a guiding applica on versus what might be a breast implant or what might be an iodine prostate implant.

DR. SMITH: How about a high dose rate where you have to say well time -- there are all kinds of things.

DR. SUNTHARALINGAM: Or a high dose rate. It says before implanting the seal sources a qualified person under the supervision -- so forth -- will verify the source to be used prior as prescribed. Each situation is going to be slightly different.

MR. KLINE: Do you feel this is more applicable

for intercavitary interstitial and not the --

DR. SUNTHARALINGAM: Yes, you can't do this for high dose where you just have one source.

MR. KLINE: The seeds will be --

DR. SUNTHARALINGAM: The seeds will be very different. This problem was addressing the guidance incidents. I think the need for this was more the guiding the cesium sources.

DR. BRICKNER: You could stop with the period and leave out the whole note. What you are saying there is a qualified person will verify that the radionuclide and source strength are as prescribed, period.

DR. SUNTHARALINGAM: We have a problem even if you say the -- you can't apply that by every brachytherapy situation.

DR. BRICKNER: What not?

DR. SUNTHARALINGAM: Say prostate iodine seeds.

DR. BRICKNER: What it says is that the strength of the seeds are what you have said they are going to be. You have the right strength seeds when you go to the operating room. It doesn't say how many of them, but you got the right seeds out of the safe and not the wrong seeds.

If you get a new shipment every Monday and you take the old shipment instead of the new one or the new one instead of the old one --

DR. SUNTHARALINGAM: This is essentially saying a QA program should say that you need to check the source once again before you take it to the OR.

DR. BRICKNER: Yes, that's all it says. If you take out the notes, which are just confusing. Take the whole note out. The note just applies to one of many problems. I have the general statement that before you stick it in the patient, whatever it is, you do make sure that you have in your hands what you think you have in your hand; that you took the right thing out of the safe or bucket.

DR. SUNTHARALINGAM: I think it is also trying to catch and address the source configurations. If you had to go in a tandem of 20-10-10 then you also want to verify it.

DR. BRICKNER: I would forget that.

DR. PAYNE: That comes later, I think.

DR. SUNTHARALINGAM: Does it come later one?

DR. BRICKNER: Yes.

MR. KLINE: That 4.3 addresses radionuclide and source strength and that's it.

DR. SUNTHARALINGAM: All right.

MR. TELFORD: Now we can go to 4.5, Dr. Brickner.

DR. BRICKNER: Put in dummy or equivalent sources because you don't go around loading hot sources in patients and then taking --

DR. SUNTHARALINGAM: Right.

MR. TELFORD: An exception would be templates --

DR. FLYNN: Fixed geometry.

MR. TELFORD: Fixed geometry.

DR. FLYNN: Right.

DR. BRICKNER: Yes. I believe you used the word usually --

MR. TELFORD: Ordinarily active or dummy sources.

DR. FLYNN: For permanent and temporary implants --

DR. BRICKNER: Radiographs will usually be obtained, not always.

MR. TELFORD: Radiographs or other imaging modalities are usually -- I already have ordinarily -- maybe obtained and used as a basis -- should be obtained and used as a basis for -- how is that?

DR. BRICKNER: Fine. Just so that you have an escape clause for those few cases where no radiographs or images are mad.

MR. TELFORD: Then we would say in another sentence that this would not be the case for fixed geometry or template applications, you wouldn't expect to do that. How about high dose afterloaders?

DR. BRICKNER: I don't know. Do you take radiographs of the applicator before you put the sources in?

DR. SMITH: You should have dummies -- they have a

system where you can put a dummy source in.

DR. BRICKNER: I don't know. Is that what you normally do?

DR. SMITH: Yes.

MR. TELFORD: Dr. Smith, you are saying that high dose rate afterloaders are covered if we talk about dummy sources?

DR. SMITH: Yes, in general they are.

MR. KLINE: That would be --there would be an exclusion for high dose rate afterloading devices only for dummy sources, is that where your --

DR. SMITH: No. What we are saying is that if you use the word dummy sources you are including high dose rate applicators because they do have dummy sources that you can run down and take radiographs of if you want to.

DR. FLYNN: You can say any time that you use temporary implants use dummy sources, whether it is low dose rate for cervix or high dose rates for temporary implant. For permanent implant, obviously, you can't use dummies.

MR. TELFORD: Anything on 4.6?

DR. SUNTHARALINGAM: I want Dr. Brickner to respond to the statement, qualified person there. Wouldn't one want that to be --

DR. BRICKNER: Where?

DR. SUNTHARALINGAM: In 4.6 , after implantation

wouldn't one want that to be actually carried out by a physician, a physician under the supervision of an authorized user will promptly update and sign --

DR. BRICKNER: No. If my physicist goes up and puts the sources in the tandem then he writes in the chart that he loaded what he loaded.

DR. SUNTHARALINGAM: You are allowing a physicist to load the tandem?

DR. BRICKNER: Yes.

DR. SUNTHARALINGAM: In the patient?

DR. BRICKNER: Yes.

DR. SUNTHARALINGAM: That's not good practice.

DR. BRICKNER: That's a matter of opinion, isn't it?

DR. SUNTHARALINGAM: Because you are now -- I will find that --

DR. BRICKNER: We need to talk to the physicist. The fact that he does it is a problem.

DR. SUNTHARALINGAM: The fact that he does it is a problem.

DR. BRICKNER: You can discuss that at your next union meeting. In the meantime, you --

MR. TELFORD: Okay, 4.7.

DR. DEYE: We have the agreement and the lack thereof again.

MR. TELFORD: Scratch that. Four point eight.

DR. BRICKNER: My physicist made the suggestion that this be allowed to develop, whatever that means. Your detailed method of checking the manual dose calculations and the computerized dosage that was detailed at this point in time.

DR. SUNTHARALINGAM: I also have a comment. Why say now how to. All what one is saying that you need to have a program of checking the original calculation.

DR. BRICKNER: He thought you were getting awfully detailed and how to do it, and probably the physics folks would come up with better ways of checking.

MR. TELFORD: Don't be detailed, but how about just saying before 50 percent of the dose has been given --

DR. BRICKNER: Fine. There was no disagreement with that. He just didn't like all the details.

MS. PICCONE: Would you still make that same comment when based on the way the reg guide was described to you this morning? The rule doesn't have specifics but the purpose of the reg guide was to provide a program with specifics that would be acceptable.

MR. KLINE: Are you saying this is too specific?

DR. SMITH: What are you going to do for high dose rate? I mean, how --

MR. KLINE: We are going to have to put in -- that

is going to be in addition, independent of that 50 percent criteria.

DR. BRICKNER: Just make sure this carries a clear paragraph at the top that these are one suggested solutions to the problems.

MR. TELFORD: If we could list these as acceptable methods include --

DR. BRICKNER: Yes, better.

MR. TELFORD: We give these as examples so that --

MR. CAMPER: What should we add to the examples?

DR. SUNTHARALINGAM: More than what you should add, what should you delete from what is said here. My concern again is --

MR. CAMPER: An example and a regulatory guide. This is not a regulation.

DR. SUNTHARALINGAM: The regulatory guide, true. But then when you are trying to compare somebody else's QA program that they submit to you, you are also trying to use this as comparison.

MR. CAMPER: As a minimum.

DR. SUNTHARALINGAM: As a minimum.

MS. PICCONE: So, let's have more examples of what is acceptable.

MR. KLINE: First of all, a clarification. This is not used as a comparison or critiquing criteria for a

licensee's application. It is examples only which you can use bits and pieces of in whole or in part. We have other documentation that we review application with which we talked about earlier, the SRP which is standard review plan and a number of other documents we are generating.

DR. SMITH: The trouble is that when you start making lists like this, if you make a list at all in this kind of document it needs to be complete. One could sit down and start thinking about things that could be added. Making a list itself is problematic, I think, because you are liable not to -- for particular situations we can think of things that would be left out.

MR. TELFORD: What if we said the list includes the following things?

DR. SMITH: Or suggestions of things to be checked are.

MR. TELFORD: Okay.

DR. SMITH: If you don't say that then the list might be taken to be all inclusive and it is not. It can't be. You suggest these are the types of things that could be checked. These aren't methods, these are things to be checked. These aren't methods of checking, these are things to be checked.

DR. SUNTHARALINGAM: Four point eight point on.

DR. SMITH: Yes, 4.8.1 are things to be checked.

We are not talking about methods here.

DR. SUNTHARALINGAM: Unfortunately that said manual dose calculation will be checked for -- those things can be checked when it is computer generated. Why should it only be for manual dose calculations.

MR. KLINE: Well, 4.8.2 address computer generated.

DR. SUNTHARALINGAM: Yes, but these things to be checked can apply even for computer generated.

MR. KLINE: Yes, that's true.

DR. SUNTHARALINGAM: Data from the prescription --

DR. SMITH: Can't you just say the types of things --the following are suggested types of things that are to be checked. Just take out the word manual there, you don't need the word manual there.

MR. TELFORD: The items to be checked for dose calculations include the following.

DR. SMITH: And include but are not inclusive of, or something like that. You don't need the word manual at all.

MR. TELFORD: Got it.

MR. KLINE: Can I make one more comment? Any feedback from people here regarding the gamma knife criteria?

MR. TELFORD: That is teletherapy.

MR. KLINE: Okay.

MR. TELFORD: That's [illegible]xt

DR. SUNTHARALINGAM: [illegible]fe?

MR. KLINE: Yes.

MR. TELFORD: Anythi.g [illegible] in four?

[No response.]

MR. TELFORD: Okay, let's go to five. The things we have talked about before apply here, like a written directive.

DR. BRICKNER: Under the written directive, 5.2, you have a long list including the port -- why don't you just skip -- the site, the dose and the number of fractions.

MR. TELFORD: All right. The site, the dose, --

DR. BRICKNER: Total number of fractions.

MR. TELFORD: Number of fractions. You know the total dose and you know the number of fractions.

DR. SMITH: Shouldn't you at least say electrons or protons --

DR. BRICKNER: No.

DR. SMITH: What are we talking about here?

DR. BRICKNER: Cobalt doesn't put out many electrons.

DR. SMITH: Excuse me. Proceed, I am corrected.

MR. KLINE: The only reason why I believe that was put in there modality was that we didn't want any confusion

between one treatment chart accelerator and the other one cobalt 60.

DR. BRICKNER: It doesn't matter.

MR. KLINE: Do you feel that would be any problem?

DR. BRICKNER: They are all -- all the modalities are going to -- except for the little cesium source out there if there is one.

MR. TELFORD: We have 5.3 allows changes; 5.4 after administering a fraction you record that dose; 5.5, what things do you want to check weekly.

DR. BRICKNER: Wait a minute, 5.4 every day they are supposed to make a record of whether there is an agreement or lack between --

MR. TELFORD: No, scratch that. Put a period after dose administered.

DR. BRICKNER: Thank you.

MR. TELFORD: You might in an example of like the time set for the machine and the time exposure or something to record that. Now we are on 5.5. What items would you like to see in a weekly check? Cumulative dose?

DR. BRICKNER: You have that.

MR. TELFORD: Anything else?

DR. BRICKNER: You have said implementing any change in the prescription.

DR. SMITH: If the cumulative dose is correct

everything else is correct.

MR. TELFORD: All right. In 5.6, you said before 25 percent of completion we have been told that in some cases you only have four fractions or we have been told that the ACR says within two treatments or two fractions.

DR. BRICKNER: I think we finally settled on 72 hours.

MR. TELFORD: Within 72 hours?

DR. BRICKNER: Yes, because we have to worry about weekends. That's a real hassle, the 25 percent.

DR. SMITH: We use two treatments -- 72 hours is fine.

DR. BRICKNER: Do you like 25 percent better?

DR. PAYNE: I like 72 hours.

DR. BRICKNER: We wrestled with it a long time, 72 hours. If you do this on Friday afternoon there's no way you are going to make it in 24 or 48 hours. You are not going to get it checked on Monday morning. Of course, the patient is not going to get treated.

MR. TELFORD: The 25 percent? What do you think is sufficient here?

DR. FLYNN: I would prefer hours rather than percent, just so you would have -- I am thinking of departments having certain standards within them. You have different patients with one week of treatment, some with

seven weeks of treatment. You are not going to hire someone from the outside to come in just to calculate what 25 percent of the prescribed dose is.

If you have -- say that all charts are checked within 72 hours, that's real simple. That's a clear policy that a department can have.

DR. SUNTHARALINGAM: If you said before then third treatment is given, then that will take care of the weekend rather than saying 72 hours.

DR. BRICKNER: We wrestled with this for about an hour and came up with 72 hours.

MR. TELFORD: You are saying 72 hours is very practical, understandable.

DR. FLYNN: Understandable, and it can be understood in the department that all charts are checked within a certain number of hours.

DR. SMITH: I think people can live with that. Five, six one has the same problems.

MR. TELFORD: We would make the same corresponding change?

DR. SMITH: Yes.

DR. BRICKNER: Was 5.7.2 --

MR. TELFORD: Let's don't get there yet. On 5.6.2, when we have computer generated dose calculations like for the new thing is the gamma knife, is it the

locations that ought to be double checked there and the entries that you make to the computer generated design; is that --

DR. SUNTHARALINGAM: I think high dose rate remote afterloading should be addressed as a separate item, and there are guidelines. You might look at what was handed out by the AAPM.

DR. PAYNE: Single shot, 2,500 rads,whatever.

DR. BRICKNER: He asked did you need to check the location for accuracy or the dose for accuracy, and the answer is both.

DR. SMITH: All input parameters need to be checked for accuracy.

MR. TELFORD: The gamma knife, you have to worry about the loading of the sources, did you load the right ones, did you have the measurements --

DR. PAYNE: The sources are permanent, so you don't worry about that.

MR. CAMPER: The sources are permanent.

DR. PAYNE: The sources are permanent -- 201. You have four helmets, four different helmets, that is field size. You have to get the right helmet, you have to have the right location --

MR. TELFORD: But 201 sources -- can't you block any of them?

DR. SVENNSON: Wait a minute here. We have to go one at a time.

DR. SUNTHARALINGAM: There again, there are documents written. From my understanding, prior to delivery of treatment as second independent check has to be performed. That is what the statement has to be in a good QA program. Prior to delivery of treatment independent check of all pertinent parameters --

MR. TELFORD: For examples, number of sources, block or not blocked, dimensions, input data into the computer --

DR. PAYNE: Proper helmet selection.

MR. TELFORD: -- proper helmet selection.

DR. SUNTHARALINGAM: All this.

DR. PAYNE: Patient position.

MR. TELFORD: Okay.

DR. SUNTHARALINGAM: But treat that as a separate item.

MR. TELFORD: All right.

DR. SMITH: I am still concerned about you making lists. You say all input parameters. When you start making lists, that --

MR. TELFORD: We would say includes.

DR. SMITH: Yes, be careful with that.

MR. TELFORD: The check includes.

DR. SMITH: They will just check what you have on the list and don't check something important.

MR. TELFORD: We will modify the guide six months hence.

DR. BRICKNER: Keep the government printing office in business.

MR. TELFORD: Now we can move to 5.7.

DR. BRICKNER: My physics folks took exception to requiring the use of an individual who did not perform the full calibration to check on that. A trained physicist will find something that is off by more than five percent, and there is no reason to think he can't go back and double check all his own work. Otherwise, he has to go dig up somebody else equally qualified someplace else, which at times may be an inordinate expense.

MR. TELFORD: Would that person use another method necessarily, or wouldn't it be a good idea to use a second independent method?

DR. BRICKNER: You might suggest an independent method if that is available and applicable.

DR. PAYNE: As a physicist, I don't object to this. What I have done, and it is cheaper as I just get TLD's from M.D. Anderson, $35.00. That is paragraph two.

DR. SUNTHARALINGAM: That is an independent method.

DR. PAYNE: That is fine. I don't have to have another physicist come in and spend $1,000 or $3,000 or $5,000. All I have to get is a $35.00 set of chips. The only problem that I have is that I have trouble sometime making the 30 day time period. If I get the chips, I calibrate my machine, I contact M.D. Anderson and try to coordinate that. They send them to me. I am not going to know for probably a month or a month and one-half -- I can probably get the chips and get it checked within 60 days. I won't know the results necessarily, 46 days.

MR. KLINE: Do you have any problem with the accuracy?

DR. PAYNE: No, I have no problem with that.

DR. BRICKNER: How about time, is the time all right for you or not?

DR. PAYNE: I guess I would say 45 days, just knowing the logistics of getting chips from those people.

DR. SMITH: Are we saying in 5.7.2 -- are you guys agreeing with that?

DR. SUNTHARALINGAM: No.

DR. PAYNE: That's okay, or I hope it's or, right? Or, so you can do one or you can do two.

DR. BRICKNER: The 30 days says you will do the independent check within 30 days. It doesn't say you have to have the answer within 30 days, does it?

DR. PAYNE: I have even trouble getting the chips in 30 days. If I call up today I might have them in 30 days, but it is sometimes a problem. You have to call today.

DR. SMITH: I have trouble with 5.7.2.

MR. TELFORD: We hear you, 45 days.

DR. SMITH: You are suggesting in 5.7.2 that another physicist using another dosimetry system do an independent check?

MR. TELFORD: No.

DR. SMITH: Am I misreading that? Another individual using another dosimetry system --

MS. PICCONE: Look at the paragraph 5.7.1 on when you need to do that.

DR. BRICKNER: All right, let's look at paragraph 5.7.1.

MS. PICCONE: This isn't something that you do very frequently. It is after a source change or if a spot check differs, and how frequently does that happen?

DR. SMITH: Yes, but you see a spot check, you may go back immediately after a spot check yourself and usually find yourself that something has gone wrong.

DR. DEYE: But not five percent, Al.

DR. SUNTHARALINGAM: May I --

MR. TELFORD: Yes.

DR. SUNTHARALINGAM: My understanding of the current regs for teletherapy is that if your spot check differs by more than five percent you now have to do a full calibration.

MS. PICCONE: Right, you do. But you don't have to get someone or independent check.

DR. SUNTHARALINGAM: You do. According to the way this is worded -- I do a spot check and I am seeing a seven percent difference. Now I have to do a full calibration, right? This one says after a full calibration measurement that resulted from the change of a source or during a spot check measurement then you get the output difference by more than five percent.

I have now done my full calibration. Now I am asked to go and find another physicist --

MS. PICCONE: Or --

DR. SUNTHARALINGAM: You are saying you first find a physicist.

MS. PICCONE: No.

DR. SUNTHARALINGAM: Or get TLD's.

DR. DEYE: That is only going to happen rarely. That only happens when your spot check was off by five percent or more, and that is very rarely. That should be very rare. If it is not, there is something wrong with your system or you. I don't mean him --

MR. CAMPER: I would think you would want to check.

MR. KLINE: Your spot check or full calibration, whichever is most recent, if they differ by more than five percent. Assuming sometimes you could have your full calibration in December and then you are off by five percent, and then next month --

DR. DEYE: This doesn't go into effect with every annual calibration. This only goes into effect as I understand it, for those full calibrations that resulted from a spot check that was off by more than five percent. That is a rare event, or it should be a rare event.

DR. SUNTHARALINGAM: Why am I doubting my calibration,even if it is once in five years. I am a qualified physicist, I am accepting a machine. I accept a brand new machine. Are you asking me now to go in and find either another physicist or send TLD's for that first measurement or that first --

MR. CAMPER: That's right.

DR. SUNTHARALINGAM: I don't think that is necessary in a QA program.

MR. CAMPER: Look to your left and look to your right.

DR. SUNTHARALINGAM: You people are extending this QA program to -- I can't --

MR. TELFORD: Remember my example from Cumberland, Maryland. People had a source change and they didn't tell the computer that they had a source change --

DR. DEYE: Your facts are wrong on that case.

MR. TELFORD: Oh, yeah? Where are they wrong?

DR. DEYE: The program was changed. The institution began using another program for which they had specifically told the physicist they did not use.

MR. TELFORD: It was a specific program, that's right.

DR. DEYE: The program that they normally used was updated. The program that they claim they never used and they said that in writing, was not updated. And then later they began to use that program without having changed --

MR. TELFORD: For those patients though, and that was the only program of interest. What you say is true --

DR. DEYE: That's not the way it was stated there.

DR. SMITH: I agree with Suntha but it's two and two, so take your choice.

MR. KLINE: That is what the NRC used to do in field measurements and they would come and check outputs. If that's any consolation --

DR. DEYE: Let me just ask this. Why do the protocol groups then require that we have to use a TLD program if we are going to be part of the protocol group.

We must have M.D.Anderson send chips to our institution. Is it because they don't trust us? No, it's because the normal process of QA says you have an independent check of your program.

DR. SUNTHARALINGAM: Even that is being evaluated. A tremendous amount of money has been spent and little has been detected. That whole program is under review now because of the cost.

DR. DEYE: Frequency of TLD?

DR. SUNTHARALINGAM: Frequency of TLD and even frequency of RPC and going to the center and doing measurements.

DR. DEYE: Going to the center is expensive but TLD is cheap.

MR. TELFORD: You have a source change, so once every five years you send in a couple of TLD.

DR. SUNTHARALINGAM: Even before a source change I accept a brand new machine. I put in a new cobalt teletherapy into my department. You are saying just to ensure your measurements you should now participate in a TLD dosimetry system.

MR. KLINE: We feel that if there is a mistake it is so significant with the number of patients it could affect that it warrants the time to have a double check. It is once every six years and if at all it happens in that six

years where a unit goes out of calibration.

DR. DEYE: This is the one requirement that would have stopped Riverside, Ohio from occurring.

DR. SMITH: I am not against the source change. I think I can live with that. It is the spot check that bothers me.

DR. DEYE: It is only if the spot check is off by five percent. That's rare. I have never had that happen.

MR. TELFORD: How often have you had a spot check that is greater than five percent?

DR. DEYE: Never happened.

DR. SMITH: IT depends on who does it. You normally have a dosimetrist or someone do that spot check for you. They will come back sometimes with five percent. You have to go and chase that down and resolve it.

DR. PAYNE: You are right. I prefer to do my own spot checks at one institution. At the other a technologist does them and she has been good. I can see a situation where an inappropriate spot check has been made and I make another spot check and find it okay. To me, that is still a spot check. I haven't left the spot check yet.

We could get into some -- I am not even going to bring that up. That's not -- you are not going to see a paper trail on that one.

DR. SMITH: You have to be careful, because if you

use this for spot checks and you are paying people to come in or paying for TLD, when somebody in-house could go and check that and say you screwed this up. You got your SSD wrong. You don't need to go out and hire somebody --

MR. TELFORD: If the spot check is not off, then somebody just made a mistake and you caught it.

DR. SMITH: Right. In-house, I mean institutions aligned with the same -- you have to be careful here. Let's go.

MR. TELFORD: Okay, 5.8 These are annual full calibrations. What should you include here? We have a list of things here that we think --

DR. DEYE: This is just an example list. This is not a necessary list, all right?

DR. SUNTHARALINGAM: These are all guidelines.

DR. DEYE: As long as you don't make those mandatory, I don't have a problem with that. It's an example list.

MR. TELFORD: We are looking for devices that would modify or affect the beam. You are saying that you don't object to this list of examples?

DR. DEYE: I don't agree with your example including bolus for example. I would never do that in my institution, but you are not telling me I have to. You are only giving that as an example, and I choose not to accept

that example.

MR. TELFORD: Dr. Flynn?

DR. FLYNN: I wouldn't use bolus. I would just leave that out.

DR. SMITH: I would too.

DR. FLYNN: That is individualized for each patient pretty much.

DR. DEYE: The same thing for the -- even the stock material for my compensating. I don't check every batch of --

DR. SMITH: Likewise, I use acrylic plastic, and I just verify the thickness and things like that. Those are examples, that's okay.

MR. TSE: How about blocks?

DR. DEYE: Yes, I dc blocks annually. I don't know why I do them, I just got in the habit of doing them. Annually makes no sense. I think it makes sense to do it when you first get the machine --

MR. TELFORD: You are right.

DR. DEYE: I see no reason to do it annually thereafter.

DR. SUNTHARALINGAM: The reason I think for this 5.8 is again because of the one incident in Pittsburgh where the wedges measured initially and not measured for another six years until a physicist changed positions and was

measured wrong the first time.

DR. DEYE: I would certainly do wedges every year.

DR. SUNTHARALINGAM: Right. As a result of that, one is now trying to add all sorts of things depending on the time and doing your measurements. The others are not as significant.

MR. TELFORD: In 5.9, this is before a certain amount of time or percent of --

DR. FLYNN: Seventy-two hours.

DR. DEYE: We could use time or percent there.

MR. TELFORD: Dr. Flynn says 72 hours?

DR. DEYE: This is difficult. What you are getting at here are like total body.

DR. SMITH: Taking a measurement.

DR. DEYE: Where field sizes and distances that fall outside the normal range, in our institution if we do total body irradiation, that's what you are getting at there. I think you have had instances where people have screwed up on their total body. I think waiting 72 hours on that, since those treatments are usually only given over a couple fractions anyway, could be really problematic.

DR. FLYNN: These are the special cases.

DR. DEYE: Yes.

DR. SMITH: You have to do your set calculations and you can't do your set calculations without these

measurements in the first place.

DR. PAYNE: You almost have to do it before you do the treatment, period.

MR. TELFORD: Would you like to modify your recommendation then?

DR. PAYNE: I guess I would just say before the prescribed dose has been administered.

MR. TELFORD: In other words, before completion?

DR. PAYNE: Yes, before completion. I guess that is right, before completion.

DR. DEYE: I think that is reasonable, because it won't get you into a problem with just say an extended SSD because when I do a full calibration I check the one over R square out to some large distance like 140 centimeters. I don't check it out to three meters, which is what this really wants to apply to.

If you just said I had to check the output before I treated the patient under those conditions that I hadn't normally checked --

DR. SMITH: Doing TBI should have a dosimetry system based on measurements they are using to calculate --

DR. SUNTHARALINGAM: Measured once. If it was not included in a recent full calibration.

DR. DEYE: Right. Then it asks to --

MR. TELFORD: Or it is outside the range.

DR. DEYE: Right.

MR. TELFORD: Dr. Smith, you are saying that you should have a measurement system if you go outside your normal range. In other words, you would not rely on the inverse square law.

DR. DEYE: I am not relying on the inverse square law out to three meters. I am saying that in my full calibration, my annual calibration, my range will include 99.9 percent of our treatment cases out to say 1.4 meters. What this is alluding to are those few cases we get that are treated at three meters. I think what you are saying here is very reasonable, except that I would not say before 25 percent. I would say before any dose is given.

MR. TELFORD: Before any?

DR. DEYE: Yes.

MR. KLINE: Is that because most of these doses would be high dose to begin with, so 25 percent might not be --

DR. DEYE: Right.

MR. KLINE: -- by the time the damage is done.

DR. SMITH: This is much too lenient.

MR. TELFORD: Dr. Smith and Dr. Deye say before any dose is given.

DR. DEYE: Yes.

MR. TELFORD: Fr. Flynn.

DR. FLYNN: I didn't read the whole paragraph before I responded. I agree.

MR. TELFORD: Dr. Payne?

DR. PAYNE: Yes.

DR. SUNTHARALINGAM: I am lost here, but it's all right. Go ahead.

DR. DEYE: Five ten has a problem. You are much too specific there.

MR. TELFORD: Yes. We want to compare --

MR. TSE: Before you go to 5.10, in 5.9 there is an item on field size. Do you think field sizes go beyond your measurement, should you measure either large field size or small field size?

DR. DEYE: Yes. I think before you use a field size that is outside the range of your normal calibration of field sizes, you should take a measurement before the treatment. An example would be the stereotactic radiosurgery where you might be using a couple of millimeter beam size. That is well outside your annual calibration field size range, and I think before you ever treat that patient you should have to verify those outputs.

DR. SMITH: The rule is that you can interpolate. You should never extrapolate.

MR. TSE: We listen from earlier suggestion -- okay. How about suppose you have one dimension versus

another dimension, how --

DR. DEYE: That is interpolation. If you are just talking rectangle versus square.

MR. TSE: No. The one dimension is smaller than minimum you measured. The other dimension is by six for example.

DR. DEYE: Then I think it needs an output measurement. You are now extrapolating.

DR. PAYNE: My measurement is four by four, then I can't cheat below that in any dimension.

MR. KLINE: One other comment some other physicists brought up under unusual circumstances where you design custom blocks. Let's say you have a circular or irregular field design which is circular in the center of that beam off axis or directly on central axis.

That then is a different field size that is very hard to interpolate between your table of field sizes for field factors. Do you feel that would fall into this criteria?

DR. DEYE: If it had an equivalent --

MR. KLINE: If it is hard to determine field size.

DR. SUNTHARALINGAM: It is not a problem for cobalt teletherapy. Irregular shape fields within the limitation of the field size that the machine can give you is not a problem. The problem is in the high energy and

electron beams. In teletherapy it is not a problem.

MR. TELFORD: In 5.10 you want to have a comparison between computer output and some measurement to check the dose being delivered. What would you recommend that you -- how would you recommend doing that?

DR. DEYE: I would take a standard condition, namely the calibration condition from my first check between the computer and my --

DR. SMITH: It has to match your input measurements first.

DR. DEYE: Yes. Then I would also -- obviously you are going to -- you do say depth dose has to be checked there versus measurement, wedges. You get into the whole issue -- we in the AAPM put a task group together to decide how to verify the validity of treatment planning computer codes. There is a publication out on that now I guess that -- did they ever put anything out yet?

DR. SMITH: It's not out yet.

DR. DEYE: I have seen early drafts of it.

MR. TELFORD: Is there a draft available?

DR. DEYE: Yeah.

MR. KLINE: That's a draft?

DR. DEYE: Yeah, it was ready to go to the printer, but I guess the problem was who was going to pay for the printing.

DR. SUNTHARALINGAM: That was for two specific situations where it was give us some test cases and try it out on your treatment planning.

MR. TELFORD: Would it be beneficial for us to have a copy of that draft so that we could apply the --

DR. DEYE: You could apply the principles. Rave Nath is the head of the therapy Committee, NATH. Dan Miller is the guy who did all the work. What they did was, they went ahead and took very exact and time consuming measurements under -- with humanoid phantom under various beam conditions for four MV and six MV energies. They measured the physical dose under tangential, irregular field and all kinds of weird conditions.

They made up tables of that. Now what the did was send you templates of what the physical conditions were, let you run that thorough your computer and now you compare your computer output to the measured values. The validity of it here is --

MR. TELFORD: What we are looking for is some simple check that one or two or three things that could be --

MR. KLINE: Most people in common practice of medical physics, I guess, once you get a new software package you thoroughly check it out and do a lot of measurements. We are not looking for that sort of thorough,

comprehensive evaluation of that particular company's software program versus your treatment planning system.

DR. DEYE: That's what I thought. Given that, I would just do a few simple things. I would check the output of your computer versus the measured output of your machine for the calibration condition of the machine, say a ten by ten condition under known SSD conditions. I would also check the output of your machine -- that is for your computer for that same field size, the calibration field size for each of the wedges supplied with the machine.

I think I would leave it at that, given where you are coming from and what you are trying to achieve here. Had you done just that, had they done just that at Sacred Heart, they would have caught their problem there. They didn't compare their measurement to the computer program they were using in the clinic. It has to be the program that you are using in the clinic, not some other representative program on the system.

I think if you check for the open ten by ten field and the ten by ten field -- since that's the one that we always calibrate -- with each of the wedges supplied with the machine, both the computer output and the measured output and expected agreement within five percent let's say between all those comparisons, that would very reasonable.

MR. KLINE: Would that be a SSD or SAD or however

you define it, or would you want it in different depths?

DR. DEYE: Now you are getting into depth dose characteristics.

MR. KLINE: Could you pick two points -- let say the depth at maximum or -- something like that.

DR. DEYE: That would be very good. Take two depths for each of the situations that I just described, open beam and each of the wedged fields. D-max and say ten centimeters depth. Then you have done your output and you have done your depth dose, and you have seen whether or not your wedges are significantly hardening your beam or not from a clinical standpoint.

MR. KLINE: We are going from extreme treatment depth.

DR. DEYE: You are covering the clinically relevant range. You are not going extreme. We have patients that are 50 centimeters thick. You are covering the clinically relevant depth.

MR. TELFORD: Dr. Flynn, do you have something to say?

DR. FLYNN: No. This is out of my area, but I was going to ask you the question of why do you think in here they would propose different angles of the beam.

DR. DEYE: Forget that.

DR. FLYNN: Also, the mantle fields -- you are

trying to check to make sure the computer is on target.

DR. DEYE: Right. Just trying to see if the right basic, most important information is in the computer, like the output of the machine. The only reservation that I have with this is that some people complain that computers don't give you an absolute output. ACEL for years has refused to have a dose calculation program in their computer because they didn't want to take on that liability.

What you really get is only a relative dose between say D-max and depth dose. You have to know the output of your machine in order to do a dose calculation with the output of -- MR. KLINE: Which is fine.

DR. DEYE: Therefore, I just told you to compare the output for a ten by ten and D-max with the output of the treatment planning computer at D-max, for an ACEL it won't give you an absolute output at D-max. It will tell you the output is normalized to one.

MR. KLINE: It will give you a relative number that it can relate to what that output should be at D-max 430; is that correct?

DR. DEYE: No. It will call that one.

MR. KLINE: It will call that one.

DR. DEYE: Basically, and all other points will be relative to that one.

MR. KLINE: In other words, everything is

normalized to D-max.

DR. DEYE: Basically.

MR. KLINE: Okay, but you know what the output in error is for the unit.

DR. DEYE: Had Sacred Heart been using a ACEL treatment planning computer, again, the mistake could not have happened. You don't put the output of your cobalt in there. It does not calculate the output of the machine, it only gives the depth of the cobalt and doesn't give the output of the cobalt.

MR. KLINE: Even then if you know that and if you did know the output or if you knew the percentage depth dose, even if you use something to show that you made some effort to relate the true dose to what you think it is -- I think there are situations I don't know about with computer that can be a problem besides the traditional percentage depth dose, calculations that you can usually use with the computer or determine with the computer as you mentioned.

I am not that familiar with ACEL. I have heard about that.

DR. DEYE: Well, I am telling you something that is not quite right there either. I am thinking as you were talking. It will give you the dose rate. You don't have to put the dose rate in, but if you can put the dose rate in--

MR. KLINE: If you can put the dose rate in?

MR. TELFORD: Is there a way to check that kind of treatment planning computer?

MR. KLINE: For example, in the full calibration -- I believe it's dose rate that we specify -- no we don't specify dose rate. We just say output.

DR. DEYE: I am in a dilemma here with 5.10 for AECL. If you put the dose rate in the AECL then you could check the output of the computer versus what you measure. It is conceivable that you would just put in one for the output.

MR. TELFORD: Do you know what to measure and therefore, you can make a measurement?

DR. DEYE: You just measure things relative to D-max for a ten by ten field, because you are assuming that all you are getting out of the ACEL for that condition is relative dose to the calibration condition which you then will apply the true measured dose rate to in order to come up with the final treatment time.

MR. TSE: Dr. Deye, somebody going to make a calculation to obtain the dose. What we said in this item 5.10, at the end of paragraph, we say that you need to make such a calculation --

DR. DEYE: Oh, I didn't read on.

MR. TSE: Thereby to compare.

MR. KLINE: If it's relative and you have to use a

multiplication factor --

DR. DEYE: Then fine, just make sure that stays there. I didn't read far enough to pick that up. So, for 99,9 percent of the cases you can compare the absolute output of your treatment planning code to the measured output of the code. For an open ten by ten and for each of the wedge field ten by ten -- each of the wedges with a ten by ten field, at both D-max and at 10CM depth.

MR. KLINE: For each of the wedges.

DR. DEYE: So, that is basically if you got four wedges that is five times two -- ten comparisons because you got the open field in there two. Four wedges plus an open field, two depths each. Measurement compared to computer output, so that is ten comparisons if you expect within five percent. In those few percent of the cases where you got an AECL computer or maybe some other company that I am not familiar with and you haven't actually put an absolute dose rate in the computer so you only get relative numbers out, then we have to go with this parenthesis here.

MR. KLINE: We didn't say within five percent. We are just saying verify.

DR. DEYE: What does verify mean. I think we have to put some kind --

MR. KLINE: We just said before first use you perform certain things. The results will be checked against

phantom measurements.

MR. TELFORD: We used five percent before, so --

DR. DEYE: Yeah, I think you got to have a number there. I can say yeah, I compared them. They were off by seven percent, so what.

MR. KLINE: The problem is that it depends if people are picking out central axis, off of axis -- you are going to find problems.

DR. DEYE: We just told them.

MR. KLINE: -- peripheral of beam on central axis.

DR. DEYE: We just told them. That disappears if you go with the ten measurements that I just discussed. They are all central axis measurements, they are well defined depths. They are not blocked fields, they are open field and wedge field only. We are expecting five percent agreement. You are going to learn whether the code is correct, you are going to learn whether depth dose data is correct.

MR. KLINE: Let's say it is greater than five percent, then are we in a position to say that is not acceptable software program?

DR. DEYE: You are in a position to say that something needs to be done. Either the measurement is wrong or the software is wrong. This system, as just checked -- not to be used to treat patients until the error is found,

until the source of the discrepancy is found. If there is a five percent or more discrepancy in one of the ten comparisons that I just mentioned, then that system should not be used to treat patients until the source of that error is found or the source of that discrepancy is found.

MR. TELFORD: Actually, that just about completes the guide, because 5.11 is an emergent condition escape clause. I guess that's all. If you think of some references or some standards or recommended guides that any of the societies use that you think we ought to incorporate part of it in our guide or reference it just as sort of a bibliography, I would really appreciate you telling us about it or sending us a copy or flagging it somehow to out attention.

We would like this to be as complete as possible and allow any kind of set of examples that a society would endorse to be used by the licensees.

DR. DEYE: You have the ACR QA document.

MR. TELFORD: Yes.

DR. DEYE: That would be one thing I would send. I think this stuff from Nath, I can't really -- I only have preliminary copies of that and would have to come either through Rave Nath or Dan Miller, who headed up that task group. It was finalized. It was just that all of these things were so massive, the patient data contours and

everything that one had to send out and they had to be very exact -- you were looking for millimeters on the reproduction. They had to be photo offset.

The problem or hangup is who is going to pay for all these copies if we start to distribute them. It stopped there. They haven't reached fruition because nobody knew how to distribute the material.

MR. KLINE: The patient examples would be the --

DR. DEYE: The measured phantom data. It had to be very exact, because you don't want to be digitizing an incorrect dimension. Of course you are going to get the wrong data out then compared to measurement. It was very laborious and expensive to photocopy all that and distribute it all.

MR. TSE: I am sorry that I did not have a chance to ask you the question about 5.10, computer check. You say that for the purpose of checking whether the source strength had changed and so on, you need to make ten different calculations; five wedges plus two depths.

My question is why do you need ten?

DR. DEYE: I didn't say that you need ten, I said ten would be adequate.

MR. TSE: What about one check?

DR. DEYE: One is better than none. What it won't catch is the depth dose being off. If depth dose were off

one measurement, one comparison can't show that.

MR. KLINE: Wrong wedge factors.

DR. DEYE: And, it won't show if the wedge factors are incorrect. I was trying to hit -- in those ten I think I was hitting the most serious and probabilistic mistakes that can occur in the use of a treatment planning computer.

MR. KLINE: If you look at the other variables and field factors, field size --

DR. DEYE: Five percent, eight percent. Over the whole range of field sizes, it's not a big deal.

MR. KLINE: The other parameters like timer which are actual full calibration measurements, that is independent of the computer planning system because that is dose rate related. Beam modification devices, do you feel that might be something that --

DR. DEYE: Like the block, if my transmission factor is off by 30 percent in my computer compared to reality, it is only going to make the dose under the block maybe seven percent instead of five percent of the central axis dose. That is significant.

MR. KLINE: Distance -- you have treated distance and that would be a variable --

DR. DEYE: I cannot conceive of the computer program that would not handle distance correctly. If it did the absolute output correctly at one distance -- actually

you are doing distance. When you do five and ten CM depth, if you made those not at isocenter and make then truly depth dose and not isocenter, that would be a good thing to require; that the measurement be both at five and at ten CM --

MR. KLINE: The number would be --

DR. DEYE: At 10 CM beyond D-max under the same phantom conditions.

MR. KLINE: I was thinking further distances.

DR. DEYE: No. You would have both one of R square and attenuation of tissue accounted for in those ratios.

MR. TELFORD: Thank you very much. The meeting is adjourned.

[Whereupon, at 5:30 p.m., the meeting concluded.]

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 AAPM, ACMP, ACR, AES, ASTRO Proposed QA Rule and Reporting Requirements

DOCKET NUMBER:

PLACE OF PROCEEDING: Reston, Virginia

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.

Mary C. Larkin

Official Reporter
Ann Riley & Associates, Ltd.