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UNITED STATES

NUCLEAR REGULATORY COMMISSION

MEETING WITH AAPM, ACMP, ACR

AES, AND ASTRO

PROPOSED QA RULE AND REPORTING REQUIREMENTS

American College of Radiology

1891 Preston White Drive

Reston, Virginia

Conference Room A

Monday, November 19, 1990

PROCEEDINGS

[9:00 a.m.]

MR. TELFORD: Good morning. My name is John Telford. I would like to welcome you all to this meeting and am happy to see all of you here. The first thing that I would like to do is, I believe everybody has a copy of the agenda. I would like to let everyone introduce themselves. I need to tell you is that I am the Section Chief of the Rulemaking Section that is responsible for developing this rule.

We have four of the five people here today that will be working on the final rule, so we have brought those folks here that need to listen to your comments most acutely. You can be assured that the comments that you make will certainly be heeded. I will move to my left clockwise to let everyone introduce themselves.

MR. CAMPER: Larry Camper, Section Leader for the Medical and Academic Section at NRC. My group is in charge of medical policy issues and what have you, and we are working closely with the Office of Research on this rulemaking.

MS. PICCONE: Josephine Piccone, Senior Project Manager in the Medical Section, NRC.

MR. FLYNN: Dan Flynn, Radiation Oncologist at Mass General Hospital.

MR. SMITH: My name is Al Smith. I represent the American Association of Physicists.

MR. SVENSSON: My name is Goran Svensson. I am Director of Physics at the Joint Center in Boston. I am interested in developing some of the ACM and ACR physics documents on quality assurance.

MR. DEYE: Jim Deye, Director of Medical Physics at Fairfax Hospital. I am representing American College of Medical Physics here today.

MR. SUNTHARALINGAM: Suntharalingam, Director of Medical Physics at Thomas Jefferson University. I am representing both American College of Medical Physics and ASTRO.

MR. PAYNE: Tom Payne, practicing Medical Physicist at a private hospital, Abbott Northwestern in Minneapolis. I am Chairman of the Commission of Physics at the American College of Radiology.

MR. SHORT: Brad Short, with the ACR staff in government relations.

MR. CROCHE: Nick Croche, with ASTRO as staff.

MR. BOGARDUS: Carl Bogardus, Chairman of the Board of ASTRO.

MR. BRICKNER: Jerry Brickner, representing ACR.

MR. TSE: Anthony Tse, from NRC office of Research. I work in the rulemaking section, department

manager for this project.

MR. TELFORD: As part of the introduction section here, there is a couple of items that I would like to go over. One is that I would like to bring you up to date as to what has happened since the rule was published in January, and quickly go over the procedures that were in the notice for the conduct of the meeting although that looks easy. Fourth is the purpose of what we are here for.

As you know, the rule was published in January of this year, the proposed rule of reporting requirements. The regulatory guide was also sent out as being part of the package and was available in the public document room. Since the rule was published, we have met with the four representatives from agreement states back in March of this year. We met with the American College of Nuclear Physicians and the Society of Nuclear Medicine in the summer.

We have also conducted a pilot program in which we had approximately 24 NRC and 48 agreement state volunteers. These were selected in proportion to their numbers because, for instance, the NRC's Region I which is headquartered in Pennsylvania and Region III which is headquartered in Chicago have the vast majority of the NRC's licensees. Of the 24 a high proportion was taken from Region I and III. For example, agreement states, states like Texas,

California, New York and Florida have the vast majority of agreement state licensees. Proportionally, a higher percentage came from those states of the 48 agreement state volunteers.

In addition, we wanted to represent it to the various practices like teletherapy, brachytherapy and nuclear medicine diagnostics and radiopharmaceutical therapy. We also wanted to represent the location, whether it was urban or rural, and we also wanted to try to represent the type of hospital, whether a county hospital or a rather large hospital that may, for example, have a larger budget.

We completed the selection at the end of February, and we gave all the volunteers the proposed rule and asked them to study it for approximately one month. We started having pretrial period workshops. During the workshops -- we had five of these in the NRC's five regions around the country -- we basically explained the proposed rule to the volunteers. We asked them to go back to their hospitals and their clinics and to develop a QA program that would meet the proposed rule or, if they didn't have one at all, or to augment their program if they already had a QA program.

Then they were to try their program for 60 days. During the 60 days we randomly chose 18 of the 72, of which we sent what we call our QA team -- a group of four folks,

three of which were very experienced inspectors to their site to do a pseudo audit. The question we were asking was, were the volunteers implementing the program that they said they were, and do we think that it meets the proposed rule.

In addition, we evaluated all of the programs that were on paper, like a paper exercise of evaluating their programs to see if we thought that it met the proposed rule. After the 60 day trial period we had five more post-trial period workshops in which we invited the volunteers to give us their comments and suggestions on -- their comments on their experience with the rule and what it meant to them and their suggestions on how to change it. So, we have conducted those workshops.

What we are doing now is meeting with all of the professional societies or agreement states that have expressed and interest and that would be so kind as to give us suggestions for how to modify this rule before it becomes a final rule.

Let me move to the meeting notice. We have members of the public here today, of which we do have a couple. Let me bring their attention to the proposed agenda, that at 4:45 or whenever we get to this point in the agenda we will entertain questions or comments from them. Up until that time, we will devote all that time to liscening to you folks. As you have guessed by now, the

purpose of this meeting is to listen to you on your suggestions and comments on how you would advise us as national authorities or as representing national societies acting as a national standards writing group, how you would advise us to improve this proposed rule.

Let me now move to the next item on the agenda in which I want to let each of you have five minutes or whatever you would like of individual air time, and you can give us your opening remarks. We put down some bullets here about any general comments that you would like to make on -- for example, interactions and model QA programs that your society might have, or your general comments on the NRC's proposed rule on our reporting requirements. Just anything that you would like to say as a beginning.

I will start with Dr. Flynn.

MR. FLYNN: I want to defer to Dr. Brickner. We had talked last night.

MR. BRICKNER: We had dinner together last night in a moderately noisy environment, and it was felt to be more effective if two of us spoke to you on behalf of us, so to speak.

We were disturbed about two or three items. We looked at the numbers involved and, first of all, we want you to understand that we have spent a great deal of time and effort developing the quality assurance program. I have

been involved for five years, and Ed 15 years in the patterns of care study which you are well aware of and that we have discussed at a similar meeting. The concept of quality assurance and quality improvement is something that we are dedicated to.

We are also extremely interested in working with you in developing regulations and a quality assurance program from those regulations that will be effective without being interfering. We are not sure that we have that before us, and we are concerned about that. We feel like things are being rushed a bit, and that we are seeing this and saying we are going to go through it line by line and approve or disapprove things, and we are not sure that you are ready for that at this point.

We are looking at an instance of one in 40,000 teleradio therapy sessions, one in five or 10,000 brachytherapy sessions in which something reportable has come to you, of which probably only one-half injured a patient. Now, I understand that you want zero defects at your job; is to have no problems with radioisotopes, and we understand that. But we submit that this frequency is so low that we are not under a crisis management type situation.

We also suggest that your estimates on the amount of manpower and money involved in this reporting procedure

that you have outlined is grossly underestimated, and it's going to be a very expensive item. There is another problem which arises which bothers me and anybody who is in the clinical management of patients. You have practically assured full employment for some attorneys. When we use the term "misadministration" and you tell me I will write a letter to a patient and to the referring physician and inform them that a misadministration has occurred, you have just put me in a terrible position medically and legally.

Let me give you a for instance. These are some of the things that I want to come back to a suggestion for you. If I see a 32 year old lady with cancer of the cervix and I say to my technician I want four fields to the pelvis, 200 rads today and put her on the cobalt, they treat the first field, she starts throwing up and gets hysterical. They rush in the room and she's got shakes, chills and fever.

The first thing we do is, we get her off the machine. We start an IV on her, we admit her to the hospital and treat her for sepsis. But I am going to have to go through the full reporting because I only gave 25 percent of a prescribed dose. This is going to cost my hospital money, me money and already put into the patient in her family's mind that she was misadministered to the first day of treatment.

Now, whether you clarify it until hell freezes

over, they are going to associate any further illness with a misadministration. The fact is that 50 rads are totally insignificant. As a practicing oncologist, I immediately dismiss that and worry about her sepsis. You have put me in a position where I have no options, and that's the problem with the rigidity of regulations.

What we tried to do in a QA program was to say there are problems. We all have some of those problems whether we admit it or not. We insist that you put a program in place and we will reward you for finding your problems and fixing them, the reward being joint commission approval and continued practice and income for Medicare. What you have written is here are a list of rules and traps, and if you put your foot in one be sure to call me because I am going to come and punish you.

That's not an overstatement that it's a protagonistic situation. Your first response is, I won't report it. I will figure a way to cook the books. Why should I expose myself to this kind of harassment and write letters to a patient and invite her sue me if I can just change the date or something. You immediately give me an option that is illegal, unethical and immoral, but is the quickest and easiest fix.

What I am saying to you is, before you take a statement like 50 percent over or under is a

misadministration and the patient will be notified, I think that you need to have two or three of your people sit down with a small group of four or five practicing oncologists and say here is what we want to accomplish. How can we do it that doesn't put you in great jeopardy but gives us some assurance that you are actually going to do it, and see if we can't work something out more effective in this kind of a rule.

You say to me, if you gave her twice the dose, don't you think we ought to know about that. Possibly so. You have some other things in there like you have attempted to make a compromise on the daily fraction related to the total fraction -- total dose prescribed. That is completely nonsensical. The first week, if I am going to treat 7,000 rads my slot factor the first week is 700 rads. That's more -- that's the whole week. The last week it's 700 rads totaled up to that time, which is a very small fraction. I mean, it's not a rational way to do it.

Let me speak just briefly to brachytherapy because we have a problem here. It is extremely difficult for anybody who does not do brachytherapy to understand it. What you have done is, you have said I must write a prescription and then do it, and if it deviates by 20 percent call you. Like a surgeon, I frequently don't have a prescription. My prescription is, I am going in there and

doing the best I can. Whatever I can accomplish I am going to evaluate and live with.

When I put seeds into a prostate, I don't know what the dose is going to be. My prescription is somewhere between 1,000 and 5,000 rads, whatever I can get. That's not much of a prescription. When I do a cervix, I don't know how many sources I am going to get because I don't know how bit a tandem -- a long a tandem I can get in this patient, whether the old voids are going to be offset, parallel, asymmetrical or not, so there is no prescription. I do what I can do and then I make things fit.

So, the rigidity of the system which says write a prescription, and if you deviate by 20 percent you are in trouble doesn't really make much sense in that situation. There were a few other matters. We are aware of a number of ongoing studies that you have funded that we understand won't be reported back for a period of time; human factors analysis of how do we make mistakes. I understand you are doing a study on that, which is a wonderful idea. We would love to see the results of that and work with you on it.

There are a number of studies that we understand that things got a little out of sync. Grants are out to do studies, the results of which won't be back until after this is already law. We would suggest considering the impact on us and the cost to the public who will bear the eventual

cost of all the reporting and the investigations. It might be best to get the results of the studies, put together a joint task force and approach this again from a slightly different tact of a bit less punitive approach.

I understand that when you write regulations and you write law, punitive is law. That is inseparable. We would like to minimize that or put at least some encouragement in there to do quality improvement work without this constant threat. We are a little concerned that we have seen no impact from what was input before. Dutch Flynn wrote three pages in reasonably good English, and there were others present who wrote response to it, and we are not aware that there has been any response to the response and we were a little concerned.

That is clinically from my viewpoint. I am hesitant to go through and do a line item approval/disapproval, because I am condoning an instrument that I think needs some significant rework and I feel like that if you don't buy stock in this company today it will be closed tomorrow. I don't like it when I am pushed so rapidly, and I am a little concerned that we need more analysis on this. We need more results of any studies that you have underway.

For instance, I would like to know what studies you have funded, what their purposes are, how they are being

done, and what that information might mean to us when it comes back. I am all in favor of preventing. As I say we are deeply committed to quality improvement, not only because it is required by a joint commission but because that's the bottom line of what our 15 or 17 years of patterns of care work has been about. We have found problems. We know they are there. Most of them are fixable.

Most of the problems that you cite in here that are significant problems are people screwed up. They pulled the wrong source out of the drawer and nobody checked them. Writing letters until hell freezes over won't change that. A regulation or a program that requires double checking is an excellent idea. But some of these things, when you get to ten percent plus or minus the total dose, is that the right number? There's not a magic number. If you are treating 3,000 rads for paladin of a bone metastasis, plus or minus 100 percent doesn't much matter. If we are talking about 7,000 rads to a small volume brain tumor, plus or minus ten percent matters a whole lot.

These broad, hard, rigid statements sometimes clinically don't mean anything. They can get people in trouble when it's not necessary. I am rambling now, excuse me. Did I miss any of the points gentlemen, that we discussed last night that I was to bring up?

MR. FLYNN: No.

MR. SMITH: I would like to speak to you on behalf of the American Association of Medical Physicists. I am the President in that society and The American College of Medical Physics. I happen to be on the board of that society, and the ACR on Radiation Protection.

Medical physicists have been dedicated to both the principle and practice of quality assurance for many, many years. We started publishing quality assurance documents in the early 1970's which established standards for the calibration and acceptance of high energy radiation therapy machines.

In 1984 we published the physical aspects of quality assurance in radiation therapy, and I have copies of that if you would like to have one. Most recently we published quality assurance documents from imaging and mammography. We really are no strangers to quality assurance, and we recognize its value and have witnessed the positive impact of well designed and carried out quality assurance programs. They are important.

We also recognize the negative impact, in terms of increased costs and substandard outcome of quality assurance programs which are not well designed and carried out. When we first reviewed 10 CFR Part 35, we sincerely believed that reasoned comments or changes and clarifications would render the document acceptable provided they were implemented. But

upon further study and discussion we now believe the document to be so fundamentally flawed to the extent that a point by point discussion of its elements would not be meaningful.

We firmly believe that implementation of the current proposed rule would result in greatly increased cost of health care, general confusion caused by its imprecise definitions and lack of understanding of the physical and biological processes which it attempts to address, and diminished health care. Those, I think gentlemen, are the impacts of this proposed rule.

We believe that the proposed basic quality assurance program is well intentioned. Good quality assurance programs are vitally important. We wholeheartedly support your efforts to ensure that every facility which utilizes byproduct isotopes for medical procedures has a comprehensive QA program. However, it must be made a matter of public record that the incidents of reportable deviations in this medical area is astonishingly low, on the order of one reportable incident in about 10,000 administrations.

The genuine desire on the part of the vast majority of medical practitioners to provide excellent care and the great American legal system have worked together to drive the incidents of unintentioned events to a level so low that any further gains would be obtained only at the

expense of inordinate time and effort, which translates to an enormous cost to the American public.

It has been our experience that a little QA, where there has purposely been none, has a dramatic impact. Adding an overlayer of redundancy on a QA system will provide additional gains but they will be small. Most QA systems already contain redundant elements. We have learned, however, that stacking a third layer of redundancy on any QA system costs tremendous time and effort to obtain minuscule gains. We can almost guarantee that should an additional regulatory QA program be implemented, the step that would be taken by the vast majority of facilities is to implement dose measurements on every radiation field and on every radiation therapy patient. That already is happening in some cases.

This procedure, which most of us who have used it have found to have very little gain, adds nothing to a QA program. But it can be charged to a patient at about $150.00 per measurements. Assuming an average of three treatment fields per patient and 500,000 patients per year receiving radiation therapy, this would raise the cost of health care by $225 million. This cost would not increase the curing of cancer of even one percent.

We cannot understand how such measures can be undertaken at a time of national crisis in health care

costs. Bear in mind that these figures do not count the NRC cost in implementing and administering such a program. We would readily support an NRC full grant to ensure that every facility have a written comprehensive QA program modeled after one of the existing JCHO or ACR programs.

We cannot support in good faith the implementation of the philosophically and technically flawed document before us. We have sincerely tried to develop comments which would correct the imprecise definitions, eliminate the unnecessary elements, correct the improper technical statements and concepts and render this document useful. We have concluded that the present document drew out in an unsupported premise will not produce clinical results. We sadly suspect that no rational study has been performed which clearly establishes a need for the document.

You have funded contracts to determine whether proposed rule can be reasonably implemented. That really is the wrong question. The fundamental question is, is it necessary? As qualified experts, we offer our assistance in determining what the need is in addressing that need with a reasoned document based on medical, scientific and technical knowledge. Please let us know how we can assist you in your effort.

MR. CROCHE: I believe that Dr. Brickner and Dr. Smith have spoken on behalf of all the individuals that are

here. I don't think anyone here disagrees with any of the comments that either Dr. Brickner or Dr. Smith have made. Those were general comments on behalf of all the organizations which are represented here today.

MR. SMITH: I would like to finish this, because this is a statement which I think should be taken very seriously. Up until this time in radiation therapy every patient treated and those patients which are being treated today are guaranteed there are areas within that patient which there is more than ten percent error in the stated dose. That is because our treatment planning programs, however sophisticated they are, have inability to accurately calculate absorbed dose in transition regions. That is, regions where there are interfaces in tissues like bone and muscle between muscle and air, for example, the lungs on the order of probably 15 percent and sometimes higher.

This is for every patient that we treat. We have an inability to calculate accurately and tell the physician in every element of tissue in that patient, what the delivered dose has been. On the order of -- in every patient that has been treated to date and is being treated now, because of the inability to -- we know that there is at least 15 percent error on the average in the stated dose in every patient treated for lung cancer in this country.

If we strictly apply what you are telling us,

every patient that we treat every day, every fraction will result in a misadministration because we know that there are regions within the patient for which we do not know the dose better than 15 percent.

MR. BRICKNER: It doesn't matter. If we know the output of a machine and we say we have delivered "x" dose to a point, even though we know there are all these variations in there, over the years we have learned the result of doing that. The result has proven beneficial for this group of patients.

We have to be very careful about making statements about what the dose is, because dose doesn't mean anything. It's an extremely complex concept when you say dose within a patient, and are you ten percent over the dose. To clarify these regulations as they are written now, you will have to write an excellent textbook on radiation oncology and everybody will have to use your book and go by it. That is really what will happen.

MR. SMITH: There are many definitions of dose when you talk about radiation therapy. You have target dose, dose to normal tissues, integral dose. All of those have a very precise meaning. To use a definition of dose without recognizing the many variations of meanings which to us are significant, but you only use the word dose. There are many doses. The prescriptions now days often are in

terms of volume doses, target volumes.

Because of body homogeneities, because of constraints in approaching specific tumor volume because of critical structure, we know that there are regions that have hot and cold spots well over the order of ten percent, but those are clinically accepted and known. I wonder how you reconcile your statement of dose against actual clinical practice, which is very complex in its physical and biological implications. There is no match between your document and the way medicine is practiced.

MR. BOGARDUS: Our problem is that we are dealing with a complex biologic system. We are dealing with a patient, each one of whom is a different individual. We are dealing with 120 different types of known malignancies that we treat, each one of which behaves different. Even within certain categories in malignancy they behave different.

We often will prescribe a dose to a tumor volume, only to find half way through therapy your response is not what you thought it would be, at which point you may dramatically change what you are doing, either raising or lowering that particular daily dose fraction. You have then deviated from your original prescription plan. We do this all the time.

We are dealing with a complex biologic system, and for us to say to you that yes, we do vary 15 or 20 percent

and maybe 100 percent in dosage across tumors and across a volume of treatment is not an error and is not a misadministration. What it is, it's our clinical acumen, a technique and talent that has been gathered over many years of treating a lot of patients so that we know what to do as we continue our course of therapy on a given case.

It is something that is extremely difficult to put down in a very rigid framework. This is why a cookbook of radiation therapy has never been devised. There are no cookbooks of radiation therapy that tell you how many rads to what point are supposed to be given for each individual tumor. Almost everything that we prescribe is in relatively broad terms, modified by the clinical response of that patient before we are completed with our course of therapy.

MR. FLYNN: One example would be in lung cancer, where some facilities believe that to use a lung correction factor and other facilities believe it is not important to use a lung correcting factor. There are national protocols which do not use a lung correction factor, and these national protocols are being administered at such facilities like the NIH and military hospitals and other Federal facilities.

That would require the NIH and these federal facilities to report misadministration, because the different between more than ten percent if you believe one

correction factor should or should not be used. So national protocols, as I say which do not use the lung correction factor, do account for the inhomogeneity in lung cancer.

MR. BRICKNER: None of these comments are to mitigate against one of the major thrusts here, which is that if you think you put 15 milligrams of cesium in a patient you damn well ought to be able to document that you picked the right source out of the bucket and put it in the applicator on the right end of the applicator. That is quality assurance that is terribly important.

To my knowledge and his knowledge that what happens in the tissues millimeter by millimeter is a whole different world -- don't start telling me about the dose to point A because that's meaningless. Yes, there should be some type of quality assurance in place to be sure that I used the applicator I thought I used, I got cesium instead of a leftover radium source or something else, that my cobalt machine if I still use it was indeed calibrated. Some of the things that you have in there about if there is a difference between a measurement and mathematically calculated projection of measurement that certain things should be done, those are all excellent points. That is quality assurance.

But, plus or minus ten percent of the dose -- you have brought in a magic word that is just a real problem. I

think you need to work with us point by point in a group setting where you can come to better understand the problem, and maybe we can come up with some good ways of putting in a quality assurance measurement that includes dose. To just make some of these statements, it won't work.

MR. CAMPER: May I make a suggestion. At this point in time at least, let us try to continue around and get any opening comment that you have on behalf of your organization. Some of the points that are you are making, most of the points that you are making are excellent points. They are very specific, rather academic and what have you.

I think we can deal with those better when we talk about specific elements within the proposed rule, particularly within the reg guide or what have you. We certainly welcome your comments, as specific and as technical as they might be, but I think we will gain more if we go through it in that format. At least for the time being, if you have any general opening comments, okay?

MR. SUNTHARALINGAM: The general comments were summarized by representatives rather than each one of us giving general comments. I think the decision was made by this group last evening that the opening general comments -- I think that if there are specific points that were addressed, it was purely to point out that inconsistencies and the flaws in the existing document. I don't think any

one of us has anything more to add in terms of general comments.

I think what might be appropriate might be some response from you, the NRC, to some of these opening comments. Also, you might want to clarify for us -- we also took some time to respond in writing, each of the organizations, to the document that was for public comment. Here we are, eight months later or six months later, and we have not seen any single change even for discussion today. One can go through a lot of areas where it was pointed out there were inconsistencies and there were difficulties, not an adequate study has been done.

We were told at the beginning that a pilot study has been done. It would be very enlightening to us if there are some results of this pilot study made known to us. It would be very enlightening to us, what are your criticisms or remarks to the responses that we gave to you in writing.

I think what the general comments inferred or implied was, we think it would be a waste of time if we are asked to go through the existing document page by page and point by point and we are to say yes, these are acceptable and these are not acceptable changes. I don't think any one organization is ready and wants to do that today.

MR. DEYE: In lieu of that, something we thought of last night that gets to maybe some of what you wanted to

get out of that point by point discussion, would be for you to perhaps send the proposed QA rule to the appropriate committee within ACR that put together their document on QA standards and perhaps a similar committee at JCHO, and ask them whether or not the elements that you have enumerated in your QA rule are coincident with or divergent from, either in principle or technical fact, the elements of their programs since they are already out there inspecting and certifying organizations on the basis of their programs.

That might be a way of getting some of the task force input that Dr. Brickner alluded to earlier without even forming a new task force, if you will, since you are fairly far down your line here. You have already gone on the record in the past as having an objective of not laying yet a different QA program on licensees than those that they are already subject to.

We are already subject to JCHO, we are already subject to ACR, in a voluntary sense on the latter at least if we want the accreditation of ACR. I think it might be useful, not to be presumptuous and put a burden on you, but it might be useful if you were to send your program to those two committees and ask for their input.

MR. TELFORD: Are there any other general comments?

[No response.]

MR. TELFORD: There were a few comments here that we do need to respond to. The public comments, the letters that we sent in, in response to the rule being published in January, we have those letters and have read those letters. We thought that many of them contained some very good ideas. Please don't get the idea that those were lost or anything like that.

What I hoped you would see is that we are trying to meet with everyone that had an interest, every organization that had an interest, so that we could have a kind of meaningful discussion on the proposed rule and what you thought of it and how you would change it. You see, with the public comment letter -- for example, most of the remarks made here this morning or a lot of them, had to do with reporting requirements and not the QA rule itself, not the 35.25.

Sad to say, a lot of the comments relate to current requirements. If you would turn to page five of this handout that I have given you, the current requirements that are currently in 35.2 for reporting a misadministration, you are pointing out dose or dosage, you are pointing out ten percent and things like that. Sad to say, these are current requirements for all NRC licensees, and sad to say, those became reportable misadministration as of the first of this year for all agreement states.

Your comments are kind of old news.

MR. DEYE: We were under the assumption that it was open for discussion again, because in your Federal Register notice --

MR. TELFORD: Everything is open for discussion.

MR. DEYE: Page 1442 specifically states the Commission would especially appreciate public comment on the proper use of the term misadministration. Therefore, we felt that it was not a closed book and the whole concept of misadministration, be it the old proposed -- the old definition or the new proposed.

MR. TELFORD: Yes, everything is open for discussion. What I did was send letters to each organization represented here, all five plus the Commission on Physics, to invite discussion. With public comment letters, if someone happens to focus on the reporting requirements, they can only talk about that version of the reporting requirements. We can't go on to the next step. We can't say what would like to change and why would you like to change it. What about this and what about that, it just doesn't happen when you are only limited to public comment letters.

As I understand it, this group chose to get together, all six groups chose to get togetner at one time. I do have to remark about the timing. Dr. Brickner, it's

not as if this is the stock that you have to buy. My gut feel here is that we may get through everything in a day and it may take three days. We are completely open. However long this group or any other group wants to take, we will be there and talk to them. It's not like one time through, it's let's get started.

MR. BRICKNER: We are saying a day, two days or three days, but when this meeting is concluded you have this wrapped up and have a regulation to propose?

MR. TELFORD: It does not preclude future meetings. You are talking to the staff here who has the job to write the final rule. I think you really won't appreciate what I am trying to say until we go through the rule and the reporting that we have learned a lot from our volunteers. Most of what you have said this morning we have heard before from the volunteers. We have an acute appreciation for those things.

That's why we want to talk to organizations like this, to get down to the nuts and bolts to figure out what would be acceptable. There are a lot of things that we can change and I am sure it would take the spirit of a quality assurance rule without the problems associated with some of the reporting requirements.

MR. BRICKNER: We would be very interested in what your volunteers had to say.

MR. TELFORD: Don't feel pressured by the factor that this is a one shot meeting.

MR. SUNTHARALINGAM: You have some feeling from the NRC staff as to when this rule has to be written and presented to the Commissioners?

MR. TELFORD: Yes. We are supposed to bring the final rule to the Commission in March of 1991.

MR. SUNTHARALINGAM: I believe that was the general statement or remark that Dr. Brickner made. Our concern is that there is a lot of activity going on, and NRC is also spending a lot of funds, having given out contracts for three or four studies that will impact on this program. Therefore, our feeling was that don't rush through the rule, even if it be for March, 1991. That is too early.

Here we are sitting November, 1990, not having had any feedback from the NRC pertaining to our written comments that were submitted. We don't know the direction in which you are going. Now you are coming back to us and saying let's meet and talk. We are giving you some input and we need to get some feedback from you, what do you think about the comments that we made.

MR. SMITH: We sent you those comments in April, and we have no recognition at this point that we have come here, that you have acknowledged those or that you have critically evaluated them, that you have incorporated them.

Then we are hearing that you are soon to be asking for more comments. You haven't even done anything with the comments that we gave you in April.

How do we know that today's comments will have any more effect than those we had in April?

MR. TELFORD: The comments and letters that you are talking about are public comment letters. In ordinary rulemaking, the way you hear about our response to the public comment letters is when the final rule comes out in the Federal register. The comments are analyzed and evaluated and there's a response given there.

I think during our discussion, which I hope we get to, you will find out that some of your comments have been heard.

MR. SMITH: Will you give us an evaluation. We don't really think we should give you more comments until we hear what your evaluation is of our previous comments.

MR. TELFORD: We don't do that.

MR. SMITH: This is confusing to us. Why would we repeat those if we have already given them to you, and you have not given us any evaluation of them of what your thoughts are of them.

MR. DEYE: Are you saying that by the nature of the process that the written comments that we submitted cannot be part of the dialogue because of the nature of the

process within the NRC, whereas the comments we bring up today could actually begin a dialogue so that we hear back either critically or the validation of what we are saying?

MR. TELFORD: Yes. For example, Dr. Smith's comments on increased costs, those are just a bunch of general statements. I would like to find out what are they due to. Point to something in the rule. You see, with a public comment letter you can make a lot of statements in there about increased cost, but I have no opportunity to find out why. You just made the statements.

I would like to know what are you pointing to in the rule, and what is really the problem. Let's talk about the particular point probably in the reporting requirements, not in 35.35, but it's in reporting requirements and what in 35.33 or 35.34 that is giving you a problem. I would like to find out what that is. Let's find out how you would fix that.

MR. CAMPER: Let me add to that, if I may, please. I know at times it is difficult for everyone to re-regulate and, in particular, I think for the medical industry to fully accept or appreciate the process that we go through. I would like to emphasize with this particular rulemaking that, many of the steps that we are taking are beyond the normal scope of the process.

As John was just pointing out, public comments are

responded to in a certain orderly fashion as part of the due process. In this case we are making a concerted effort to go to pilot participants, to various organizations representing the medical community, the American College of Nuclear Physicians, the Society of Nuclear Medicine, this group and what have you, due to the nature of the regulation and due to the nature and sophistication of the individuals being regulated -- at times we find ourselves in a position where we are receiving generally negative comments and we can understand your concerns, and the general negativism of those comments.

Be that as it may, please do understand that what we are doing here -- it may be a little bit difficult to grasp readily is -- we are trying to seek information that is somewhat unusual at least to the process normally.

We recognize that there may be a general feeling of negativism about these things, but believe me when I say to you that it is productive to the extent that you are comfortable in doing so, trying to address specific items that we can then go back and look at as we go through the rule writing process. I would emphasize what John has pointed out too. During the last several months there has been a tremendous amount of data gathering taking place, both by our QA inspectors and in post-pilot workshops, and in meetings I just alluded to.

It takes a lot of time to meet and review and to compile this data to look at it as we look at the rulemaking process. We intend, for example, to present some summary of our findings and what have you to our Advisory Committee on the Medical Uses of Isotopes in January for its deliberation. I share these points with you, with the emphasis on trying to make it clear to you that while you may have a general resistance to the rule -- and we understand that -- it is constructive to try to address these things on a line item basis.

Some of the comments that we have heard already, I think, could be viewed and better addressed as we address these things specifically. Again, I would emphasize as John has pointed out, this doesn't have to be a one day scenario. On the other hand, I would point out that currently we are marking on a directive to prepare a rule to the Commission by March of next year. Timing is extremely important, and right now the meter is running. Let's make best advantage of our time that we can.

MR. TELFORD: They have asked about some studies that I think NMSS is doing; can we talk about those a little bit?

MR. SMITH: If those were RFP's those contracts were a result of a formal course which would be important to the process. How many of those are complete, have the formal

reports available. We would like to know what that process has been and what the status is, and we will have knowledge of those results.

MR. CAMPER: I can address that somewhat, and then what I Will do is -- Dr. Piccone is one of the project managers for one of the contracts in question. She can perhaps give us a little insight into one of them. There are three contracts in question at this point. One deals with brachytherapy, another one deals with teletherapy, and these are human factors types of concerns.

The letting of those contracts is in process now. The timing on those is somewhere in the order of a year or so. The other contract is to look at what is going on in the area of quality assurance, and I will let Dr. Piccone address that in a moment.

We have a concern about timing on these things. In the best case scenario the contract would come in, certain analyses would take place, and then those would be looked at in terms of how they relate to the rulemaking process. Unfortunately, the contract process does not always lend itself to such orderly progression. For whatever reason, contract award dates slip, contractors are unable to meet milestones in their contracts and what have you.

That becomes a management problem. Like I said,

we would all like to see the cart before the horse, so to speak. Of course that's not the case in this. However, we feel that while we will gather additional information and we will look at that information in due course, and it may come to have an impact upon this entire process at some point in time. We feel that the information we have gained thus far and are continuing to gain as it relates to the project time schedule for March will still be workable. We are still getting a lot of information.

We would like to have all that is possible in due course. We will look at these contracts and what they have to say to us. At this point at least, there is no intent or not intention of postponing the rulemaking to wait for that information. We feel that there's an adequate amount of information being gathered. As I have mentioned a minute ago, the Commission is making a great deal of effort to go out to the community and gather information in a fashion that is not necessarily always done in all rulemaking processes. We do share your sentiments and your concerns about getting information for the contracts.

I can only tell you that we will continue to pursue those contracts, we will look at the information, and we will bring it to bear in the fashion that seems reasonable. I cannot sit here at this moment and tell you that we are going to wait for the date of those contracts to

come in before we go to rulemaking. Currently the rulemaking is scheduled for March of 1991. Again, that is not to say that could not change between now and then.

To sit here and tell you that the rule will definitely come to be in March of 1991 would be conjecture on my part. It is the current schedule, but I cannot be sure of that.

MR. SMITH: But you are saying --

MR. CAMPER: Let me just finish up, if I may. Perhaps Dr. Piccone could make a comment or two about the contract that was awarded recently that is about gathering additional information.

MS. PICCONE: A contract was awarded at the end of September, so it just started. It is a contract that will go on for about 12 months, so it will be completed in September of 1991. In general it is an information gathering exercise to gather information on existing quality assurance programs, voluntary and mandatory, and also to develop a survey that can be used for licensees to see what quality assurance programs they have in place now.

Do they have quality assurance programs, are they using one of these existing programs, is it voluntary or mandatory. You have a voluntary program and maybe it's mandatory in their institution -- to get that kind of information. Also, the contract was to analyze a survey

that NRC had started over the last year on essentially looking at where the state of the art was, so to speak, the age of the equipment and that kind of thing.

That contract which we refer to as the quality assurance contract is really an information gathering on what is in existence. It has -- they are gathering new information on what people want to do with the proposed, what suggestions to the proposed, just what they are doing now and in relationship to the organizations. They will be going out to many of the same organizations that we are meeting with and have been having some dialogue with.

MR. SMITH: Let me interject. By virtue of funding that study you are saying that you don't know what is out there now? You don't know what quality assurance, or else you would not have funded the study.

MR. CAMPER: That's not --

MR. SMITH: You say that data is coming in, but it's only funded until September. Not much data could come in at this point.

MR. CAMPER: I would make three points about this. Some of the remarks that I am hearing make the implication that we can't write a rule without these contracts. That is not the case.

MR. SMITH: I am asking why would you want to pursue this rule before you have your own data gathering

exercises completed.

MR. CAMPER: Let me emphasize the point I just made. The implication is that we can't go to rulemaking without these contracts, and that is not the case. It may well be for example that the data gathered with these contracts could come to play on a regulatory guide, for example, that would be developed to support a rule.

The second point that I would make is that this is not something that while some of these contracts have recently been implemented are currently in process. This process, by no stretch of the imagination, just got started. We are now about three and three and one-half years into this rulemaking process. There have been significant adjustments and changes along the way as we have looked at this rule. For example, the suggestions and recommendations by certain societies and the ACUMI that we go to a performance-based rule and that a pilot program be conducted as opposed to a proscriptive rule which is what we originally developed.

So, it is a process that has been ongoing for some time just as the additional information being gathered by the contracts will be ongoing for some time. By no means does it imply that we are not prepared to go to a rulemaking. We don't necessarily need the contract data to do that.

MR. SMITH: We know we don't have to have it. I am asking why would you want to go to the rulemaking process before your on studies are completed? I don't question that you can, I am asking why would you do it?

MR. TELFORD: The contract that Dr. Piccone described could be thought of as a characterization of the licensee population in total.

MR. CROCHE: Does the potential exist that your final rule may be changed on the basis of any of the studies that are currently underway? You are gathering this data, and I understand that you can go ahead with your final rulemaking process in the absence of these studies. But since they are out there and you are in the process of accumulating data as it comes in, is there any potential that you would look at the final rule or in the development of the final rule and make a change on the basis of these studies?

I think there would be a concern. You have something out there for comment not that, for at least from out standpoint or from our perception has been -- it is a lack of our understanding of how your process works -- that we have made comments and have seen those changes. Yet, with these contracts the potential might exist that it gets changed. You just have to deal with a perception or the concern here.

MR. TELFORD: These are ongoing studies. You could make the statements you just made about don't you really need this information.

MR. CROCHE: I didn't make that statement.

MR. TELFORD: Dr. Smith made it. You could make that statement any given year. NMSS is going to have ongoing studies to learn more about the problems that exist or the licensees or whatever. No, we don't need those studies to do this rule. It may be that those studies produce information that goes into a regulatory guide. It could be for this section of part 35 or some other section of part 35. It will be relevant someplace but not here, not necessarily to the 35.35.

I don't understand how you can read 35.35 and -- I mean, it's not that complicated.

MR. SMITH: It's very complicated and very complex.

MR. TELFORD: The 35.35?

MR. SMITH: I take the issue with --

MR. TELFORD: You mean the reporting requirements, 35.34.

MR. SMITH: Yes.

MR. TELFORD: That, I could go along with. So, no, we don't need these studies to do this rule.

MR. SMITH: What was the reason for the study.

MR. SUNTHARALINGAM: Is that another branch of NRC that deals with -- we are having some conflicting concerns.

MR. TELFORD: Yes, it is another office within NRC. The Office of Research is doing the regulation and is primarily responsible for the regulation -- that's me. I work there. Larry Camper here works in Nuclear Material Safety and Safeguards. It is that office that is doing these studies.

MR. SUNTHARALINGAM: Is there some coordination? Is this in anticipation of what the Commissioners might ask you? What we have in front of us was three years ago, and you people tried to put forward the rule. There was some concern as to the lack of background information or the lack of field testing and so on when it came for public comment, then essentially it was put back to you and said we are going to do some of these studies and come back with the rule.

As you said, there has been a timing problem in trying to get contracts out. We understood that -- and we may be wrong -- that you people were given the charge that you need some of this information also -- is that wrong?

MR. TELFORD: That's wrong.

MR. SUNTHARALINGAM: What initiated it?

MR. TELFORD: You said studies and that's an interesting word, but it's not these studies.

MR. SUNTHARALINGAM: There are three studies.

MR. TELFORD: It's the pilot program.

MR. SUNTHARALINGAM: Yes, initially the pilot program

MR. CAMPER: The primary adjustment from the 1987 timeframe was to go to a performance based rule which we have, and to conduct a pilot program which we have. The studies that we are doing -- the contracts that you are referring to are ancillary to that. These are studies that are being conducted by our division in an ongoing fashion.

For example, if one looks at the misadministration rule which has been in place for some time now, and some five, six, seven or eight years later we develop a study to look at human factors and out of that comes something that is profound, if the question is could that ultimately cause us to look at the misadministration rule and make some adjustments in it, of course.

Could it be just one more database that we look at and say there's nothing significant enough here to cause an amendment and go to a rulemaking process, if you will, the answer is yes. Those are ongoing studies, but those studies are not directly related to the requirements from the 1987 period. Those are two very specific things, and we have brought those back to bear now.

MR. DEYE: On the study that was appropriate to --

MR. TELFORD: Excuse me, Dr. Deye. Dr. Suntharalingam, you made a misstatement. You said what is before you that you have had since 1987 and that's not correct. What you have before you is published in January of this year. What was published in the fall of 1987 was the proposed rule that was a proscriptive rule.

About March of 1988 we took the proscriptive rule to the Commission. There were comments from the medical associations that a proscriptive rule was not desirable.

MR. SUNTHARALINGAM: I stand corrected. What I implied was this whole program in trying to establish a QA rule has been in existence since 1987 or 1986, when you first took your proposal to the Commissioners after some public hearing --the lack of background information and the lack of field testing, and therefore, you were asked to proceed on those. That was what I implied.

MR. TELFORD: Yes, indeed. We took the proposed rule in its performance based form to the Commission May of 1989. There was a lot of deliberation among the Commissioners and the staff got a directive in December of 1989 which said the things that you are alluding to, mainly have a field test of this proposed rule, do a pilot program, go meet with the agreement states, meet with the associations.

The rule was published in January of 1990, and in

the Federal Register we have solicited comments from everyone. We have solicited interactions, meetings with groups. I didn't get many of those. I got a lot of invitations to come talk about the rule to various meetings. I did that, but I didn't get any -- I got precious few letters that said we want to sit down and talk to you about this rule.

We took the initiative to send out the letters to you folks to say we are seriously interested in talking about this rule. We think we could really use your guidance at this point, and I think you would be surprised what we can do with it. That's the purpose of this meeting, it's the beginning of that dialogue that we are trying to initiate.

MR. SMITH: If you have funded studies to see what quality assurance programs are out there in the community, how they have been implemented, and what impact they have I assume you don't know that information right now if you have funded studies to find that out. If you do know it, why did you fund the studies.

MR. TELFORD: Excuse me, Dr. Smith, the studies are not a subject of this meeting.

MR. SMITH: We can't bring up the studies?

MR. TELFORD: Let's talk about that later. We are chewing up a lot of time about these studies. No, that's

not a true statement. In the January of 1989 we invited 18 licensees in to have a two day discussion with us, nine people per day. That was in January of 1989, before we took the proposed rule to the Commission and we discussed the rule and the guide.

Those folks told us look, we are already doing 90 percent of what is here. We have a very good idea of what licensees are doing. We just went through a pilot program with 70-odd volunteers representing virtually every kind of licensee, every kind of practice that exists, whether it's urban area or remotely rural, whether it's just nuclear medicine diagnostics or whether it's a large teaching hospital. Those folks were randomly selected without bias.

We have a very, very good idea of what licensees are doing. Let's just think of this study as additional information that part of the staff would like to have. It is not essential to what we are doing here.

MR. SMITH: There are some 12 or 1,300 facilities in this country practicing radiation therapy -- that's not even talking about nuclear medicine and diagnostics. Do you feel like you have adequately sampled those people and know what quality assurance programs they are using, how they have been implemented, and how effective they are?

MR. TELFORD: There is a more relevant question that we did ask. The question is, if you go out and

randomly select a sufficient size sample of licensees and ask them to try out the rule, can they do it. What is the impact to them? We have done that. That was the pilot program. We have those answers and that is sufficient.

MR. SMITH: As I stated in my comments, I hope you heard that the relevant question isn't whether or not what you are proposing can be implemented. The relevant question is, is it necessary? What evidence do you have that shows us that what you are proposing, in view of its enormous cost, is a necessary exercise?

MR. DEYE: As a carry on to that, which is a question that I was going to ask before and it's appropriate to even the agenda as you would narrow it down. I think this pilot study, the 72 institutions, was necessary by your own process and admission prior to the final rulemaking, at least by directive from the Commission they wanted to see a pilot study. That pilot study has been completed now, I think.

Can we see the results of that pilot study to help us see which things have already been -- there's no sense in reinventing the wheel -- if very important points have already been made by that group of institutions to you, then we can focus on those other areas that we perhaps think were not addressed in the pilot study. It does seem to me that the one particular study would be germane to any further

discussions either today or in the future about this QA program.

For example, a question that comes tc my mind when you were listing the institutions before, what fraction of those 72 when they submitted their QA programs to you were found to be acceptable with no significant change to their QA program within the light of the regulatory guide that you put forward in January, 1990? We would find that interesting. If it's a very low number or a very high number, it may tell us something about the field that we are unaware of also

Maybe there are things here that we, as professional organizations, need to know about the field. We don't have that database ourselves. I don't know that we have sampled the facilities out there to see what fraction have implemented any kind of QA program.

MR. TELFORD: Let me go back to Dr. Smith's question. Dr. Smith, you are basically questioning the need for the rule. You are alleging that it's a high cost. Would everybody want to spend your time talking about the need for the rule? I didn't envision putting that on the agenda today.

MR. SMITH: I think all of us have the very basic question about the rule, yes, because we know the incidents of reportable occurrences from our own experiences and data

are extremely low. We don't know what it is that you are trying to fix.

MR. CAMPER: The problem that we have, Dr. Smith -- if I may, John -- is this. We are really not here today in this forum to debate the efficacy of this rulemaking, okay? We appreciate your concerns, and this is not something that we haven't heard before in other places. The task that we have before us now as a staff is this; the Nuclear Regulatory Commission has thus far determined that it is concerned about quality assurance in the area of medicine that it regulates. It has charged the staff with developing a quality assurance rule.

Whether or not the efficacy and their logic is sound or not, is not something that we can debate. They have looked at the incidents of misadministration and the character of those misadministration. Albeit a small number, I would concur with, they have looked at them and said this is something that is troubling to us. We look over the areas that we regulate and ask ourselves as a Commission, do we emphasize quality assurance in this area to the extent that we do in other areas that the Commission regulates and what have you.

For a myriad of reasons they reached the decision that they wanted to pursue a quality assurance rulemaking. They directed the staff to do so. We really can't sit here

with you and debate the efficacy of the rule --

MR. SMITH: You don't know what you are fixing, and how can you --

MR. CAMPER: Let me just finish, if I may. If you accept the premise that we really cannot sit here and say to you yes, there should be a rulemaking or no, there should not be a rulemaking, realizing that authorities higher than us in the organization have made that determination thus far. Our task then, if you will, is to try to get as much information as we can to get through the process.

I think that the benefit of meeting with this particular group, given the backgrounds of this group and what have you is, if we go through these things to the extent possible on a line item basis I think that there's a lot of comments that you can make of a specific technical nature that would be helpful in the process. But if we are going to continue to debate the efficacy of the rule, I think we are going to find that we are just going to be bogged down. We are just going to sit here and -- we can't tell you that no, there shouldn't be a rulemaking or yes, there should be a rulemaking. That's not our job to do that. Unfortunately we just can't do that.

What we can try to do though is interact with you to the greatest extent possible to get as much input as possible. Preferably, based on my experience with the pilot

programs and through talking with other physicists and what have you and other physicians in the pilot program workshops, we have gotten a lot of very constructive comments, particularly in the area of teletherapy and brachytherapy that we are listening to.

I can tell you also that there are a number of us in the staff that are dealing with this issue that are concerned about the definition of misadministration; that are concerned about whether or not the thresholds they currently exist in the regulations or as proposed in Part 35 are appropriate. So, I would just simply emphasize that, to the extent possible, rather than debate the efficacy of the rule getting as much input of a specific nature would be beneficial to us.

MR. PAYNE: I would like to make a comment which does address the situation. As a practicing medical physicist, I have the extreme pleasure and fortune of being not only the practicing medical physicist but I'm in a private institution, so I am also the radiation safety officer. That concerns me.

I would like to follow up your statements. I agree to the extent that the current regulation is unyielding. It is difficult to work with. So, from the standpoint of the position that the current -- the regulation that we currently live with and currently work with -- I have had a

number of instances where it's interesting -- do we have a misadministration or do we not. You, the Nuclear Regulatory Commission, has been equally caught up in that dilemma.

From that position I advocate that we need to go forward, because where we are now is not tenable. I guess I would defer. I appreciate the de minimis situation and all of that, in other words, do we really need it. I would say yes, we need it and not from the standpoint of debating the numbers, the fractions, the one per 10,000 and the one per whatever -- but because our current regulations is not currently sufficient. I think from that standpoint, I would advocate that we will be -- we have to move forward.

On the other hand, I would like to point out that the problems we all face in -- the prescription now in brachytherapy, in teletherapy is changing. We are moving more and more away from a simple prescriptions, the physicians are and we are physicists in working with the physicians. Simple prescriptions are changing. We are doing three dimensional treatment planning. We are no longer talking about point doses. We are not even talking about line doses. We are talking about more complicated things, dose volume histograms and various things.

There is where I really see some problems. I really appreciate clear prescriptions, clear instructions, following written instructions. That, I think all of us

condone and want to work with. On the other side as you indicated, the part where the deviation from the prescription and especially when it's linked to dose on daily basis and on total, that gets us into trouble. We could write a rule today, but as the practice in radiation therapy changes over the next three to five to ten years, we may not be able to live with what we put out today.

MR. BOGARDUS: Let me make a comment, as a practicing radiation oncologist. I have gone through the proposed 35.35, and I understand where we are. What we have now, 33 and 34, have a lot of problems. Many of us are basically ignoring it, simply because it's easier to do that than to try to figure out what we are supposed to do. That needs change.

The other thing is, it is obvious from your standpoint that you have no choice. You have been told, thou shalt write 35.35, and that we are going to help you in some fashion. With those as given, and having looked at your 35.35 as you have it here, I fully agree with 90 percent of this -- we are doing it anyhow. All we are arguing over are a few basic numbers and definitions. I would agree that, why don't we get on with it, look at the things that we can tell you that yes, this is God, Mother and the Flag, and we agree with that. When we hit a snag, then let's argue on the snag.

MR. BRICKNER: Let's start out with the definition. If you have the opportunity to come back and look at that damn word again, why don't you save that word for pulling the wrong isotope out of the safe or treating the wrong end of the body. Only the grossest would be called misadministration. The rest of them leave, as you use the sentence in here, variation from the prescribed dose or variation from the prescription.

Variation from the prescription is something that I can discuss with the patient, explain and tell him it wasn't intentional, tell them whether it did or didn't hurt them. But misadministration, usually they send their lawyer in ahead of the. Those are real life problems, and I would suggest to you consider saving misadministration for the gross things, when you use the wrong isotope or the wrong size sources, something really crude where it was pretty well implied sloughfulness on your procedure and leave variations as variations.

With that, I agree with Dr. Bogardus, that with the codicil that I don't necessarily condone a whole lot of the things that we have spent an hour ventilating about. Let's get it on.

MR. TELFORD: Does anyone --

MR. SMITH: Is it possible for you to disassociate completely the misadministration in the statement of

numbers. Like I mentioned earlier that every patient we treat, by virtue of the physical nature of our calculations, has a misadministration by your definition. That is extremely problematic that you have attached numbers to the word misadministration.

MR. BRICKNER: For instance, some of the definitions are any therapeutic use without a prescription, use of a wrong isotope, unauthorized use, for instance using a isotope for a procedure which they have said is not authorized for it. Those are misadministration.

The minute it gets to dose and numbers, let's talk about variations. That is a suggestion to you, and I can't say if that's the way it ought to be. I can say it would be more comfortable with me to live with and it would not remove from you any of the things that you are attempting to do.

MR. SUNTHARALINGAM: May I make a request again, and obviously the decision is in your hands. One is again to say where time and rehashing of certain things -- if we are to identify problem areas, it would be helpful but, again, that is a decision you have to make. Can you at least summarize for us the findings of the field test study, the possible aspects of problem areas, and we may be able to give some input into those.

Secondly, I think it might be -- after we take a

break -- appropriate to address at least for a short time, the concept of misadministration. I think we have asked for public comment on do we want to continue to use the word misadministration, is misadministration adequately defined, or do we want to take the time and talk about -- that's correct in what is already existing. We live with it, we made comments, and sure the regulatory agencies can listen to everything that people have to say and put something down as a rule.

We know now from the past experience -- it may be worth a little time spent in addressing this whole concept of the use of the term misadministration and, secondly, it's clinical implications.

MR. FLYNN: I want to second what someone said, especially since it is a small handful of organizations nationally involved with radiation oncology. We are used to critically examining each other's pilot studies in cancer treatment. If we were to be able to see -- since this pilot study has been completed -- if we were able to look at that, using our expertise, we may be able to point out it may be 95 percent great and five percent pitfalls to the possible misinterpretations of the results of the pilot study.

If we looked at that, we could make helpful comments to avoid those pitfalls if you misinterpret data and misinterpret the answers to certain questions in the

pilot study.

MR. SUNTHARALINGAM: Some of us obviously have concern that we don't know what is going on. You have emphasized that it is a volunteer program. My understanding of what you are saying is volunteer and they were not paid to participate, but they were still selected. I mean, it was not put out for public proposals for anybody who was interested in participating on a volunteer fashion on this pilot study. Correct me if I am wrong.

MR. TELFORD: Yes, it was.

MR. SUNTHARALINGAM: It was?

MR. TELFORD: Two statements. There was a notice in the Federal Register that if you wanted to be a volunteer, give us a call. Nobody called.

MR. DEYE: I never saw it in the Federal Register because I don't read the Federal Register every day. I would have been very happy to volunteer, but I never saw any notice asking me.

MR. TELFORD: There is an inherent problem with that approach. We were going to take anybody that wanted to volunteer. The problem with that approach is that everybody with a good program, those folks might volunteer. Those folks in the middle of South Dakota that you would really like to know about, they are not going to volunteer. So, if you stratify your population and randomly sample a subset

from those strata, now you are going to get folks from the middle of South Dakota which we did.

You make some good points, Dr. Flynn, about the responses that we got during the post-trial period workshops about the answers to these questions. We have some of those questions that we wanted to work into the discussion today. We didn't really want to present it to you as the results from the study. I mean, each of these post-trial period workshops was a two day affair.

One transcript from one meeting is two volumes about two inches of paper, so we are talking about ten inches of paper. It just turns out that these folks were there and heard all the answers.

MR. SMITH: Do you have summaries of that?

MR. TELFORD: No.

MR. SMITH: Could we have --

MR. TELFORD: No, we don't have summaries of those. We have the transcripts. We are trying to work with the knowledge of those things. The answers that we are suspicious about, we wanted to ask you about those beginning today because we view you as the national experts.

MR. DEYE: Can you give us a list of those questions? You wanted to ask them.

MR. CAMPER: What we plan to do, Dr. Deye is, as we went through this thing line item by line item, we intend

to interject in the appropriate places for example, under the brachytherapy or teletherapy. Some of these issues deal with things that came out regarding the regulatory guide, some pertain specific to the definition of misadministration in those areas.

Our experience thus far has been that if we follow this format and address these things item by item, it is much more beneficial. We do have some questions, about two pages of them in fact, that we wanted to toss out as we go through these various line items to get your feedback.

MR. BRICKNER: Let's get on.

MR. TELFORD: Should we take a break of ten minutes.

[Brief recess.]

MR. CAMPER: Before we proceed, I want to make one additional clarifying remark about something that I was saying earlier about the Commission's interest in the quality assurance area for medicine. I want to be clear that, just as we as staff cannot debate the rationale or efficacy of this rulemaking.

Please understand that the Commission in itself does not operate in a vacuum either. The Commission, as you all know, has a legislative mandate. There is something called abnormal occurrence reports which go to Congress. Misadministration are contained within those. The

Commission sees misadministration, particularly therapeutic and looked at its legislative mandate, and expresses a concern. The concern then takes many different courses.

I want to be certain that for the record I indicate that the Commission doesn't desire to particularly be overly burdensome on the practice of medicine either. But it, too, has its requirements and must deal with those.

MR. TELFORD: Can we move to the third item on the agenda, which has been labeled a roundtable discussion of the proposed rule, Section 35.35. In the handout as part of the agenda here on page two, I just want to say to you that there's four pages. The next four pages you may find to be relevant.

There is the purpose, and then the pages three and four are the proposed objectives. Page five is what is called audit and evaluation requirements. What I want to do is go through those. You may have a package like this that has a copy of the Federal Register notice as well as the regulatory guide. If you don't have one of these and would like one for the purpose of our discussion, just raise your hand and we will get you one of these.

The reason you may need this is that these are the exact words that we put in the Federal Register. For example, page 1449 of the Register Notice you will find 35.35. Look at the exact words. Let's turn to page two of

the handout which is the purpose of proposed 35.35. The stated purpose here is basically the opening paragraph, the first paragraph of the proposed QA rule.

We are missing Dr. Smith, and he was asking about this. The purpose of this is to prevent errors in the application of byproduct material. What the first paragraph says is to each licensee, you shall have a QA program. It will be designed to prevent, detect and correct the cause of errors. The objective of your whole program will be to prevent errors.

MR. FLYNN: I guess the problem that I have with that is that you said the word prevent. I would use the word minimize, because it implies that the errors that are being committed should have never occurred; that there is no possibility for any human error whatsoever, and I think that would be wrong.

It would be like the Department of Transportation saying we have a new highway policy and we are going to prevent all auto accidents and all auto deaths. If an error should occur, it should have been prevented. I think if you minimize errors and also detect and then correct the cause, you are minimizing it. You can't eliminate all errors. You are taking away the human element part of this process all together and that's impossible.

MR. TELFORD: Okay, let's talk about that. You

say minimize -- that's an appealing idea.

MR. FLYNN: It doesn't mean that you find them acceptable. It just means that you minimize them.

MR. TELFORD: When do you stop? How low is low enough? Prevention, I understand. Prevention says try not to let them happen and when they do happen, detect what went wrong, figure out what it is and put in a fix. Minimize is a completely different concept.

MR. FLYNN: Right.

MR. TELFORD: I don't disagree with it, but would you agree that if we say minimize we would need to declare a stopping point?

MR. SUNTHARALINGAM: Aren't there studies out on the disciplines as to what is typical human error rates in some procedures that are carried out by individuals on a routine basis? Obviously, when one is trying to minimize it, one wants to achieve at least that level as far as being documented. There is no documenting human behavior patterns and human error rates, something that someone does on a routine basis. One percent of your activities, two percent of what you do, there are some numbers like that floating around.

Obviously when we say we want to minimize, we want to first minimize it down to this level.

MR. PAYNE: Let me throw in an outside example

that came to my mind, and that is fire prevention. We generally talk about fire prevention. We don't talk about fire minimization. I can live with this. I can live with the word prevent. I recognize our concerns. But in my fire prevention, I guess thinking of that, I can handle it.

I don't know what other word to use. We had a problem with an earlier report that we dealt with in the physics community where a physicist will guarantee that the prescription is followed, and I had real trouble with the word guaranteeing that we follow the prescription. I cannot guarantee but I can develop programs to prevent a situation where the prescription is not filled.

What happens is that it will be violated and we know it will be. There will be a situation, and now I guess the consequence is does that person lose his job or do I lose my job. Those are hard line places. Maybe I should get in a different business, I don't know. Those are the hardliners.

MR. TELFORD: We were trying to allude to some sort of a concept of humanization by saying that your program should be designed to provide high confidence that errors would be prevented. We realize that if we said minimize, that we would need to declare how low low enough is.

MR. FLYNN: The goal should be the requirement,

and the requirement is to prevent. But then, you are saying that if an error is committed it should have never been committed because the error is so --

MR. DEYE: Could I suggest that in the concept of QA there is a contradiction here. If you go and study the literature on quality assurance. The concept of preventing all events is not a valid, logical relationship concept of quality assurance. If you study the literature of the JCHO, they did not come to the hospital and say they are going to prevent all occurrences of all types.

When we set up monitors for JCHO, we are encouraged to set up only those monitors that reap significant results. If a monitor shows over a period of time that it does not have a high enough incidence of significant results, you are strongly encouraged to drop that monitor and move forward with your QA program or you are, in fact, wasting your time.

So, to put together in the same sentence the word quality assurance with total prevention of errors is illogical relationship of words. I get back to the concept of minimization and you say what about standards. It was offered that, in fact, standards are suggested in the field for various error types and that one could build that into the program. The concept of total prevention is a contradiction.

MR. TELFORD: Dr. Deye, may I direct your attention to the second sentence under 35.35 A. The second sentence says the objective of the basic quality assurance program is to provide high confidence that errors in medical use will be prevented.

MR. DEYE: Will be minimized.

MR. TELFORD: Wait a minute. To provide high confidence -- you are trying to say this is an absolute --

MR. DEYE: It will be viewed as an absolute by your inspectors. We can't take what you are doing here out of the context in which it is going to be used.

MR. TELFORD: But there --

MR. DEYE: Let me finish, please. An example is that an institution that I know of that was inspected within the past month was cited because out of three years worth of records there were three records where an individual had not signed the record, and they were cited. I consider that unreasonable. In the context of enforcement maybe it's not.

In the context of quality assurance it certainly is unreasonable. We can't forget what we are doing here today is in the context of regulations to be enforced by inspectors in the field, and to use words like prevent instead of minimize only invites significant problems for the user.

MR. TELFORD: You bring up an interesting point

about a regulation being enforceable and inspectable. That's why Dr. Piccone and Mr. Kline are here. They are experienced inspectors, and they are also part of the QA team. They are intimately familiar with the licenseability and enforceability and inspectability of regulations.

We do have to assume that we can carry through the intentions of the words we write. I don't think we ought to be writing words -- that we don't use words because we suspect that the inspectors won't do the right thing. I think we have to write words that we can carry through the intentions all the way to the inspectors and be assured that the inspectors will carry on with the same intentions that we have here.

MR. DEYE: I would still come back to my first point which is a strong suggestion that if you read the literature on quality assurance which is the title phrase of this whole rule and discussion, that it is not in congruence with the word prevent. The word prevent should in fact be changed to a concept of minimize.

MR. BRICKNER: The purpose of quality assurance is to detect problems, correct them, and document the treatment and correct it. The quality assurance may provide you with a high confidence but the program of quality assurance is to detect, correct and verify.

MR. TELFORD: Or, to make sure that it's done

correct the first time.

MR. BRICKNER: It is to identify problems, correct the problems, and verify the problems that have been corrected. That's the purpose of quality assurance.

MR. DEYE: Not to prevent every mistake. No QA program written has as its goal to prevent every mistake. The writers, bearing any other QA expert that you want to look at, recognizes that mistakes will occur. I am only suggesting that you have a logical juxtaposition here which is illogical, or a written juxtaposition that is illogical.

MR. TELFORD: I am trying to agree with your point, that I am not after zero. Zero defects is impossible. I am not trying to say that we should have zero defects. Mistakes happen now and then. What sentence are you focusing on?

MR. DEYE: On both sentences that have the word prevent. I think Dr. Flynn is the one who raised this point, and I think it's an astute observation on his part that the word prevent should be changed to minimize.

MR. BOGARDUS: What about your own term of NRC of ALARA, because that's what we are really aiming for, to get these down as low as reasonably achievable.

MR. FLYNN: You use prevent in part one and you use ALARA in part two, would that be clear and also satisfy your goal?

MR. TELFORD: In the first sentence if we use minimize --

MR. FLYNN: No, don't use minimize. Just take prevent out and leave detect and correct. And then, if you want to use the word ALARA in part two, to provide high confidence that errors in medical use will be ALARA.

MR. TELFORD: Will be minimized?

MR. FLYNN: As is reasonably achievable.

MR. TELFORD: I don't know -- that's an open ended --

MR. FLYNN: Okay, minimize.

MR. TELFORD: It's the same problem that we faced before. How low do we go? We can talk about published studies, but then you have to ask the question are those studies relevant to what we are doing here? What studies are? I mean, is it blood bank studies, is it -- we have been told by several organizations that the rate of mistakes in terms of administering ordinary radiopharmaceuticals is somewhere between ten and 20 percent.

Is an error rate of ten or 20 percent for a teletherapy, is that an acceptable rate? Is that low enough?

MR. SMITH: A ratio of 14 percent in some cases I question whether you can even talk about ten or 15. I think I point out in my public letter to you that the calibration

of some radioisotopes is uncertain to 14 percent to start out with.

MR. TELFORD: Forget about the threshold for a bit, about what is and what is not a misadministration. Just say that there's an acceptable misadministration, an acceptable definition exists. Assume that for a moment.

MR. DEYE: Say one percent you throw in a factor of ten which is, in may safety circles, considered a reasonable number to throw in. You go with a one percent acceptable rate. By acceptable you don't mean that the individual occurrence was acceptable. What you mean is not indicative of a bad program; that a program of which a one percent rate is occurring is not de facto prima facie a bad QA program. Maybe it needs further study, maybe other factors should be looked at.

In and of itself that one percent misadministration rate or error rate -- whatever term one chooses - is not prima facie evidence that the program is ineffective.

MR. TELFORD: Agree, but the Commission, in its safety goal, has used one-tenth of a percent for being -- that's how low you need to go for power reactors, for the cause of death due to reactors, it would be one-tenth of a percent of all the causes. Appearance of cancers, ten percent due to the reactor versus all over causes.

If we wanted to go for a --

MR. SUNTHARALINGAM: Let me make a comment. I think I will be forced to put in a quantitative figure where I don't think we can stand by and justify whatever quantity of figure that we might put in there. As soon as you start putting in one percent of one-tenth of a percent -- I am sure there is literature pertaining to human errors of people who do repeated procedures in an eight hour working day. We say we want to minimize that to zero but what we may be facing is that you are working a four hour day. What be raising another concern about if you want to minimize down and bring this number to a zero level, that people are doing these routine procedures should not be putting in an eight hour of work.

Whether they do eight hours of work they are bound to have rating over the year come out with certain errors in what they do. I am sure the intent of this whole program is obviously to keep it as low as possible and minimize it. I think it may be, again, a legal terminology, the difference in minimizing something and preventing something.

MR. TELFORD: You just stated your objection to using one-tenth of a percent. You see, that's why we didn't use minimize in the beginning. It's an appealing idea, but it requires some quantification. You can't get people to agree with how low should you go. Then you get accused of

being arbitrary of having chosen a number.

You are alluding to the fact that these mistakes are human errors.

MR. SUNTHARALINGAM: As we gave you the example in three years of signing documents, just because one of your licensee's didn't sign on three lines in those three years, they were cited for noncompliance. To me, that again in a three year activity, three separate line items is a very small fraction. What we are saying is that because you say prevented, you should have signed every line, is what it comes down.

MR. SMITH: We all agree that errors cannot be prevented, all errors. How can you say that you will have a high confidence that they will not be prevented. We all agree that it is impossible. There is some contradiction in the statement itself. You can't have a high confidence of something not happening, which is impossible to stop from happening. Do you see my point here?

MR. TELFORD: No, I don't.

MR. SMITH: There is an inherent contradiction that you have a high confidence in doing something which is impossible.

MR. BRICKNER: It doesn't say 100 percent of confidence.

MR. TELFORD: It doesn't say absolute.

MR. SMITH: But the thing is, we cannot prevent errors. So, how can you have a high confidence that they will be prevented.

MR. TELFORD: The operative sentence in the Register notice is that the objective of the basic quality assurance program is to provide high confidence that errors, as in medical use, will be prevented. Instead of saying they will be prevented which is an absolute statement in which Dr. Brickner points out, would be saying that you have to prevent all of them -- rather than saying that, it says provide high confidence that -- meaning that it acknowledges the fact that there is some small number that will occur. There is no logical disconnect in this whole statement.

MR. SMITH: I have no confidence that you can prevent errors, none whatsoever. Zero confidence that you can prevent errors.

MR. TELFORD: I am sure that you have confidence that you can prevent some of them.

MR. SMITH: But you can't prevent them from happening.

MR. TELFORD: You can't prevent all of them from happening.

MR. SMITH: So, there is zero confidence of errors. You can minimize them but you cannot prevent them. It's impossible.

MR. FLYNN: Does the NRC still use the concept of ALARA? Maybe I am behind the times.

MR. TELFORD: Yes, it does.

MR. FLYNN: You would object in paragraph one that prevent be crossed out -- not put in minimize, but just prevent be taken out. In paragraph two, instead of the word prevented you put ALARA there if it's a concept that you are using and it's in force.

MR. TELFORD: I don't know how low to go here. It is the same idea as minimize.

MR. DEYE: But you didn't know how low to go with ALARA either, and you allowed the institutions to help you define that either individually in their proposal to you of their QA program. For example, here, you may accept or reject their number. I may write that I am only willing to go to ten percent and you write back and say sorry, I'm not going to license you at that level. Try again, your program ought to be able to do better than that.

Maybe I write in one percent and you know that's what 90 percent of the institutions in the country have told you they can achieve, and you say you are agreeing with 90 percent of the other licensees that wrote in and we might accept you on that. The other beauty of that technique is, it allows it to develop with the field. Prevent doesn't develop with our abilities in the field, be they record and

verify systems or other technology that comes on line. Prevent is prevent.

Minimize takes into account development of technologies in the field, and I think you can ratchet that number if you so choose over time.

MR. TELFORD: The thing that we haven't gotten to yet is the fact that there's an annual review. The annual review allows, as Dr. Brickner points out, the ability to look at what went wrong if anything went wrong, to make corrections and to move on. If you have as the objective to either minimize or to prevent,then you know what to do when you get to the review step.

The only thing that I am hesitant about ALARA is that it does leave open the possibility for ratcheting. I mean --

MR. DEYE: That's true, but I think the ratcheting only works to your favor here because it would probably be downward. Let me give you another example of this, again, because of our QA program that we have through JCHO.

We monitor our port films, okay, on a weekly and monthly basis and keep statistics on that as one of our QA monitors. We do not set out with the intention of preventing every incorrect port film. Since we don't set out with that intention, we look at the port films in aggregate on a monthly QA basis and look at the statistics so that we get

positive feedback to our technologists and other people in the department who do that work.

If they knew that we wanted to prevent every incorrect port film, they would personally be much more reticent to bring to our attention any single mistake. If they know that we are only looking in that data in aggregate, they realize it's a statistical QA program that is trying to have a positive feedback loop to the system and they are much more willing to bring that data to our attention, be it on port film or any other report of the treatment machine where they made a mistake.

If they know we are out to prevent every mistake, then every mistake by definition is culpable, and every individual who produced that mistake is culpable and they are not going to bring it to our attention. So, we don't take that approach.

MR. TELFORD: I can agree with your statement, but it seems to me that it applies to each objective or how the QA program is designed to meet objectives down to the details. We are talking in broad scope here.

MR. DEYE: No, this is broad terms. Broad terms, our QA program is set out to minimize errors within our department as it exists today, aside from your program here. We don't set out to prevent all mistakes, so we are back to this point.

MR. TELFORD: We don't expect that all mistakes will be prevented. We don't expect that. I do expect that each program will be designed to prevent the mistakes, that's true. But I don't want each one to be culpable. Let's say we could use minimize or ALARA --

MR. FLYNN: ALARA.

MR. TELFORD: You are going to change your letter now, right?

MR. FLYNN: ALARA, especially since you guys created the concept.

MR. TELFORD: Do we --

MR. BRICKNER: You define ALARA and technology defines ALARA. Capability, if you find at the end of the year or two that there's no way that you are going to get below two percent, two percent may be what ALARA is.

MR. SUNTHARALINGAM: Another fundamental problem -- the more and more we read into this, I think there are specific processes of a QA program. Quality assurance, as most of us know in how we practice, is to maintain a certain standard of practice. This program, it seems to me, to be essentially a program to detect errors. There is a difference.

There is a big difference in what we have been promoting and writing. Those are QA programs to maintain a certain standard of practice. Here we are talking about

prevention and minimizing, but I have yet to find a definition of an error. We say provide high confidence that errors -- somebody define for me what is an error.

MR. KLINE: Let me make a comment on that regarding Dr. Deye's comment on quality assurance. I think we are getting into the definition of what is quality assurance and what is quality, and I don't think anybody in here is the expert level that you discussed -- Demming and his various offspring and theory. Currently there are about five major groups in the U.S. that teach quality. All these are based on the original theory or the concept behind Demming, and Demming has books and publications and has turned into a very big science in itself. It has turned into quite a thing with industry, and now in the medical practice is pushing and feels that it is very good.

The premise behind quality though is that based on Demming's philosophies, is the prevention of or zero defects concept -- non-conformances and non-compliances to -- in other words, not to set a level but to constantly work toward that goal of getting it to zero, work towards it. IT is the concept that we are looking at here, not so much the actual number.

To say minimize, you put a threshold level on it which is very hard to detect or very hard sometimes even to measure. I think the intent of what you might want to focus

on here is the objective -- not so much what is the definition of quality assurance and which group has said that this is how you define quality assurance.

We realize that nobody here is the exact -- is the authority in the field on quality assurance. If we were, then we would have probably a program that might be more workable or possibly better written. The intent is to follow that concept.

In regard to this objective, if you were to put in any other word but prevent, I don't know how it could be achieved. I don't know how you can --

MR. DEYE: Demming recognizes that there is a diminishing return, there is a point of diminishing return in any quality improvement program. He believes that it is futile and totally cost-ineffective and, in fact, countermands good quality for finite resources pursuing beyond this tail on the curve.

MR. KLINE: The objective is to prevent. The objective. This is true. As you monitor and as you track, graph or whatever, you start to realize that we cannot prevent this occurrence rate. We cannot get it any lower than it is. We need to put our resources somewhere else that are more significant. We need to improve this other area which we have yet to investigate and we think we have a high incidence of errors.

He never says that --

MR. DEYE: Isn't that built in there --

MR. TELFORD: Yes.

MR. DEYE: -- where I can make that decision and say that --

MR. TELFORD: That's why it's a performance-based regulation. That's why it has a reviewer audit requirement every year.

MR. DEYE: I'm sorry, but I don't see where the word prevent gives me the option to quit studying particular monitors and deciding to move onto a different monitor because that monitor -- maybe there were still some errors in that area.

MR. TELFORD: It's the difference between the forest and the tree. Right now we are talking about the entire forest. You are focusing on the tree. That's okay. We haven't gotten to that point yet. The individual types of problems that you may have in your hospital may be different from some other hospital.

MR. DEYE: I am discussing generalities. I am using my hospital, but I know that it exists across the whole field in the United States. That's one of the reasons you have us around the table. Ed brought up an interesting point about the QA expertise. If the rule is going to be called quality assurance, then I would like to strongly

suggest that the NRC get a consult from the true quality assurance expert in the phraseology and the objectivity, the direction of this thing and what its objectives are.

You are asking us to help you put words in here. We have certain strong feelings about it, and as you say, none of us are experts. Believe me, it changes the whole meaning of this QA rule which words you put in here. Otherwise, none of us would be wasting this time, I guess, over minimize versus prevent. We all understand the significance, so maybe we ought to all agree that you should employ a consultant who is truly expert, and Demming happens to live in Washington, D. C.

It might be an interesting thing to run this QA rule by him and see if it fits into the concept of QA. If it doesn't, then let's not call it QA. As Dr. Suntharalingam says, it's error detection program which would be maybe more correct.

MR. TELFORD: It just so happens that a fellow of a lot less widely known reputation works in my division whose job is quality assurance, and I have shown him this rule. He said this is just standard stuff. You are following the same gospel that everybody else tries to follow in quality assurance.

However, there is this difference between the quality assurance that you normally think of as you would

need for JCHO accreditation versus the quality assurance we are after here. This is not all about the quality assurance of your entire department but rather the safe handling and use of the byproduct material. After the prescription or written directive is written, does it get administered correctly. That is what this is about. It's not about all those other things about --

MR. DEYE: In those areas where there is overlap between JCHO and the NRC, would you agree that you have the same objectives with the JCHO?

MR. TELFORD: We are going to be meeting with JCHO next month to find out the answers to those questions.

MR. SMITH: If the objective is to prevent, I think that's laudable and there really should be objectives whether they are realizable or not we tend to accept that concept. Wouldn't that also say that the reporting should not be just a reporting of the occurrence but a reporting of the corrective action, because without corrective action there is no impact on prevention?

MR. TELFORD: We have that in the proposed reporting requirements. We have that. We even have two different levels of reporting. We have reporting within the department just to get to the idea that Dr. Deye is talking about so that everybody doesn't get prosecuted for relatively small mistakes.

MR. SMITH: The concept that I am trying to get at is, any quality assurance program is a corrective action, because unless the corrective action is a focus of the whole quality assurance program.

MR. BRICKNER: What do you say if we go through the other three pages and come back and see if this prevention still bothers you.

MR. TELFORD: Don't get my wrong here, I am perfectly willing to entertain the idea of ALARA or minimize. But then, I think that carries along with it a responsibility to say how low that low enough is.

MR. DEYE: JCHO has you define your standard when you set up your minimization program. You would want to review that standard that I defined for my program and hold me to that. I fully understand that, and I think it's doable.

MR. BRICKNER: Let's carry on.

MR. SUNTHARALINGAM: I still haven't heard NRC's definition of concept of what constitutes an error.

MR. TELFORD: We are going to get to that.

MR. SUNTHARALINGAM: Before we leave this page it is critical -- it is part of 35.35. It says provide high confidence that errors -- give me some example of this definition of what is considered error.

MR. DEYE: Actually, error is not defined in the

definitions. I think that's a good point.

MR. TELFORD: About five pages in, the page labeled requirements. The page you were looking at said that we want to prevent errors in medical use. Medical use is a defined term of art in 35.2 currently. It just says it means the application of byproduct material or radiation therefrom from diagnostic and therapeutic studies. In other words, we are talking about patients, we are not talking about research.

A mistake, an error,currently defined as one of these six mistakes but these are all misadministration. In the proposed rule we have two levels of errors; one which we call an event and two, which we call a misadministration.

MR. SUNTHARALINGAM: I am just asking for a clarification. You are telling me that an error of this magnitude means either one of those two. That's all I want to understand for our next level of discussion. An error has not been defined, and you tell me that is what in your concept is what it is.

MR. DEYE: I am a little confused by that answer. Correct me if I am wrong, but having discussed with at least one person who participated in your pilot program the requirements that they were asked to meet, I would assume that they had to use your definition of error. Yet, I was told that they were not required to use either the new

proposed definition of misadministration nor the new definition of therapy event in their analysis and field testing of the QA program.

How can they be testing whether or not their QA program provides a high confidence that errors in medical use will be prevented if their definition of error doesn't include the definition you just gave me. They were not asked to define error as being therapy event or the new definition of misadministration.

MR. TELFORD: Their purpose was not to test 35.33 or 35.34 which is the reporting requirements. Their purpose was to try out 35.35 which is the QA rule.

MR. DEYE: You are telling us right now that the definition of error in 35.35 includes the concept of therapy event, for example. Yet, the people that were field testing it weren't asked to use that.

MR. TELFORD: They didn't need to. Why should they need to?

MR. DEYE: Am I the only one confused by that?

MR. SMITH: If they were testing the quality assurance program and did not have the instruction to exercise your definition of misadministration or incident, how did they do the testing?

MR. TELFORD: Testing what?

MR. DEYE: Testing your QA program. They were

field testing the proposed QA --

MR. TELFORD: The 35.35.

MR. DEYE: Right.

MR. SUNTHARALINGAM: In that process, were they asked to develop or write down that there were any errors or misadministration?

MR. TELFORD: They were asked in the questionnaire, they were asked to give examples of mistakes that they detected or experienced during this pilot test, yes.

MR. DEYE: And yet, their mistake wouldn't have to include the definition of a therapy event.

MR. TELFORD: Their mistakes or errors that they detected could be a misadministration or it could have been a whole lot less. It could have been just one person didn't properly identify a patient but the next person caught it. Is there something missing there?

MR. DEYE: If you came to me and I participated in a program, and you asked me to field test this 35.35 and basically I think what I am doing if I am field testing it is trying to keep a catalogue for you of how many times my QA program detects errors and what types of errors it detects.

Then, I would also want from you a definition of errors and if you had given me a definition that included

the concept of therapy event, there would be a ten-fold difference in my reporting rate to you -- just to pick a number out of the air but it's one I have thought about somewhat -- a ten-fold frequency of my reports to you whether I included your definition of therapy event or I didn't include your definition of therapy event in the definition of the word error.

It seems to me that the results I gave you back at the end of that six months period of time would be very different, depending upon whether I was asked to use therapy event as part of my definition of the word error or was not asked or required to use therapy event as part of my definition of the word in my field testing of 35.35.

MR. TELFORD: That is the number of responses that you would have written --

MR. DEYE: I think it would play back into your assessment of the adequacy of my QA program, and the adequacy of the rule and how much effort it was for me. If it's a ten-fold difference in effort on my part to report then --

MR. TELFORD: You are commenting on proposed 35.33 and 35.34.

MR. DEYE: Yes, 35.35 I think I am commenting on.

MR. TELFORD: The reporting events are all in 33 and 34.

MR. DEYE: You can't totally separate these. If we are trying to define the word error, I am just using this as an example of why the definition of the word error is appropriate. Sooner or later we have to do something with the word error. Probably we are going to have to report. It's probably not worth belaboring. I think the definition of the word error needs to be more succinct, and I am not sure that the way you have defined it is the way it was defined to the trial study of 35.35.

I do not believe that 72 institutions had the word error defined to them as being either the new expanded definition of misadministration or the new definition of therapy event.

MR. KLINE: Let me elaborate on that. You bring up a key point and it's important that you do disseminate and separate out what is considered a misadministration and what is not, what is a smaller problem. When we were in the field looking at the various groups and asking them these sort of questions and asking them to set up a program for 35.35, follow an equivalent program, regarding misadministration they were asked did you have any misadministration. That is pretty much based on current misadministration rules.

If they wanted to incorporate the proposed new misadministration rules they have the liberty to do that.

We did not I believe, want to impose a large number of requirements, we wanted to focus only on performance of 35.35, the testing of that rule and not have them bothered or to have they confused by more misadministration as part of that quality assurance program though they are integrated.

In essence, when people were asked did you have a misadministration, they were typically responding to the current Part 35 misadministration reporting or misadministration definition. In a practical sense people reported on any errors, any problems they detected. They didn't look at what is the definition of an error. To most of the facilities an error was that we put down the wrong field size.

MR. DEYE: That was my question. An error in the context of the field test had a different or broader definition.

MR. KLINE: That's correct.

MR. DEYE: Than what was just described.

MR. CAMPER: That's a good point. Clearly, if you look at the objectives alone, if you want to go through there and identify a number of errors, you are absolutely right. The question really asks for begging then is, when we look at errors what I think happens is that there are errors that are operational in nature if you will, and there

are errors which we view under the category of misadministration. What we need to do is go back and take this signal that you are sending and make sure that the term error is as identified and clarified as possible.

You make a good point.

MR. SUNTHARALINGAM: Before, if there is an intent to leave this page, I would like to the item that says note. Since I didn't get satisfactory response early this morning, I want to take a statement that is written in the comments from the College of Medical physics out of that statement and now put it for discussion here and get a response from the NRC staff.

One of the many concerns that the American College of Medical Physics expressed to you and I am re-expressing it here is, while the intent of the new rule is a performance-based QA program the introduction of the regulatory guide makes it appear once again as a proscriptive rule. Therefore, the American College of Medical Physics recommends that the regulatory guide not be published as is. I would like some response and discussion on the NRC's view of the comments that I have made.

MR. CAMPER: Let me get a clarification on what you are saying. Are you saying published as written?

MR. SUNTHARALINGAM: As written. That is what appeared in general, the past performance is any indication

-- the NRC staff has essentially a set of required activities, thus proscriptive, and delaying licensing of applications or even site visits.

MR. TELFORD: I think you are focusing on the fact that the guide uses the word will. The guide should be read as if that verb is should. I believe that the next version of the guide will say should. It will not say will, and should not be read as if it says will. When you have a performance-based rule, the function of the guide is to provide at least one acceptable way for meeting performance objectives of the rule.

What the staff would like to do is have at least one and perhaps two or three ways to meet the rule. I just fixed your problem.

MR. SUNTHARALINGAM: I wanted to get some reaction.

MR. SMITH: Conceptually we have the belief that you should tell us in a QA document what should be done in terms of limits and so forth, but we really do not think it is necessary for you to tell us how to achieve those limits. I think there are a number of ways -- there are always a number of ways to accomplish something and we don't think it's necessary for you to spell it out.

Once you have spelled it out, I think experience has been that those also become something you look at --

MR. CAMPER: You are implying that the regulatory guide tells you how to do it; is that what you are saying?

MR. SMITH: Let me say that you suggest ways of doing it. Why is that necessary?

MR. CAMPER: Would you buy off on the idea that there might be facilities out there that would not know how to go about doing them?

MR. SMITH: That would not?

MR. CAMPER: That's right, would not.

MR. SMITH: There would be qualified experts that could find out. There are lots of qualified experts in the field.

MR. CAMPER: That may well be, but would you buy off on the idea that there are a number of facilities out there, small facilities in outlying areas or what have you that would readily look to and embrace the idea of an example of how to do this?

MR. SMITH: Examples are okay. If you are certain that you will guarantee --

MR. CAMPER: That's a regulatory --

MR. SMITH: They will only be used as examples. For example, let me give you -- if you have a dose calibrator and you say that your dose calibrator must be capable of giving you calibrations within ten percent accuracy; if in your guide then you say that when it is

known that your dose calibrator is plus or minus five percent and you must do something about it, then you have an example. Can you get cited or in another word get in trouble, if your dose calibrator is more than plus or minus five percent although your limit is ten percent.

In the past those kinds of things have happened to us.

MR. CAMPER: Let me try to address this concern a little more generically than a specific citation. We recognize, particularly those of us who spend time on materials licensing, recognize what happens in many cases unfortunately with regulatory guides. It seems to happen more times than not in the agreement state situation rather than with NRC.

In reality what happens is, sometimes regulatory guides become constructed particularly by new reviewers, as the way to do it. We recognize that, and we recognize that. One of the things that we have contemplated doing that has come out of pilot workshops -- and I have asked this question at every pilot workshop and it's kind of my classical closing questions.

What is the general feeling amongst the pilot participants that in the regulatory guide we would use language that would make it very clear that this is a guide, this is not the bible if you will, the only testimony

available on quality assurance. For example, one of the things that I am concerned about is that there is a fair amount of literature already available on the subject of quality assurance in the practice medicine or particularly in medical imaging or therapy.

We would include a bibliographical listing of some of this quality assurance literature and draw it to the attention of licensees that this exists and that they are also cautioned to refer to that. As you might imagine, generally that has been pretty well received by pilot participants, particularly by the physicists in the group and the physicians.

We are going as we move ahead in the months ahead, to try to do what we can along those lines, to make it clear that it's a regulatory guide and that there are other sources of information available about this subject.

MR. BRICKNER: Can you include in a regulatory guide, as much as Medicare sends letters of their instructions of their carriers, sometimes the carriers don't read English and interpret them any damn way they care. I would suggest to you in the same vein you may instruct your participating states on how they should inspect, but it would be even better if the regulatory guide included as paragraph one a statement that it is a guide and not a single methodology that you are condoning to the exclusion

of others.

If you put something in there that gives us something to respond to an inspector and say wait a minute, read paragraph one. It says this is only a way to do it, we are doing it a different way but it says that's okay.

MR. TELFORD: That's the intent. That's intent of how they plan to use this guide.

MR. BRICKNER: Can we go to page three?

MR. TELFORD: While paragraph one says that each licensee should have a QA program, we list eight objectives as the eight things to do. Because it's a performance-base, each licensee gets to decide how to do these things.

MR. BRICKNER: These are the things that you want them to accomplish. You are saying accomplish these any way you see fit within reason.

MR. TELFORD: More or less, yes, sir.

MR. BRICKNER: I don't see that number one is anything we could greatly argue with.

MR. TELFORD: I would propose to go through these one at a time, and would not be surprised if we chew up every one of them. How about the physicians among you?

MR. BOGARDUS: Number one is great. It's the physicists that are arguing with you.

[Laughter.]

MR. BRICKNER: It simply says that the program is

to ensure that the use is indicated, period. That makes sense. You have not stated in there and anything about only in conditions approved by the NRC or on the label instructions and all that kind of crap. That is something they can design on their own program.

MR. TELFORD: This just says that you, as the authorized user, you decided to give this patient some byproduct material or a dose of radiation so you should take some overt step that says you have done that.

MR. BRICKNER: Number two, in a teletherapy or brachytherapy or any radiopharmaceutical procedure -- and I don't know anything about 30 microcurie of 125 or 131, so I leave that to others. prescription -- and I refer back to your definition if I understand it correctly which is on page 1447 center column next to the bottom. One of the things I was concerned about and expressed to you when we started the meeting is really addressed here.

It says in brachytherapy, it means a prescription dose. Means the quantity of radiation absorbed dose or equivalent stated on the prescription, as documented before administration, and as revised to reflect actual loading of the sources immediately after implantation. So, I can say what I want to do is x, y, z. After I do it, I can say what I am going to be able to do is far different than here's what I am going to try to do now that I see what I have in

there.

Am I interpreting that correctly?

MR. TELFORD: Yes.

MR. BRICKNER: Then, what I should try to do is live within the parameters of statement number two.

MR. TELFORD: Yes.

MR. BRICKNER: In teletherapy it's the radiation absorbed dose stated on the prescription as documented before administration. Does anybody know anything about what 30 microcurie means; is this a breaking point of some sort?

MR. DEYE: That's the discharge. You don't have to have them in the hospital if it's below 30 microcurie -- millicuries.

MR. PAYNE: I assume the logic that I see can see to this would probably be if you had I-131. Thirty microcurie potentially could give you approximately 30 rads centi-Sv if you will to the thyroid gland. I don't know about the I-125. That's where that comes from.

MR. BRICKNER: They are saying then, if you go above 30 microcurie you need a prescription since you are getting therapeutic rather than a diagnostic referral; is that what all this is about?

MR. BOGARDUS: You need a prescription for a diagnostic referral. The patients can't just come in and

ask for a thyroid scan, a doctor has to prescribe it, regardless of the dose.

MR. DEYE: You get into problems there with in-patients.

MR. BOGARDUS: In-patients are the same. If I want an iodine scan of the thyroid, I am the one that is going to write the prescription or the physician's order for it. It isn't written by anybody else by me, and it can't be written by anybody else but me.

MR. DEYE: You being the referring doctor up on the floor --

MR. BOGARDUS: The referring doctor on the floor says I want a thyroid scan on that patient. The doctor in the nuclear medicine is the one who makes the determination that patient will get 15 millicuries to scan the thyroid or 100 millicuries to scan the thyroid.

MR. DEYE: I think you will find that many nuclear medicine departments, that scan will be done without the guy in nuclear medicine writing the prescription. I think the inspectors will confirm that is a difficulty for in-house physicians.

MR. TELFORD: The way that we understand that most business is done, we have tried to embody in objectives two and three. For instance, if you have an in-patient, the nuclear physician might be available to sign the

prescription. If you get an out-patient, the out-patient could come to the nuclear medicine department with or without a written referral. Typically it's over the phone.

The referring physician calls the nuclear medicine department, and a receptionist talks to a receptionist and says I am sending M .. Jones over for a thyroid scan. Now, when we wrote this proposed rule we envisioned that the ideal way was for Mrs. Jones to arrive with a written referral in her hand. According to the definition on 1447, we said a written directive signed by a physician, not a nuclear physician just any physician.

At least the request is clear that it is for a thyroid scan.

MR. BRICKNER: By an authorized user or a physician.

MR. TELFORD: The authorized user can always sign, but if it's a referral typically you are going to get -- you get many of those from a non-nuclear physician. The technologist would follow standing orders as invited in the clinical procedures manual.

MR. BOGARDUS: That's my point. There are written standing orders somewhere. It's the same as in a diagnostic department. I don't recommend how many rads I have to give a patient to get a barium enema done. It's just that you know what you are supposed to do, and there are written QA for

that. That's exactly what you are saying here. The 30 happens to be some number that got extracted.

MR. BRICKNER: Number three, to ensure prior to medical use that a diagnostic referral or prescription is made.

MR. FLYNN: Excuse me, are we done with number two yet?

MR. BRICKNER: All right, let's back up to number two.

MR. FLYNN: I had a comment on number two, and it had to do with a point that you brought up that I wrote to the NRC in my letter. That is, prior to medical use, I think I would suggest that it be changed to prior to completion of medical use or prior to completion of prescription. Often times we, in other hospitals, may have patients who have severe medical illness and we load the sources in the patient prior to the computerized treatment plan.

There is going to be 48 hours or 51 hours. The reason being -- what you may not appreciate is that when some of these patients with a severe medical illness were maybe getting cesium implants for cancer of the cervix or cancer of the endo -- they are so sick they can't be operated on. The longer they spend in bed, the higher chance they have heart attack or pulmonary embolism.

We load the sources -- I know they do it because I visited. Before we have the exact time that we are going to take them out --

MR. BRICKNER: Read 1447, second paragraph up in the middle column. In brachytherapy prescription in brachytherapy means the quantity or radiation absorbed dose or equivalent, which could be milligram hours, stated on the prescription as documented before administration and as revised to reflect the actual loading of sources immediately afterward. You can change it to anything that you want.

MR. TELFORD: Let me tell you about something that we have learned from our participants in the pilot program on the use of the word prescription. For brachytherapy, for example, it has been suggested that we don't talk about a prescription prior to implant. We talk about something called a pre-plan for example or a treatment plan.

Then as you say, you go into the OR and load the sources. At last you know how many you can get in there. Then you go back and figure out where all the sources are, and do the calculation to figure out how long you are going to leave them there. At that point you can write the prescription.

MR. BRICKNER: That would be reasonable, yes. A statement of the intention of the general plan and write the prescription when you know --

MR. FLYNN: What we usually do is take films with the dummy sources in place, and as the physicist is spending several hours on a computer coming out with a plan, we may be already loading the active sources in the patient prior to getting the dose calculations.

MR. BOGARDUS: That is covered, the way the definition reads.

MR. TELFORD: If we had the intention of calling that a pre-plan such that -- I think you are talking about an afterload device, where you determined location based on dummies. Now you are going to need to calculate how long to leave the actual sources there, the lab sources. If we talked about a pre-plan up to that point of actually loading up the sources, and then allow the calculations before you write the prescription then in the case of brachytherapy, the prescription would be signed after loading.

We have come away from the pilot program with the idea that it may be of value --

MR. BRICKNER: You can't do a prescription ahead of time in brachytherapy.

MR. TELFORD: You can't do the exact prescription ahead of time. We can handle that problem in that fashion.

MR. FLYNN: Otherwise, if you delay six hours because the physicist is doing multiple plans, you could get two or three deaths a year because that patient was

bedridden for another six or ten hours.

MR. SUNTHARALINGAM: I have a couple of comments. I think we are probably caught in the dilemma of physicians request of and order for the use of a byproduct material. The second component it is a physician as prescribing treatment. On page 1447 if you define prescription -- you are defining prescribed doses in your definition of prescription you are bringing to some specifics which may be difficult to meet. Maybe a prescription means a written direction or order for medical use. A specific prescription dated by and signed by a authorized user or physician.

Then when you say containing the following information, now you are essentially telling them what they should do.

MR. TELFORD: We are specifying a minimum information content.

MR. SUNTHARALINGAM: Yes, but in trying to specify that minimum information content you are getting into the logistical problems of day to day practice of medicine.

MR. TELFORD: For example?

MR. SUNTHARALINGAM: As was identified in item number D, for brachytherapy. For treatment time, number of sources, activity and all that is a --

MR. TELFORD: That's why I just acknowledged in this proposed solution --

MR. SUNTHARALINGAM: What I am suggesting is that overall if you take the -- your definition of prescription, not going into specifics of what you might even consider minimum information. You may not run into the logistical problem. You have us sitting here and identifying every possible scenario in a clinical -- it would be very difficult for the physicians to put down in writing everything that needs to be done.

MR. TELFORD: The objective of a written prescription, the directive is to establish what needs to be done. For example, for brachytherapy we talked about a pre-plan, then you would need to tell somebody how many seeds you are going to bring to the OR and what strength and what apparatus you are going to use. In the pre-plan that's all the information that you might specify.

After loading then indeed it's most of the information given. You need to write down what is the goal. This is the goal.

MR. SUNTHARALINGAM: That would be a written prescription by a physician. To me I am sitting here wondering -- there must be some specific reasons why you put down these objectives.

MR. TELFORD: Yes.

MR. SUNTHARALINGAM: Have there been incidents or events in the past that surfaced --

MR. TELFORD: Simple logic. If we just stopped at saying --

MR. SUNTHARALINGAM: Simple logic says that is what is currently being done, then I am --

MR. KLINE: There have been incidents where specific points in the definition were the root cause and the reason behind the misadministration for the event or the error. These fundamental requirements in that definition were tested in the field. We tried to get a generic definition that would encompass within reason what is written on a prescription or a pre-plan, or however you would like to define it.

We felt that with the problems that had been occurring in the past and reported to NRC, that this definition would be reasonable. The majority of facilities already do this and they encompass it in their current prescription. They have to know this to perform what they are doing.

It answers it in both ways. We have felt that this would more clearly define it without becoming too proscriptive. A point of diminished return -- you don't want it to become too proscriptive, but you have to give at least minimum requirements or else if you have no requirements, then there's no reason for a rule to be written. I don't know if that helps to explain the position

-- I am speaking on John's behalf here.

MR. FLYNN: On page 1440 the most common brachytherapy error was the wrong sources. The physician had said 20 milligrams, 20 milligrams, 20 milligrams cesium either verbally or wrote it, those sources were not loaded. That was the most dominant error and is also the most serious error of all the brachytherapy incidents that you have reported to you. That's the one that I would concentrate on rather than what dose to what reference point.

MR. TELFORD: How many sources --

MR. FLYNN: That's the most common error, and is also the most serious error.

MR. TELFORD: Accuracy of loading. That's why we think that specifying for brachytherapy the number of sources and their activities would be important.

MR. FLYNN: Yes.

MR. TELFORD: In teletherapy the ACR has a long list of things that they would like to see in the prescription. We looked at that long list and said is the diagnostic stated as the stage of the disease -- the pertinent reports, et cetera. Some of those things we don't have any business asking about. Of those things that are related to what is going to be the delivered dose, that is the things we are trying to capture in C.

MR. FLYNN: I have no problem with that.

MR. TELFORD: If you don't write down what you are going to do, you don't state the goal, you might not ever do it and can't ever say I made a mistake.

MR. KLINE: We found that -- without getting too much into the pilot study -- a lot of the working level people, the technologists or radiation therapy technologists, physicists or even oncologists often there were discussions during the visit that ensued along the lines that often we are unsure -- unclear at times what is required of us in the sense that some prescription or pre-plan is orally transmitted.

The information is scratched on a pad that might have everything on it and part of it is written and part of it transmitted. Most people are quite positive with the definition, now I know what is required of me. Therefore, the blame that there is for problems cannot be solely mine because I misunderstood. It is clearly called out here, so then you can identify where your root cause of the problem was, what was failed to be performed or accomplished.

It gives clarity without maybe being overburdensome. These were general comments from the participants and not solely on --

MR. BRICKNER: That's a very real problem, and one in which probably most of us have run sizeable departments

have had patients given doses that we didn't intend of them to get. As a matter of fact, we constructed something to prevent that. Since my partner cannot write the english language in any legible form even to himself, we have a rule that all of our prescriptions will be typewritten and signed, but that leaves the technician with two or three -- therapist as they are now called -- three days perhaps treating a patient who is only a verbal.

We found that verbal can get us in trouble. We made a form that's a very simple circled word form. It gives the fields, right, left, lateral, front, back -- which machine, what dose and where that dose is to be measured, and then you write the word for chest or abdomen or something. We did it this way, since he can draw a circle that is legible. We have on there doses no higher than 300 rads, because we have had the unpleasant experience of telling a technician who was getting married next week to treat this patient right and left, lateral whole brain fields 300 a day. She did; 300 here and 300 here.

Well, that wasn't too slick. So, we have in our hospital a policy that if you give more than 300 rads to any tissue in one day you must have the doctor come over and write a handwritten note on the treatment sheet that he has approved your doing this. We can't afford any 800 rads or 1,000 rads. Those kind of communications can be easily

solved if, in their own plan to suit their own way, they say that this has to be a handwritten note or a check off or something.

Saying that you want a prescription before you start is perfectly reasonable, and it's very easy to do and takes ten seconds. I can understand it goes to number four. If those responsible people don't understand what you want, somebody is going to get hurt.

MR. KLINE: As a moral majority of the professionals that we have here and with your expertise, you know what a good program looks like. You probably incorporate one in your own hospital. For a large number of facilities that don't have full time physicists that are in remote areas that don't practice always as you would, they don't always want to follow exactly the way that things are done properly or correctly and that want to cut corners, these sort of people -- there are some actors like that -- hopefully this will help if not deter, and possibly prevent any misadministration or events from occurring.

You have to look at the total spectrum of people, I guess the inspection type people address and see in the field. It's hard to relay that unless you are actually there and see it. We have had some opportunities even during the volunteer program to see even some of the people which volunteered and had what they believe is good

programs, where there were probably some areas which there could have been problems that slipped through much less the individuals that did not want to volunteer and possibly did not want to know what their program looked like from fear of repercussions that NRC would possibly come back later and look at their program and inspect them.

We appreciate your program that you have over here, and it sounds exactly in line with some of the programs that we saw. We highly endorse that sort of quality step for assurance in that direction. That meets what our intent of this rule is.

MR. SMITH: Let me first apologize for being gone so often. My young son had an automobile accident this morning in my car and tore it up. I think we are through that and won't be leaving anymore. If a physician writes prescription for a target dose -- normally it would be a target dose -- he is talking about dose delivered to a volume. For example, he might say 6,000 centigrade to the target volume.

Then he approves in addition to that a treatment plan which shows that there may be a cold spot on the order of ten or more percent. Is there misadministration there?

MR. TELFORD: Could we entertain that question when we get to the reporting requirements?

MR. SMITH: Okay, but I am talking about

prescriptions. You were talking about difficulties in --

MR. TELFORD: Let's go back to Dr. Brickner's example here for teletherapy.

MR. BRICKNER: Let me say that it's how you write your program. My program is written that when we do multiple fields, the dose we specify is at isocenter or at the conjunction of fields, not the treatment volume. The treatment volume isn't a number, it's a whole bunch of numbers just as you say. You write your program the way you want to live with it. Do you know what you intend to do --

MR. SMITH: Does the prescription, the way you define it, include the treatment plan which has been approved by the physician. Does it, or does it not?

MR. TELFORD: In teletherapy as in brachytherapy, we could use some sort of form like Dr. Brickner showed us as the first couple of treatments. You might call that the treatment plan that you would start with before you have decided the total dose to give to this tumor and how many factions, et cetera, and how to define an exact treatment plan and what isodose curve you are going to treat to.

MR. BRICKNER: It does not include a statement as to total dose. Your definition in here under page 1447(c) total dose, number of fractions and treatment site. That's perfectly okay with me, because I'm not as concerned as he is because as I understand it -- you correct me if I'm wrong

-- this is critically important. As I understand it, I designed my quality assurance program and I decide what the word dose means and what the dose point is, and he may decide a different dose or dose point.

What you are interested in is I vary from what I intended to do by too much, you want to know about it.

MR. TELFORD: Yes, that's correct.

MR. BRICKNER: And if he varies from what he intended to do. But you are not telling us that we have to state our intentions in the same language.

MR. TELFORD: That's correct.

MR. KLINE: We are not defining dose. We are letting you define it, and in your definition --

MR. BRICKNER: In those parameters I can write down a treatment plan that says I want to deliver the dose my way of 6,000 and I want to do it in 30 fractions, and I want to do it to the pelvis. Tomorrow I have all the liberty in the world to write a whole new plan.

MR. TELFORD: That's correct.

MR. BRICKNER: I can say I've changed my mind and now want to go to 4,500 and so on. In my definition, in my department, and in my manual, any dose I talk about with external beam fields will be defined as being on the center line of the beam at the intersection of the beam. When I write a prescription that says 6,000 -- for instance in my

department and I don't know how it is in your department -- when I write down a dose for an electron beam, we have a uniform rule in the department and there's no discussion about what that does means.

That's the 90 percent isodose line for that energy. That is where the dose is measured. If I want to accomplish a surface dose or a five centimeter dose, then I do those mathematics. But when I tell the girls that I want a dose, they count the 90 percent isodose line. If you don't have a convention, then every patient is a new experience and a new opportunity for a disaster.

MR. DEYE: Other points of interest that you may calculate in the chart are not considered a part of your prescription?

MR. BOGARDUS: No. They come up eventually as where you finally get to, and that may modify or change a prescription. I may say I want 6,000 on central axis at midplane of the pelvis. Everybody knows where that is. That's a point somewhere in the middle of the pelvis that you can calculate. That will be modified later on when the physicist comes back and says you are getting too much here or too much there.

Then we will modify those doses which will then redrive that central axis dose to some other number, but that will be documented somewhere along the line. A lot of

times I will say five to 6,000 rads, and that's a pretty good variation.

MR. DEYE: I am wondering if the NRC would find that definition acceptable, since it doesn't address issues like the dose to the spinal cord.

MR. BRICKNER: They haven't asked for it, and I hope to hell they don't ask for it. What dose you are talking about is your business.

MR. TELFORD: Dr. Bogardus has probably derived his dose based on the knowledge that he wants to avoid an overdose to the spinal cord --

MR. BOGARDUS: That's exactly right.

MR. TELFORD: -- so he has come up to the maximum dose that he wants given. What we would like to see is that in his QA program he writes the dose according to the way he wants to. If he wants to use the 90 percent line and somebody else wants to use the 80 percent isodose curve, that's okay. He, as the authorized user, has said this is what I want delivered. If that gets delivered, we are happy.

MR. DEYE: Even if the field size was off by two centimeters and included an additional amount of spinal cord an overdose of spinal cord; he would say --

MR. BRICKNER: That's not their business.

MR. BOGARDUS: That's between me and my

malpractice lawyer. If I am dumb enough to set up a field that gets me into that much trouble or the same things happens, you are setting up an oblique field in the chest and that oblique field in the chest -- the upper edge of it is going to clip the spinal cord. I am supposed to know that and my isodose curves and my physicists are ultimately going to tell me that. That is not going to alter my midpoint dosage on those oblique fields. It just tells me I better get a block in up there at the correct location.

MR. DEYE: What if you put a ten by ten field that missed the cord but the technologist treated a 12 by ten field which included the cord --

MR. BOGARDUS: Then that, sir, is a misadministration. That is a --

MR. TELFORD: Could we carry on that discussion when we get to the reporting requirements.

MR. DEYE: I think it's still germane to the whole concept of the word prescription.

MR. TELFORD: Treated here in terms of ideas and concepts, but we can't treat for details until we get to the reporting requirements.

MR. BOGARDUS: That's a very valid question.

MR. SUNTHARALINGAM: I will alert you people, this whole concept of a prescription is under review by an international committee, ICRU. They have been presenting

this for about three years. They are in another meeting in Philadelphia. This whole question of what is a prescription is again being discussed -- that's why I altered you that going into specifics on what you want as a minimal documentation.

MR. TELFORD: I have a question for you. Would you prefer that we use the term written directive and to not use the term prescription?

MR. SUNTHARALINGAM: Yes.

MR. TELFORD: You would like that?

MR. DEYE: Stay away from any word that are already being used in a problematic fashion in the field, be it misadministration, be it prescription, be it whatever. I think that words that we have already used and have a certain understanding about -- the problem is that many of those understandings are muddled across the field and across the country.

So, use words that we haven't used before like ALARA.

MR. SMITH: May physicians I think appropriately more and more so these days will, in addition to prescribing target dose or tumor dose, will prescribe doses to one or more normal tissues. In your definition of prescription, if one writes down in the physician's directive, then you are not just addressing tumor dose, you are directing your

prescription to all doses which that physician may describe in his written directive.

MR. DEYE: Ted Brickner's points was that you -- to guard yourself you don't put those in your prescription.

MR. BOGARDUS: There will be certain things that we even do that way. Again, you are treating a chest, you are treating a lung. I want to take the tumor to 6,000 rads at midline, and I want to make certain the spinal cord is blocked in such a fashion that no more than 3,500 rads is delivered to the cord.

That, I often times put in, and that's something that has to be followed.

MR. BRICKNER: We do that in our treatment p: n, and we had a standard way of doing it. You could almost put in with standard approach to the cord, because there is only one way we are going to do that in our department -- actually two.

MR. SUNTHARALINGAM: I will ask a question for the NRC. Are we going to expand that prescription that you have written -- whether or not we now consider any deviation from that prescription -- I know we are jumping ahead to what is reportable -- as an error. Therefore, people have to be notified.

MR. BOGARDUS: Let's look at this error business, because there are two things here that I think we keep

getting confused. I say I want 4,500 rads as the maximum dose to the spinal cord and that's what I wrote in my written directive. The technologist forgets to put the block in. That becomes an error.

On the other hand, I am moving through the patient's treatment course and realize that the tumor is continuing to grow. I talk to the patient and say we are going to have to push this farther than I had originally thought. We are taking your cord to 5,000 and the tumor to almost seven. The patient says fine. I rewrite what I am doing and that's not an error. That is a change based on the patient's clinical behavior during the course of treatment.

I made that conscious decision to change what I originally did, and it was by more than ten percent.

MR. TELFORD: You can revise your prescription at any time. You can take it up or you could take it down. You can stop treatment, you can double the treatment. As long as you change the prescription and use the authorized user to sign off on it, it's fine.

MR. BRICKNER: If I write a prescription and deliver 7,000 rads to the spinal cord and deliver it precisely as I said I was going to, I have met their requirement. I may have a great many other problems after I have done it.

MR. SMITH: Ted, my concern is that the rule is going to prohibit or inhibit -- inhibit physicians from writing comprehensive, detailed prescriptions and not putting down doses and several -- they will feel very inhibited in writing detailed instructions. The more they write down the more likely is that some of those doses aren't going to be --

MR. BRICKNER: You can cover that by stating in your QA program that the dose under consideration and for evaluation is the central axis dose, either as stated in centimeters or as defined as a midplane dose. Other doses are not the ones that you are measuring for QA for this set of parameters.

MR. SMITH: I know myself, I have spent many years trying to get physicians to write more detailed descriptions of doses to normal tissues, because I think that's important for us to realize that when you started treatment what doses to the normal tissues are acceptable. If this is going to inhibit them now from writing down those doses, I think it would be unfortunate.

MR. BOGARDUS: How we write those, and a lot of times physicists come back and say I can't do this. There is no way humanly possible to get the doses that you have asked for.

MR. SMITH: They are goals though. They are

goals. That's the point. They are goals and they are often not met. Therefore, not meeting those goals becomes a violation.

MR. BRICKNER: Not if you write another note that says this can't be accomplished. Therefore, I am changing the prescription to --

MR. PAYNE: I guess along those lines I guess there's where we will have to be cautious in our programs and we probably will not want to take as the only directive -- in other words, if we were to say we follow a guide that is developed and we will do this, I think we are going to need to include our own definitions of what the written directive is and what the prescription is. That is what we will live by. I can see another area that we could get ourselves trapped into, and that would be we are taking a lot of port films, and if we are off by more than about five millimeters -- we treat our patient and there is this moving target.

As long as we are within a reasonable location, we are happy. If we get too far out, we are not happy. We are still treating the pelvis. It's just that we are a little bit over to one side a little. To us, that is unacceptable. We don't want to be eight millimeters to the right or to the left.

I don't want to be calling that an error. I don't

want to be writing a misadministration letter to the NRC every time we move eight millimeters to the right.

MR. BOGARDUS: You are not going to be, as long as the physician sings off on that port film because that patient 400 pounds and has three centimeters of slop in the port film.

MR. CAMPER: Let me make a comment, if I may. I don't know how comforting what I am about to say is going to be, but at least if I share with you our philosophy in looking at this maybe we will be somewhat comfortable.

With regard to inspecting these kind of things -- our two inspectors can probably address it as well or better than I can -- let me share with you an example of something. Are most of you familiar with the interim final rule that was published on the 23rd of August that was designed to provide physicians with certain relief --

MR. DEYE: I just love that term.

MR. CAMPER: Anyway, in this rule there was a requirement; it is a physician driven deviation. If a physician wants to deviate a package insert, he or she must identify this deviation, the rationale behind the deviation and what the benefit is to the patient and this type of thing. There is a record keeping requirement.

In developing the inspection guidance we went to great lengths to instruct the inspectors that look, when you

go out and you are looking at this record keeping requirement, your purpose for doing so is to ensure that the deviation was documented. By no stretch of the imagination are you to second guess or make judgment calls as to why the physician made the deviation. That is a medical judgment call.

Your purpose as an inspector is to see that the deviation was documented, and does it contain the elements of which there are three, but not to get into looking at and second guessing whether or not the physician made a reasonable judgment call in any way, shape or form. The point in telling you all of this is, is that in a similar vein here when we develop the inspection guide that ultimately accompanies this rule, I have to believe and have to rest assured that when we look at the inspection aspect of it these inspectors are not going to go out and second guess the elements of a prescription and did the physician do certain things that we consider to be a justification or what have you.

It is a question of whether or not there is a quality assurance program in place; are these requirements existing; are the objectives being met and things of that nature, as opposed to second guessing prescriptions and those types of things. It's an area involving medical judgment that we try to steer away from. Again, I don't

know how comforting that is, but that's --

MR. DEYE: Let me pursue that one second. As I understand the new definition of misadministration as proposed, if the physician at the end of the course of treatment finds that the patient was given 6,700 rad instead of 6,000 as his original prescription said. He said hey, the patient zipped right on through and had no complications, they seem just fine, and we would like to treat anyway for this patient's disease and 6,700 is probably just as good as 6,000.

Will you allow his medical judgment to say that was not misadministration of dose if he signs in the chart that 6,700 is now okay?

MR. TELFORD: I hate to keep saying this, but can we pick that up in the reporting requirements? Let me carry on with Larry's point, the elements of the teletherapy prescription that we have in the definition. Think of this as a written directive for a teletherapy. We are asking for total dose, number of fractions, and treatment site.

I think that is what you want to focus on. Do you want to change that?

MR. DEYE: You haven't defined treatment site. I don't want you to define any of these things. I just want you to understand the complexity of some of these terms. As someone said, people spend three years trying to develop

some of these terms or more. Just be aware that you are asking for a lot of ambiguity and problematic situations.

MR. TELFORD: As Dr. Brickner said, when you develop your QA program, you will say for instance that you are always going to use the 90 percent isodose curve for this kind of patient or you are going to use the center line of the beam at the intersection of the beam, or you are going to use some other points to define the dose.

MR. BRICKNER: You get to make your own rule.

MR. TELFORD: If an inspector comes out and looks at the prescription and looks at the administered dose, that is the two that will get compared.

MR. DEYE: I am now going to have to define and write down what I mean by treatment site, I guess. I don't imagine too many places have done that. For example, if the technologist in treating a boost field to the brain takes one of the lateral tattoos as central access tattoo and treats that, she is now treated half of the field outside the original volume and half within. I leave it for you to decide whether we are talking reporting requirements or definitions, and it seems to matter little to me whether she treated the correct treatment site that day. It has happened in many instances.

MR. BOGARDUS: That's an incident, because it is usually caught on port films or caught the next day, and

would have no medical significance for that patient.

MR. DEYE: That's correct.

MR. BOGARDUS: If the entire course of therapy was delivered in that fashion, then I think you would get to a misadministration level. I think we have all had the problems of a reversed wedge, the field was rotated 90 degrees on the wrong axis -- all of these things happen, but it's a single incident.

MR. DEYE: You and I can agree on that within our clinics. We do it every day. That's why a physician and a physicist have to work closely together on these things. I think the problem is when a regulatory body gives us a term treatment site, I want them to be aware that on one day you and I may agree one thing and on another day we may agree another. I hope they are flexible enough to accept the fact that we will redefine this day after day, depending on the patient's medical condition.

MR. SVENSSON: I think I am a little concerned about the discussion in a sense that the rules tend to emphasize the need for very simplistic prescriptions. I think the situations where one commonly includes the three dimensional aspects to treatments which is more and more common, it's not going to go away, and where, in fact, complete graphical plans become records that is part of the prescription.

I think the problem is that the liability of putting in such complex prescriptions are so high that in fact the physicians may want to simplify something and therefore reduce the quality of the treatment. That is sort of a general concern I have.

MR. TELFORD: How are we doing this? We have a definition of prescription. How are we precluding something?

MR. DEYE: Because if an institution wanted to use the complexity of a three dimensional treatment plan as part of its prescription process, they would be opening themselves up to a tremendous chance of being guilty of misadministration according to your definition.

They would write a document for their institution that says we shall never use three dimensional treatment planning information as our prescription. We will keep two sets of books. We will keep one set of books called prescription for NRC purposes and we will keep another set of books for a prescription as we really do treatment planning on patients. That's what you are opening up to here.

MR. KLINE: Would any language to the effect that as a minimum these things are followed; would that alleviate or possibly subdue that concern? Do you want in a prescription anything that might say as a minimum or at

least this or does that prevent --

MR. BRICKNER: Would it help if you had the term in there with dose point and treatment site to be defined by the user? Three dimensional planning, what is unique about it and what is the big deal? You say if you want to get 6,000 rads into a three dimensional volume we do that all the time.

MR. SUNTHARALINGAM: We are getting into an area where if you put five physicians and five physicists alone you are going to get ten different viewpoints expressed. I don't think that is the purpose of this discussion. I thought that they said it will be all right if we get away from the term prescription and put on written directive. I thought that was a reasonably right change to say it's a written directive.

Now, if they also add the word as a minimum the following information should be contained in the directive, I think conceptually what they are saying is that if you want to treat the lung -- what is your prescribed and what is your dose you want to take the target to. Maybe adding the word minimum -- I can't sit here and argue that, there are three physicians argue among themselves which is the correct point where you are to carry your tumor dose.

MR. CAMPER: Clearly understand what our concern is, that a prescription exists.

MR. DEYE: Are you willing to change that to clinical directive and drop the word prescription, do you think that is a --

MR. TELFORD: How about written directive.

MR. SMITH: I will tell you something that Ed would not argue about though -- I am sure that you have either done it or continue to do it knowingly. When you prescribe a dose that you know when you write that dose down in your prescription and in your final tabulation of dose that the tumor actually received up to 15 percent higher dose.

MR. BRICKNER: It doesn't matter. It is of no significance.

MR. SMITH: Why is it not, because it's a misadministration.

MR. BRICKNER: My purpose in writing something on a piece of paper is that my girls will do what I want them to do. If they do what I want them to do, the patient will benefit. Whether it is from centigrade from rads or whether it's six or five, I know that 30 treatments calculated the way that I calculate them will prevent growth or --

MR. SMITH: I know that, but you missed the point. What you know is inaccurate to start out with by at least 15 percent, and it's a misadministration by definition.

MR. BRICKNER: Do I state my intention and do I complete my intention --

MR. SMITH: Let me ask the question then. If we know that the patient received 15 percent more dose than you prescribed, is that a misadministration.

MR. BRICKNER: He didn't. He received exactly the dose that I prescribed.

MR. SMITH: He did not.

MR. BOGARDUS: The physicist is so damn good and he came around and calculated something that changed what we are doing. That's exactly the same thing that happened when we went from raunchiness to rads to centigrade. You guys keep changing the numbers and we have to keep changing the way we think about it, because my original dosages are now having to be modified by some of the crazy things that you do.

Once my physicist starts doing these air inhomogen[illegible] roblems in lung, I have to start to rethink what my dosage is going to be. As long as nobody in my institution calculates this exactly, then the prescription was followed the way that I wanted it. Once you guys start doing that, then I got to change the way I do things.

MR. SMITH: We are talking about a real problem here, and it's a problem which we confront now.

MR. SVENSSON: Can I make a comment about that? I

think it goes back to the previous comment about the definition of errors, that is exactly what this is. Dr. Brickner's prescription is an error by 15 percent, but it is not a mistake. You have to make that distinction very clear because errors are scientific concepts, they are well defined, they are well understood, they are quantified. Mistakes is a different thing, and I think the document has to reflect that difference and it does not.

MR. DEYE: This is why, for example, in your current definition of misadministration you do say ten percent between the final prescribed and calculated, which I find minimally acceptable. The trouble is that under the new one we talk about between administered and prescribed.

Administered is exactly Al's point. What was truly administered was different than what you prescribed. What was calculated may well be what you prescribed. These words force us into a legal situation as RSO's which you may not even be aware of. We wind up having to report things or not report things.

MR. BRICKNER: We better stick with calculate.

MR. DEYE: That's not what they are proposing here.

MR. BRICKNER: The rule in my department is different than the rule in Al's department. We do not consider lung attenuation correction.

that 30 microcurie came from?

MR. TELFORD: If you get above that you are getting towards the therapy range. If you make a switch at that point from micro to milli, you have some pretty severe consequences. If you look at 30 microcurie for stochastic effects and you get much above that and you have some -- you increase the probability of getting cancer within the next five years.

MR. SUNTHARALINGAM: This study can be done under 30 microcurie without a prescription.

MR. BRICKNER: With a referral, but without a prescription.

MR. SUNTHARALINGAM: Not, that's not clear. It does not s y that.

MR. TELFORD: Number three says you got to have a referral to do anything.

MR. BRICKNER: That sounds good to me. We don't have any nuclear people here objecting to the --

MR. TELFORD: We previously met with ACNP and SNM. We will be meeting with JCHO. We are just offering this as a subject for your discussion if you like.

MR. BRICKNER: No objection.

MR. CAMPER: Let me raise a quick point about this diagnostic referral prescription since this is really going on right now and we may lose the train of thought if we go

feeling among this group about this argument of diagnostic referral versus a prescription or, if you will, a written directive; do you see that as posing a problem?

MR. BRICKNER: What you are suggesting is that some people are saying that if I, as a oncologist who knows nothing about isotope, decide to get a bone scan, that should be looked at by a nuclear medicine physician or representative of the licensee to decide the dose that is used or to sign off on it or something?

MR. CAMPER: Let's say you are an OB/GYN physician. You send a patient for liver scan and one of your friends said that you should use iodine for that. You write a directive or a referral --

MR. BRICKNER: No, sir. That's not a referral, that's a prescription. If I am OB man -- God help me -- and I send a patient, I want a liver scan. I want an analysis of the liver. The isotope that they use is their business, and the dose that they use is their business, and I don't want to know about it and don't even want them to write tha first paragraph that describes it because it distracts me. I just want to know does the patient have a normal liver. That is a referral.

If I write what isotope to use, I am now in the prescribing business and I should be licensed as a user before I am allowed to do that.

proper strength and the proper material. I would guess that some licensees maybe don't; that they take the label at face value. I would be concerned at that, because even though 3M Company is pretty good, every once in a while the wrong labels gets on a container. You think you have .4 millicurie cesium and indeed maybe you have .1 or 2.5 millicurie seeds.

Putting source strength in here, that sort of means that you have to know what you are doing, what you are putting into people. You have to know how many, where, and the strength.

MR. KLINE: This is a suggestion amongst you, whether or not this might be a better term or maybe it is -- how do you feel about sequence of loading? Would that -- no.

MR. SUNTHARALINGAM: Sequence of loading is only simply on one particular -- this is not a catch all for every brachytherapy.

MR. TELFORD: We are still on number two.

MR. BRICKNER: Did we get through A and D.

MR. TELFORD: We are now on objective two. Maybe we can get through two and break for lunch.

MR. BRICKNER: Number three is fine.

MR. TELFORD: How about 2D, the 30 microcurie.

MR. SUNTHARALINGAM: Does you have reason where

have a situation in a number of hospitals where patients are referred for lung scans. Our CT department sits right next door to our nuclear medicine department.

It gets garbled up between the referring doctor, the referring doctor's nurse, or secretary at the radiology department which administers both CT lung scans and nuclear medicine lung scans. It sounds so simple and liver scans -- we do CT liver scans and we do nuclear medicine liver scans. I don't think it's ever going to change.

I think we are going to have -- we have patients now that get CT lung scans. Then, when the nuclear medicine doctor reads it out he goes why did this patient get --

MR. BRICKNER: Yes, but if the doctor on the ward writes lung scan in the chart and signs it, it's the same problem.

MR. PAYNE: It's the same problem. Because we don't have indicators. Is he looking for emboli or is he looking for a mass.

MR. BRICKNER: It's up to your department to play -- they are going to just have to have a rule of COA. They have to call the doctor and say which one did you want. You didn't specify, and we can't afford to do this.

MR. CAMPER: The general sense that I am gathering is that the idea of a written diagnostic referral is reasonable, and are the elements set forth there including

for the study.

MR. BRICKNER: Is that normal? I don't know enough about -- if I send my patient for a bone scan, do they have to find the nuclear doctor to sign it?

MR. CAMPER: What you are saying is that the concept of the diagnostic referral is an acceptable one.

MR. BRICKNER: Yes.

MR. CAMPER: What about the fact that we have defined it as being written?

MR. BRICKNER: That, I was going to bring up to you. That's a big pain.

MR. CAMPER: There are those who say that in the normal course of practice of nuclear medicine for example, that telephone referrals take place all the time.

MR. BRICKNER: That's correct.

MR. CAMPER: Should the diagnostic referral be written; is telephone acceptable?

MR. BOGARDUS: For years we have asked for the written referral and have never been able to get it, because when they do that they may put some pertinent history down which helps us greatly. The chances of getting it are just about zip, so you may as well leave it out.

MR. PAYNE: I can give you two examples. If we go ahead with the rule as it is here, these will never go away. If you allow a telephone call for a lung scan, it will -- we

to lunch. You just made an interesting remark. You said that this idea of number three here, ensure that prior to medical use that a diagnostic referral or prescription is made for any diagnostic radiopharmaceutical procedure -- interestingly enough, one of the things that I have heard criticized, particulary in dealing with agreement state individuals is, the concept of a diagnostic referral versus a prescription.

It goes something like this. If you look at the definition of prescription where it says means that a written direction or order for medical use for a specific patient dated and signed by an authorized user or a physician under the supervision of an authorized user versus, if you will, a diagnostic referral which means that a written request dated and signed by a physician before a diagnostic medical use that includes so forth and so forth.

The issue that has been raised is that the concept of allowing a diagnostic referral denigrates the control of the authorized user, and that only authorized users can prescribe the utilization of a pharmaceutical for a particular patient. This is either based upon an examination of the patient or at least seeing the physician's request and making sure that it makes sense and what have you.

I guess what I would like to know is, is there a

because teletherapy is given ten-thousandth of a sec nd whereas the brachytherapy is going to take a couple of days prior to completion of the --

MR. CAMPER: Sometimes.

MR. PAYNE: Could I offer a suggestion? Where it says for brachytherapy, the total dose or treatment, number of sources -- I might suggest that we put and source strength rather than combined activity. We may not be using activity as a description of brachytherapy sources in the future but we will have some descriptor of source strength.

MR. SUNTHARALINGAM: I am in favor of deleting what is in the parenthesis. If we just say total dose, radioisotope and treatment site, that is what is initially in the prescription. That is the physician's intent. How he accomplished that and the other details, they will be subsequent to the completion of the insertion and treatment.

MR. PAYNE: As a comment I will throw out one other thing. I think for cesium brachytherapy implants, things are pretty clear. We have defined source strengths. I would encourage us all to make sure we are -- I do a lot of at our institution we are doing quite a few I-125 prostate implants. It scares me.

In other words, when you are receiving brachytherapy sources from the outside, I go to a fair amount of effort to make sure that I have received the

MR. DEYE: Neither do we.

MR. BRICKNER: We have clinical results based without it, and we don't care to go into a new hodge podge where we don't know what the dose is --

MR. CAMPER: Are the items in A through D -- on page 1447 under definition of prescription, getting back to Mr. Kline's comment a moment ago -- are the items A through D, are those minimally acceptable, given that they are going to be --

MR. DEYE: As a directive rather than a prescription, yes.

MR. PAYNE: D is a problem. I think that's -- Dr. Flynn indicated that because we may not have in the written directive --

MR. CAMPER: This is after implant.

MR. PAYNE: Yes.

MR. SUNTHARALINGAM: It doesn't say for brachytherapy that intended total dose --

MR. BRICKNER: He just gave you an out on that a few moments ago.

MR. PAYNE: What did you call it, proposed plan?

MR. CAMPER: Pre-plan.

MR. PAYNE: Sometime you are going to have to decide how long.

MR. FLYNN: Prior to the completion of the plan,

MR. CAMPER: That is the question that I am trying to get to.

MR. SUNTHARALINGAM: The two should be separated.

MR. BRICKNER: Totally different.

MR. SUNTHARALINGAM: They can't be all things. You may say look, first we need a diagnostic referral and you can't do a study on this as a diagnostic referral.

MR. BRICKNER: Doctor asked for it.

MR. SUNTHARALINGAM: The doctor asked for it. It could very well be that the licensee himself is requesting the study. That is fine.

MR. CAMPER: Looking at number three then where you say ensure prior to medical use the diagnostic referral or prescription is made for a diagnostic radiopharmaceutical procedure.

MR. BRICKNER: Or prescription, only if you happen to be a licensee who wants to do the study.

MR. SUNTHARALINGAM: To be clear you can take out the word prescription from the opening sentence.

MR. BRICKNER: I would take it out, and now if you want someone --

MR. SUNTHARALINGAM: If you feel that there should also be a written prescription by the licensee pertaining to that diagnostic study what he has to put down as a minimum requirement, what isotope and what activity is being used

the patient's name, the clinical diagnostics procedure --

MR. BRICKNER: I don't think a written referral is necessary. I think a telephone referral is acceptable, on the presumption that isotopic diagnostic studies are safe enough that you don't have to go to great -- you don't have to do the same intensity of scrutiny before you give it that you have to in a therapeutic situation.

MR. FLYNN: If you require a written document to be received by nuclear medicine in those cases where it's not and they don't do the scan, harm could come to the patient by not having a study done in a timely fashion, much more harm than the occasional problem that occurs by not having a written document. I think you have to balance those two.

MR. TELFORD: Let's say that we used a telephone referral system, and let's say that we specify some minimum amount of information. This should be received and written down by the nuclear medicine department. What information would you say needs to be there?

MR. FLYNN: They ask the patient's name and just basic clinical history. They will check to see if that patient had another bone scan by another physician and say this patient had a bone scan a month ago -- they say that being the case, let's cancel --

MR. TELFORD: You said name, clinical history and

the requested study.

MR. FLYNN: You usually require the date of birth or some I.D. number on that patient also.

MR. BRICKNER: Referring doctor's name.

MR. TELFORD: Referring doctor's name.

MR. FLYNN: Patient's name.

MR. TELFORD: Patient name, clinical history, requested study.

MR. BRICKNER: Some identification.

MR. TELFORD: Social security number, date of birth in addition to name.

MR. BRICKNER: That's about it.

MR. TELFORD: So now, the nuclear medicine department has this information in a written form and, assume that it follows a standing order of the authorized user --

MR. BRICKNER: Somebody wrote it out.

MR. TELFORD: Somebody wrote it down at your end. Assume this requested study follows the standing order in the clinical procedures manual. The technologist knows what to do. Is that okay?

MR. BRICKNER: Yes.

MR. TELFORD: Following the directive of an authorized user. If it differs at all from the clinical procedures manual, then they should --

MR. BRICKNER: Not do it.

MR. TELFORD: Not do it, okay. Who should they call?

MR. BOGARDUS: A responsible nuclear medicine user. They are supposed to ask you to do a study, not specify the wrong isotope, because if they start telling you what isotope -- at this point you got to do a little bit of thinking about it.

MR. KLINE: Assuming that you document the study on the other end of the phone according to the definition, what are your feelings about people that are now using electronic transfer of information, computer systems who send computer over the line. In this definition it says signed by the physician.

MR. BRICKNER: I would take that out. E-Mail is fine, fax is fine.

MR. KLINE: If you are sending a prescription it might be a computer, and we have a problem with the signature of the referring physician.

MR. BRICKNER: This isn't a prescription, this is a referral request.

MR. KLINE: You would eliminate that signature requirement?

MR. BOGARDUS: Yes, I would, for diagnostic studies. For instance, I don't request a physician's

signature on a referral request to evaluate a patient for cancer.

MR. KLINE: The referral is documented on the receiving end with a phone call in this particular situation, and whether or not a physician's signature is warranted on that referral.

MR. BOGARDUS: Diagnostic studies, you simply don't need it. A study done on a wrong patient is a problem, but it is nowhere near the problem that a massive hangup that this would create otherwise, and you would have a tremendous amount of difficulty and lives lost simply because you are waiting for a signature of a physician.

MR. BRICKNER: I would change this to read diagnostic referral means a request by a physician before diagnostic medical use.

MR. BOGARDUS: That's all you need.

MR. BRICKNER: I wouldn't ask for his signature or even the date. It has to be a physician that asked us to do the study, a patient can't request it nor can an unlicensed practitioner request it.

MR. KLINE: We were contemplating actually the physician's office in the description --

MR. CAMPER: I have one just quick follow on question, and then we can go to lunch. If you look at prescription, definition of, on page 1447. In the same vein

that I raised the point that we were just discussing, it has also been raised by the same group that when you get to the definition where it says for specific -- by an authorized user or a physician under the supervision of an authorized user --

MR. BRICKNER: What is an authorized user, I don't know.

MR. CAMPER: An authorized user is an individual whose training and experience has been reviewed by the NRC or an agreement state and has been found to meet minimally acceptable qualifications to address the radiation safety, public health and safety concerns.

MR. BRICKNER: That's not the institution, that's me.

MR. CAMPER: That is you. That individual physician is then listed on the license to use certain materials for certain purposes. The difference then here is, you have an authorized user which we now all understand versus a physician that is being preceptored by that authorized user on his or her way to becoming an authorized user typically.

The question really then is, can only the authorized user prescribe or can the physician being preceptored also--

MR. BRICKNER: You guys that have residents are

going to have to answer that, but I just -- I believe that the authorized user has to sign everything that is therapeutic in dose.

MR. BOGARDUS: The authorized user must ultimately sign it.

MR. CAMPER: This is for diagnostic or therapeutic. Focus on therapy, if you will. Consider just therapy.

MR. PAYNE: Diagnostic, I would say most radiology groups -- I come from Minneapolis. The Twin Cities, the radiology groups are very big, usually up to 20 or 25 radiologists in a group. On the NRC license, it is typically to find only maybe five or six members of a group on a license. They cover for each other. They cover for each other so that, therefore, the other 15 members are followed the preceptor. Some are new members to the group trying to gain experience.

I think it would be a problem to provide coverage if you are going to require only authorized users to work with the prescription.

MR. BOGARDUS: Even in therapy it's going to become cumbersome to have only the authorized user, because in a big residency training program our residents frequently sign a lot of things in the chart. It is signed by a physician, but it is often times very difficult for me the

licensed physician, to sign these thousands of things. All I would be doing is roping signatures against what the resident did. I know what happened with the patient, but I don't have time to go back and sign every single document that he put together. He is doing it under my authority.

MR. TELFORD: How about not every single document but every single prescription?

MR. PAYNE: Most residents prescribe in a lot of places. We review it in chart rounds.

MR. BOGARDUS: We review it, and we try to sign and countersign everything because we have to for a lot of reasons. I would hate to have a signature here and there missed and get picked up by one of the inspectors and cited for it.

MR. TELFORD: Is there some rule of thumb that you use for when you allow new residents to start signing prescriptions for therapy?

MR. SUNTHARALINGAM: Probably varies from place to place.

MR. BOGARDUS: They are doing their own treatment planning and design usually by their second, maybe third year but certainly not their first year. Then you can't put that in the regulation.

MR. FLYNN: We countersign all our signatures at Mass General.

MR. BOGARDUS: We try to, but sometimes it's impossible.

MR. FLYNN: Sometimes the resident may be three days ahead of me because I was off in the operating room somewhere else. A lot of things are done on a weekly basis, both quality assurance and weekly status checks on patients. At least weekly I catch up. Sometimes in a week's time I catch up. Of course, I take all responsibility for his errors. He is still being supervised by me. I catch up, so I countersign within the week prior to the next week's course of treatments.

MR. BOGARDUS: We do exactly the same thing, and I think most people do. But there will be charts that get lost in the shuffle. A patient dies, something major happens, they get transferred, that's the one chart that is going to get picked up six months or a year later and say hey, four places you didn't sign and you are cited.

MR. FLYNN: That's why I come back to ALARA.

MR. BOGARDUS: ALARA is fine, and I don't mind that.

MR. CAMPER: This generally --

MR. BOGARDUS: It's not a hard fast, absolutely 100 percent rule.

MR. CAMPER: This generally argues for the physician being preceptored to also prescribe?

MR. BOGARDUS: That is the goal.

MR. TELFORD: They have added one point here, and that's the second signature by the authorized user at some point in time, which is really not captured in the phrase that we have here.

MR. CAMPER: Thank you for those particular comments. That has been an area of particular controversy, if you will, as I have interacted with some of the agreement states and individuals.

MR. TELFORD: I thought we were going to get through item two. Maybe we got through objective three as well. Would anybody object to breaking for lunch.

MR. BRICKNER: Looks pretty good.

[Whereupon, at 1:07 p.m,. the meeting recessed, to reconvene at 2:00 p.m., this same day.]

AFTERNOON SESSION

[1:30 p.m.]

MR. TELFORD: Let's pick up the discussion with 35.35, objective number 4. I think we got through the first three objectives, but if a thought comes to you later on, just bring it up and we'll go back.

MR. DEYE: I've always had a little problem with this kind of terminology here, and also, I have seen this -- I guess we even exist under some of that terminology now. To ensure that it's understood, I just -- I am not quite sure how do I ensure that something is understood.

Do we test people? Would that be enough insurance? Do we just do in-services and document the in-services? Do we just look at their credentials and say if they're certified radiation therapy techs or certified nuc med techs that we assume they can understand what a rad is?

You see where my problem is. I'd like guidance on how to do that.

MR. TELFORD: You talked about whether or not the person is certified. You talked about training programs. You talked about, in effect, testing of the person.

Would it be sufficient to leave it up to the individual institution to figure out which subset of those that they should use?

MR. DEYE: If you're willing to do that, that's

fine with me.

MR. TELFORD: We would like to see -- in our guidance, we will say something -- we'd like to see some subset of those.

MR. DEYE: Okay.

MR. TELFORD: We can't -- for example, we can't say, yet, you must use a certified technologist, or we don't have minimum training qualification requirements for technologists yet. So, we can't say any of that. But we could say you should utilize certification, training, testing, counseling, whatever is required.

MR. SMITH: We have, for example, a Chinese physicist whose original language was not English, and I found out, after he has been there about eight years, that he was doing something horribly wrong in connection with the lead shield, and he swears to God that's exactly the way he was told to do it when he first came, but it was really just a language problem.

Ensuring somebody understands something, you can really go to great lengths to educate the controlling. But for example, if their primary language is not English and their first language is not English, you can still be in trouble.

MR. CAMPER: Well, similarly, we have a practical problem there, too, ourselves. How do we inspect that you

ensure?

Again, you're going to be getting back to looking at things in the inspection process, like -- first of all, when you're developing a QA program, you've got to talk about these kind of things, whatever it is you're going to do. You're going to hire certified technologists, or you're going to look at their training experience, whatever.

When our people go in to inspect, they're going to look to see if this element of the program is in place and what you say you're going to do about it. They're not going to look at it and second-guess whether you have, indeed, ensured that or not.

I can understand why that term troubles you. But we have the same problem. I don't know how we would ensure.

MR. SUNTHARALINGAM: I don't know if that would even be stretched to the extreme that far. Every patient, every prescription, you have to ensure that the prescription is understood, and therefore, will they require another level of discussion?

MR. BRICKNER: Suppose you're putting your standard procedures for your department, as we do in ours because of my temper, that no technician is to begin a treatment if there is any question in her mind as to the intentions of the physician or the statement of the prescription. They are to go and ask me even if I am

irritable or ask my partner if they don't want to talk to me. But the policy is they will never be criticized for coming and asking for clarification.

MR. SUNTHARALINGAM: Policy is one thing, but ensuring that somebody has understood --

MR. BRICKNER: Doesn't that meet the "ensure" that they understand by putting a policy in place that says if you don't understand, you are to go ask?

MR. SUNTHARALINGAM: You're asking a clarification.

MR. BRICKNER: Would that ensure it?

MR. CAMPER: Yes.

MR. SMITH: The objective is to ensure -- just like before, we talked about the executive -- is to prevent accidents, you know, misadministrations. That's up here to get past objectives very quickly and get on to what's more important issues.

MR. TELFORD: May I answer your question?

We do not expect that you would document the fact that the prescription is understood for each and every patient. We do expect that your quality-assurance program would have an element in it which addresses this objective, as, for example, the way Dr. Brickner suggests he does in his.

MR. SUNTHARALINGAM: Is this now being clarified

that this clinical procedures manual is only for diagnostic? I was concerned. On the definition page, it was left somewhat ambiguous.

MR. TELFORD: We will do our best to clarify that it's only diagnostic procedures.

Is everybody willing to move to objective number 5?

MR. PAYNE: I assume, on Part B, if terminology were to change, one can substitute written directive instead of the prescription?

MR. TELFORD: Yes, that's correct.

MR. BRICKNER: I don't understand exactly what --

MR. TELFORD: What 5 says?

MR. BRICKNER: Yes. I think 5 is redundant and kind of unnecessary. You say there must be a plan and it must be understood. Now, you're saying it must be -- that the use is in accordance with the plan.

MR. TELFORD: You did it.

MR. BRICKNER: Okay.

MR. TELFORD: Well, I mean, don't let that stop you. If you want to combine 4 and 5 or you want to take away one of them or --

MR. BRICKNER: I don't think it adds anything to it, but if you feel that you need it or you're more comfortable with it -- I don't know how I am going to ensure

the medical use -- well, anyhow, chart review will do that.

When I'm reviewing the charts, if we did what we said we wanted to do, then we did it in compliance with the plan.

MR. TELFORD: Yes. Then you have an element that addresses 5 on chart rounds, and probably all of you do that.

Any other comments on 5?

[No response.]

MR. TELFORD: Okay. We'd be willing to move to 6? This just says get the right patient.

Now, here, we will say redundantly identify or redundantly verify. We're looking for two -- we now realize we should have used the redundant word, because we were looking for the two methods by each patient.

Just as when we're talking about referrals, you said name and something else, like Social Security number, date of birth. We're looking for two ways to independently --

MR. BRICKNER: Their signature would be on, certainly.

MR. TELFORD: If you have something to check it with, yes. Driver's license --

MR. BRICKNER: Oh, no, no, no, no.

MR. TELFORD: No?

MR. BRICKNER: No, no, no, no, no. No. That's going to the ultimate --

MR. TELFORD: Okay. Explain it to me then.

MR. BRICKNER: Well, if the patient comes down, you want me to redundantly identify the patient. I go over and I look at the bracelet and it says "Jones," and I say, "Are you Mrs. Jones?" And she says yes. I say, well, Mrs. Jones, you've got to sign this before I can treat you. And she writes "Mrs. Jones." I've done it three times now. But certainly, I am not going to ask her for her driver's license to check the quality of her signature.

MR. TELFORD: Any two will do.

MR. BRICKNER: Okay. But I must document it.

MR. TELFORD: No. This says you have to have an element in your QA program that has a procedure that says you will do that.

MR. DEYE: One of the two, for example, might be that you call a patient back from the waiting room by name, and the patient that shows up, you look at their Polaroid picture in the chart versus their face; that's number two, also.

MR. TELFORD: We did learn something from our volunteers. At one hospital, the technologist goes to the receptionist and says would you point out Mrs. Jones to me? And he goes over to Mrs. Jones and says, excuse me, but my

name is so and so, what's your name?

So, rather than calling out the "Mrs. Jones, please come back," because there may be three of those sitting in the waiting room, then you go the other way. You ask them to tell you their name.

Then you need one more.

MR. BRICKNER: Any two.

MR. TELFORD: Any two. All right.

Are you willing to move to number 7?

This says identify any deviations. For instance, in your chart rounds --

MR. BRICKNER: Unintended.

MR. TELFORD: Unintended deviations, yes.

MR. BRICKNER: A lot of us are deviate.

MR. TELFORD: For instance, in your chart rounds, you would see that the prescribed dose is being given in this daily fraction or not. If you're a little bit over, then you make note of that fact, but you have a procedure which tells you to do that.

MR. BRICKNER: This is the term that I referred to that you have in here that I think could replace some of the misadministrations, the unintended deviations.

MR. TELFORD: Okay.

MR. SUNTHARALINGAM: Our feeling was that the term "unintended deviation" may not be as strong and legalistic

as the term "misadministration."

MR. TELFORD: Okay.

MR. SUNTHARALINGAM: I mean it's, again, a term that you people have used here.

MR. TELFORD: Well, we've used three. We used "misadministration," we used "event," we used "unintended deviation."

MR. SMITH: I think you need to just avoid misadministration entirely, because it's --

MR. TELFORD: Okay. We'll get to that.

Any other comments on 7?

MR. DEYE: Well, again, prescription would be written, whatever we said.

MR. TELFORD: Directive?

MR. DEYE: All right. Fine.

MR. TELFORD: And the referral procedure would be something analogous to what we described, if it's, indeed, not a written referral?

MR. BRICKNER: And diagnosis, yes.

MR. TELFORD: For diagnosis? Okay.

Is everybody willing to move to number 8?

MR. BRICKNER: That's where you have a problem, because as I mentioned earlier, you brought in a new term, "treatment planning," and you juxtapose it with "prescription," which is now replaced by "written

directive," but you have -- nowhere in your document do you describe what treatment planning is.

Now, that may be fine. Perhaps it's best just to leave it alone, let us define it ourselves. It could be a point of some contention as to what does treatment plan mean.

MR. PAYNE: I don't know. Is this really what's intended, or is it really intended that the treatments are in accordance with the written directive?

MR. TELFORD: That's number 5. This is planning.

MR. SUNTHARALINGAM: Defining your concept of his treatment plan.

MR. PAYNE: Is this like a computer treatment plan?

MR. TELFORD: This is when you're trying to, for instance, figure out the shape of the curve, the isodose curves, and which one you want to use, or any other way you want to modify the beam.

MR. SMITH: Are you really trying to ask if these are in congruence? Because it doesn't tell how the treatment plan should be. I don't know if I understand what you are trying to say here.

MR. TELFORD: Well, let's back up to the concept of something like a preplan. The authorized user has decided to give 6,000 rads to this tumor, and so, the

authorized user says please generate a treatment plan for me.

MR. BRICKNER: Three fields, four fields, rotational, but I want 6,000 here, and I don't want any to the rectos.

MR. SMITH: Yes. But a treatment plan, that just gives you isodose curves. I don't understand what's going on here.

MR. BRICKNER: That's my whole point.

MR. BOGARDUS: Let me fill something in here, because this is something that I have struggled with a lot of times.

You're using the incorrect word. You should say "ensure that the brachytherapy and teletherapy treatment plan," not "treatment planning." "Treatment planning" is a cognitive process that the physician goes through, which is basically his generation of this written directive that you were talking about earlier.

That is -- treatment planning -- it's a thinking process that I, as a physician, do. I decide on where I want to treat, how much dose, fraction, the machine energy. This is all of my treatment planning.

But a treatment plan -- I assume what you're talking there is a teletherapy isodose plan, which is whole different ballgame. So, we need to get that cleaned up.

MR. CAMPER: That's planning, then, versus the plan.

MR. BRICKNER: Yes. "Ensure that the brachytherapy, teletherapy treatment plan is in accordance with the prescription," followed by the definition of "treatment plan," a document or graphic that represents the details of the specified treatment.

MR. SUNTHARALINGAM: Even there we will have a problem, and I don't know why we need item 8, because you know, in the prescription or the written directive, there is no statement -- and I hope you are not asking physicians to make a statement -- about dose to isodose surfaces or anything else. We got around that by saying that will not be included in the written directive.

So, now, you can't say in accordance with the written directive. All the written directive said we want to deliver 6,000 centigrade to this target, period. That's all that the written directive would have said.

So, now, to say that -- to ensure that it is in accordance with the prescription, to me, there seems to be redundancy. You are first asking ensure that the use is in accordance with the prescription, which is fine. And you're also saying ensure that there is unintended deviation and that is identified and evaluated.

So, now, what does 8 add more than what is said in

5 and 7?

MR. DEYE: If you really want to get at the treatment plan, because I know there have been instances that are even recorded in your misadministration of dose history there, would it not be acceptable to say the quality-assurance program has to ensure that the treatment plan in the patient's record, if one is included, because many times they are not, but if one is included, has to have been authorized by the signature of the physician?

MR. FLYNN: The problem is some physicians may be ordering a treatment plan and then not checking it prior to the completion of the treatment of the patient. If he or she had checked it, they would have discovered a problem. Well, they shouldn't have ordered a treatment plan unless they would have checked it.

MR. DEYE: I agree. I think, therefore, they should be held to evaluating it and signing it if it is going to be made part of the record. It may be, when they look at it they learn no new information from it. They say, throw it away, we're not going to use that, so they don't put it in the chart.

But if they decide there's information that is worth saving, they must sign and date it, and it becomes part of the record. And the Q.A. program has to require that signature and dating them and, therefore, implied

evaluation by the physician.

It doesn't quite address as much as what you wanted here which says that, in addition to that, somebody is assuring that the treatment is in exact congruence with treatment plan. But aren't we doing that elsewhere in this Q.A. program when we say that the use is in accordance with the directive.

MR. BRICKNER: What you're saying is then that the treatment plan, if it exists, is in congruence with the prescription.

MR. DEYE: I don't use prescription. We're going to use written directives. A written directive is not going to include the details of a treatment plan. So, no, I'm not quite saying that. I agree with Sunset.

MR SUNTHARALINGAM: I'm still debating to hear what does number 8 add. What have we missed?

MR. TELFORD: Number 8, this area of planning and calculating, there have been a lot of cases, several cases, of mistakes being made, especially with high dose after loaders and with teletherapy.

MR. SUNTHARALINGAM: Yes, but isn't that all in item 7?

MR. TELFORD: That's after -- item 7? Yes, but that's after the fact. When you're doing the planning or you're generating the treatment plan, as Dr. Deye is saying,

if you have somebody sign off on it, if you have the authorized user sign off on it and agree to it, then that's the step that you want to happen.

You would like to have the over-check happen before the fact.

MR. FLYNN: You could have the phrase, 'if there is a treatment plan, comma, prior to completion of the treatment', so that it's checked some time --

MR. TELFORD: Prior to completion or prior to start?

MR. FLYNN: Well, it's not always -- that's what I said. We may be loading the doses.

MR. BRICKNER: And order a plan and get it on the third day, and modify or not modify your treatments.

For instance, you start four fields to the pelvis and you tell the dosimetry folks, run me some contours. And they run the contour and they try different wedges and they bring you back three plans and you pick one out you like. And it may or may not change what you're doing.

But I agree that, if you have that document in your hand, then you should sign it. You can't get paid unless you sign it, and you should sign it if you ordered it. You are to sign it and look at it.

MR. SMITH: Mr. Telford, are the[illegible] any indications, particularly for palliation treatment? For

there may not be a treatment plan.

MR. TELFORD: I'm glad you said that. We have had two --

MR. SMITH: There may be a calculation, but I mean -- but he doesn't say it here. There may not be a plan.

MR. TELFORD: We have had two suggestions for adding that phrase. But you see, in the case of teletherapy, doesn't the ACR say to have this plan and have it signed off within two fractions?

MR. BRICKNER: That's where we're having a lot of semantic problems. Because, in the ACR the quality assurance program discusses a treatment plan which is the same thing as a prescription which is pretty much the same thing as a written directive in that the treatment plan specifies total dose number fractions and site to be treated.

MR. BOGARDUS: That's an isodose plan.

MR. BRICKNER: That's a treatment plan, according to the quality assurance program. And yes, that should be checked and signed off.

Now we're talking about something different. Because we're not using words the same way now. You're using words differently. You're using prescription -- you want to change it. But you're using prescription like I use treatment plan, and you're using treatment plan as, Dr.

Bogardus says, like an isodose plan.

That's all fine, but somewhere we've got to say that.

MR. KLINE: That's a good point you bring up because there are, on treatment planning, computers also individuals who interject let's say a separate computer program or hand calculation and put it on to the treatment plan. The factors, like wedge factor, will not use a block.

Then, on that plan, might be the isodose curves you generated for that beam profile and that tissue to see what you want to deliver, at what area, what anatomical region.

This plan, I think the intent here was that it includes all that information, not that it's eliminating or separating out the written directive or prescription. But what I think the intent was is that we don't want people missing that they should put a wedge in that field, or they use the wrong wedge, or that they didn't block, according to your direction, the field or shape the field. They use a regular field, or things of this nature

MR. SUNTHARALINGAM: That may not be in the prescription or in the directive, no?

MR. SMITH: That's in what we call the set calculation. So we have a set calculation, a prescription and then a treatment plan or isodose chart. Three very

separate, distinctive things which occur.

MR. SUNTHARALINGAM: It looks like item 8 is identifying that you need to ensure that the bracket therapy and teletherapy dose calculation -- is what you're after from what you say -- is in accordance with something. But it can't be in accordance with the prescription.

MR. DEYE: Nor even with the written directive.

MR. KLINE: If you have a way to write a regulation that would address these things that I just talked about, the split beam devices, the things that are used that are critical to that delivered dose, how would you write it?

MR. DEYE: Why not put it -- if I get the gist of where you're headed, maybe I was wrong -- why not say that the documentation of the treatment record shall not be contrary to the written directive for the patient's treatment. Put it in the negative.

MR. TELFORD: I don't understand. Why?

MR. DEYE: Well, for one thing I leave it open that a written document cannot -- it can be more than an isodose curve, which is what this seems to home in on. It can be just columns which indicate field size, whether or not a wedge is used, what the wedge angle should be, what the gantry angle should be, etcetera, etcetera.

That is a little bit more than what you even seem

to be saying in item 8. So I'm just saying the documentation in the chart, the documents, the specifics of each of the treatment fields, should --

And instead of saying it has to be in accordance with the written directive, because the written directive may not be that specific, I put it in the negative and say it cannot be contrary to the written directive which I think allows one to have more things in the documentation in the chart than were ever brought up in the written directive itself, as long as they don't go in contrary nature to it.

Because, as is being said here, this is an evolutionary process. It doesn't all get done within one hour of the patient's showing up for day one, as you are well aware. You know.

We have the written directive and then maybe evolving over a two or three day period of time, we have isodose curves, we have the actual simulation and the documentation of the chart of the various factors that go into each treatment field.

And the treatment may have begun during that three day period of time with some preliminary say so on the part of the physician.

So, it's this kind of amorphous process that changes from institution to institution. As long as nothing gets written in the chart that countermands the original

written directive, it should be accepted.

MR. SUNTHARALINGAM: That's fine. Let's try another one and see again, since you have --

MR. DEYE: They haven't answered that one yet.

MR. SUNTHARALINGAM: I see. Well, enter the bracket therapy and teletherapy treatment is delivered in accordance with the prescription.

MR. TELFORD: That's number 5.

MR. SUNTHARALINGAM: That's number 5. That's what I say, some are repetitious. I don't know what sort of Q.A. program do you anticipate to satisfy item 8?

Obviously these are objectives and later on now we will have to describe a Q.A. program. What are you after in a Q.A. program?

MR. CAMPUS: Well, if you have a particular tumor and the therapist has identified what he wants and how he wants to treat that tumor, you then prepare a treatment plan to build your computer modeling and what have you.

What is the best term to characterize the fact that the proper treatment plan is developed to suit the prescription or the written directive, if you will, the therapist asked for to treat that tumor and that patient?

MR. BRICKNER: Exactly what you have here, which is fine.

MR. DEYE: Well, except that there could be

multiple --

The written directive -- we shouldn't say prescription --

MR. KLINE: Why?

MR. DEYE: -- Will not specifically -- because we've agreed not to, that's why.

MR. BRICKNER: Ed, you don't want to say -- probably though plan is what you want to say.

MR. DEYE: That's right, plan.

MR. BRICKNER: I agree. Because we're talking about a noun. But go ahead, why is it we don't want to use that term?

MR. DEYE: Well, I'm saying there's more than one treatment plan or one isodose curve system that could meet the directive. There's multiple ways to treat and still meet the directive.

So, I would rather put it that way.

MR. BRICKNER: But you can't say that it is in accordance with. You can say it is not contrary to.

MR. DEYE: Well the one you choose to use is in accordance with.

MR. BRICKNER: If you sign off on it, that's fine.

MR. SMITH: If you say treatment plan and maybe -- we've got to get the other calculations in here. If you're going to try to cover this waterfront, the treatment plan

and the set calculations, you must say, 'treatment plan and related calculations are in accordance with the prescription'. How's that?

MR. TELFORD: Or how about, 'are approved by the authorized user'?

MR. SMITH: Yes. That's even better.

MR. BRICKNER: What you might do is take the sentence you have and say, 'ensure that brachytherapy and chemotherapy treatment plan is in accordance with the prescription and approved by the prescribing or responsible physician'.

MR. SMITH: Except you just left out the other calculations, which may be all right.

MR. BRICKNER: And other calculations?

MR. SMITH: Except calculations are usually done independently of the prescription.

MR. BRICKNER: Well, you calculate the monitor units which brings in the wedge factors and things like that.

MR. SMITH: Oh the set calculations.

MR. SUNTHARALINGAM: Is this item purely addressing calculation of dose?

MR. KLINE: No, not purely, not entirely. Item five we felt was a little too broad of an area. See, we're starting to get a little more prescriptive and a little --

MR. SMITH: That's right.

MR. KLINE: But it's necessary that you address the significant features, the minimum requirements, to satisfy the intent. We felt that number 8 might more focus on the problems that have been developed in the history that you have in the front here over missed wedges, wrong wedge factors, put in backwards, dropped in it. Trays, the modification devices, compensators, whatever, that were supposed to be used that weren't used.

MR. SMITH: Wedge factors, tray factors, compensation factors.

MR. KLINE: That could add up, or could be a one shot deal.

MR. SMITH: But if you say related calculations, treatment plan and related calculations --

MR. SUNTHARALINGAM: Let's say that again. Enter that bracket therapy and teletherapy treatment plan is carried out in accordance with the approved written directive. I mean, something like that.

What you're trying to see now is, once a physician has accepted a plan, you are now asking how do you ensure that that plan is being implemented.

I mean, if the plan requires three angle beams

MR. BRICKNER: No.

MR. SUNTHARALINGAM: No?

MR. BRICKNER: No, that's number 5.

MR. SUNTHARALINGAM: That's still number 5?

MR. DEYE: Right.

MR. BRICKNER: We ask did you check the plan and is it in compliance with your original stated desire?

MR. DEYE: Right. That's all they're looking at.

MR. SUNTHARALINGAM: So it's still a dose distribution that we're after.

MR. KLINE: Whatever your plan, whatever you dictate, whatever you direct, whatever you want, whatever you write, is carried forward by your technologist, by your physicist, under your direction.

See, we're not saying that you have to have, in a treatment plan, certain key parameters. They're pretty much up to the way you would like to administer that therapy.

But we are saying that there are some key parameters that we realize that, no matter who treats, if you're going to use a wedge or let's say you're going to beam modifying device, you have to use that beam modifying device no matter what, unless you're going to somehow invent a new method by which you can shape that beam, that not many people are doing for Cobalt-60.

So you're going to have to have something to address that key element. We're just saying that, under your prescription or your written directive, that you

address that. Don't eliminate it, don't forget to put it in, or don't let the technologist not see what you mean by that directive.

MR. FLYNN: If we're interpreting this in different ways can you imagine how the people in North Dakota are going to interpret this?

Under treatment plan, should you put in parentheses, 'such as computerized isodose curve or associated calculations' as an example to explain what you mean?

MR. BRICKNER: Under definitions they're going to have to put a paragraph in on what a treatment plan is.

MR. SUNTHARALINGAM: Yes, from this discussion it's a vital matter which is still left rather vague as to, one, it is necessary and, two, what is it really addressing and what is it trying to catch or identify.

MR. TELFORD: It's trying to catch errors in calculations, errors in the plan, in the planning.

MR. FLYNN: Some physicians have ordered computerized unit planning and then never checked them until the patient's finished treatment and then there's a problem in the treatment plan that he ordered. Why did he order it if he didn't check it.

MR. SMITH: Sometimes there are sub-calculations done that aren't checked by the physicist.

MR. FLYNN: I think this idea was correct, to put in parenthesis treatment plan, isodose distributions and other calculations. Those in parenthesis. That covers everything.

MR. SUNTHARALINGAM: And copy in accordance with the written directive.

MR. TELFORD: What if we took out that. I thought I was hearing agreement a while ago that, if we took out in accordance with and said are approved by the authorized and responsible physician.

MR. DEYE: Yes.

MR. TELFORD: Well, we'll have to say authorized user, I believe.

MR. DEYE: Yes. That's been a term for the same thing.

MR. TELFORD: That's you.

MR. FLYNN: Is it?

MR. DEYE: Only an M.D. can be an authorized user.

MR. SUNTHARALINGAM: Or is, like the resident is to approve?

MR. BRICKNER: No.

MR. SUNTHARALINGAM: No?

MR. BRICKNER: I want these teachers to work for their money. They make more than I do anyway.

MR. TELFORD: Okay. Any other comments on number

8?

MR. SVENSSON: I have a comment on one objective item. I've been listening to the discussion here and, of course, these objectives are very specific in nature. And almost all of the items we have come to the conclusion that it is up to the individual institution or user to come up with recommendations as to how to deal with these issues.

Earlier today we heard also that those institutions, there are a number of institutions and a number of authorized users out there that do not have good quality assurance programs. The reason for that, as was pointed out, is that they may not have access to qualified experts.

Now it seems to me that, if the individual authorized users are coming up with these kinds of programs on their own, then there has to be a mechanism to make sure that the program is reviewed by a qualified expert.

MR. BRICKNER: Paragraph. The licensee may make modifications to the approved basic quality assurance program -- may not.

All right. The licensee may make modifications to the approved basic quality assurance program without NRC approval only if the modifications do not decrease or potentially decrease the effectiveness of the basic program. The licensee shall furnish the modifications to the NRC

Regional Office within fifteen days of the modifications being made.

Modifications that decrease or potentially decrease the effectiveness of the program may not be implemented without prior written approval from NRC.

They're telling you once your program is approved you can't change it unless they know you changed it and say it's okay.

MR. SVENSSON: My point though is that these institutions that are now allowed to formulate their own quality assurance programs may not have representation of qualified experts. This is completely contrary to all those voluntary efforts that ACR and ACMP have gone into. Where the term qualified expert becomes a very pivotal point.

In fact, all those programs have to be reviewed and implemented by qualified experts. I don't see that tie to the qualifications from this particular program.

MR. TELFORD: How would you like us to do that?

MR. SVENSSON: Well, my question is, how do we intend to do it? Because you are running the risk now that someone out there comes up with a program that you approve without the understanding whether that program represents state-of-the-art or not.

Do you have the experts in house, because being an authorized user is not necessarily the same as being a

qualified medical physicist or physician, if I understand right.

MR. DEYE: I think, you know, it's interesting -- if we're jumping around, I'll jump --

MR. SVENSSON: No, no, no, no. This is not to jump.

MR. TELFORD: No. This is on the objectives.

MR. BRICKNER: We've got some people out there that are not physicians and not qualified physicists that are authorized users?

MR. SVENSSON: No. What is an authorized user?

MR. CAMPER: An authorized user is a physician that has presented their training and experience to the agency, and has been found to meet some minimum level as set forth in the Regulatory Guide. This is typically either certification by the recognized boards or some minimum level of didactic training and/or clinical experience.

MR. SVENSSON: Now, of course, the ACR program requires a qualified medical physicist to approve the physical aspects of the program, and these items here are very much tied to physical aspects.

MR. CAMPER: I'm not sure if I understand where you're going.

MR. TELFORD: He's saying we're not requiring qualified medical physicists to be part of the program.

MR. SVENSSON: That's correct.

MR. CAMPER: And we can't do that?

MR. BRICKNER: Yes, you can.

MR. CAMPER: Here is the problem you get into. You get into a question of, it's one thing to look at an authorized user -- if I understand the context of your question. Let me just take a shot at it. When we look at authorized users, we say, "Okay, you got to show to us some level of training and experience. It doesn't have to be board certified." Are we still getting into the concept of a qualified medical physicist? What is a qualified medical physicist?

MR. SVENSSON: It's been defined. It's fairly well defined.

MR. CAMPER: Let me just finish the answer. The problem we have right now is that if we're talking about radiation safety officers, we look at it and can call for a certain level of training experience that a physicist has to demonstrate, be it a health physicist or a medical physicist, to be an RSO. Right now, we do not have a requirement for some minimum level of training experience to be a medical physicist or a health physicist or a dosimetrist or a technologist.

MR. SUNTHARALINGAM: No. You have it --

MR. CAMPER: Let me finish. With the exception of

teletherapy --

MR. DEYE: Yes. As to the calibration of a cobalt therapist, you do require credentials.

MR. CAMPER: Of course we do, and that's a state level of practice. It's not a medical physicist across the board.

MR. SVENSSON: But it has to be pointed out in this document, because otherwise you leave yourself open for the possibility that you are approving a program which does not represent the state of the art of the volunteer efforts.

MR. CAMPER: I understand, and, you know, I may personally share that concern, but the problem we've got is I don't think anyone would argue that having a specific type of individual recognized as a qualified expert to do teletherapy calibrations and what have you is distinctly different, if you will, than approving an overall quality assurance program.

MR. TELFORD: How does the volunteer program do it?

MR. SVENSSON: The volunteer program very clearly spells out the meaning of a qualified medical expert and his role in the program. It said on the first page, in the ACR model program, exactly what that means and exactly what the expectations of him is in regard to the program.

MR. TELFORD: Does everybody have to follow it?

MR. SVENSSON: We're not talking about that.

MR. BRICKNER: No, everybody does not have to follow it. It's a suggested quality assurance program to meet joint Commission requirements and to improve the quality of your departmental function, but it's not a legal requirement.

MR. SMITH: Do you make a distinction between setting up a quality assurance program and carrying out a quality assurance program, because carrying out one involves all kinds of calibrations and so forth, which, of necessity, requires a qualified expert. So do you make a distinction between setting up the program and carrying it out, because carrying it out, there's no question you need a qualified expert because you have calibrations and other things involved.

MR. TELFORD: Well, I'm not quite sure what Dr. Svensson wants here. What we're saying here is that we've got other sections of Part 35 in 10 CFR that address things like calibration which have other requirements. Now, these are in addition to all of those. But I thought that he was searching for some use, some specification for qualified medical physicists.

MR. SMITH: You see, I think somebody could set up a quality assurance program because you -- but those documents are written. I mean, you can just take them and

put them in place. But to carry it out, you'd need a qualified expert to set it up -- you don't necessarily.

MR. SUNTHARALINGAM: There is a lot of discussion when we come to how the program is to be implemented.

MR. PAYNE: I didn't mean to say I was jumping around, but in your guide, you do indicate that audits will be conducted following approved written policies and procedures by qualified personnel who are not involved in the activity being audited. In other words, a radiotherapist should not be auditing his own prescriptions because he's involved in that. That's interesting. That's on page four of the Guide.

MR. TELFORD: We're not quite to the Guide yet.

MR. PAYNE: I know.

MR. TELFORD: Do you have a suggestion, Dr. Svensson, for what we should do?

MR. CAMPER: And characterize that, if you can, as it relates to one or more of the objectives.

MR. SVENSSON: Well, I think my question refers to how you plan to ensure that the program that you are accepting from these authorized users out there, when they don't have a program, how you are going to ensure that that program represents the state of the art of quality assurance in radiation therapy.

MR. KLINE: See, the NRC does not insure it. The

licensee has to insure it to the NRC. See, it's their responsibility. In other words, if they have to contact or contract to a physicist that is qualified, that's their option.

MR. SVENSSON: But you are going to accept the program.

MR. KLINE: That's correct. We accept the program --

MR. SVENSSON: On that basis.

MR. KLINE: Based on the review by licensed reviewers in the NRC that will look at the basic QA program that they submitted as they address each issue.

MR. SVENSSON: But those license reviewers may not have the qualifications which is required by the volunteer programs to come up with good quality assurance programs.

MR. KLINE: If we have a situation arise where we have a highly technical program, where they address very specific point-on-point specifications on how things are going to be done that is beyond the scope of the license reviewer, we do have the latitude to use consultants contracted by the NRC.

We do have the Medical Advisory Committee that we do frequently use to pass through qualifications of individuals to see if they are qualified for the use of material. We do have mechanisms by which we will not just

let a program go through the cracks if we don't feel that they would be able to do what they say they're going to do.

But to come back and say you must hire a qualified expert is beyond the scope or purview of the NRC. We cannot dictate to individuals that they have to hire staff and additional staffing to do things.

MR. SMITH: You can require certain kinds of staff, and you already do.

MR. KLINE: Well, we don't address staffing needs. We just say, If you want a license, you have to meet these minimum qualifications.

MR. SUNTHARALINGAM: It could be done.

MR. BRICKNER: It's the user's problem to provide himself with adequate physics to carry out the program. Now, whether he does it on a contract basis or hires somebody full time, that's his problem. If he doesn't have adequate physics to carry out the program, I would assume that their inspector is going to say, This quality assurance program is not acceptable. You don't have anybody capable of doing the work you said you're doing.

MR. SMITH: But you can cover that in your objectives, can't you?

MR. SUNTHARALINGAM: Well, if I understand the concern correctly -- let me try this again, and I think, again, I'll bring out a statement that was sent to you in

writing by the College of Medical Physics. I think it is to point out, if it has not as yet been recognized, that the NRC presently does not have adequate personnel in terms of numbers or appropriate training to effectively establish and monitor a QA program as outlined in the Federal Register. That was a statement we made, and we'd like to get a response.

MR. TELFORD: How do you know that?

MR. SUNTHARALINGAM: Well, we made the statements, and we are now asking for a response from you.

MR. TELFORD: Can I ask how you know that?

MR. SUNTHARALINGAM: Based on -- and we said here we need to be careful not to repeat the difficulties we have experienced in the past.

MR. TELFORD: That's an interesting allegation. How do you know that?

MR. SUNTHARALINGAM: Because we have experience in the past dealing with ill-qualified inspectors attempting to be called experts in scrutinizing the teletherapy program. So we gave you our concern. If you will now tell us, "Look, we have adequate staff. We know what is a minimal QA program. We know how to evaluate somebody's written QA program," I think that is what I think you are after.

MR. SVENSSON: That is correct.

MR. TELFORD: That's a different kind of

statement. I mean, your statement was just an allegation that the NRC doesn't have adequate staff based on your observation of one or two inspector's performance. So what question are you asking us?

MR. SUNTHARALINGAM: No, no. We raised a concern, but wouldn't you want to then explain to us and say that concern is unfounded? You have adequate, appropriate staff. You have increased your staff. You are bringing in more people. We are expanding the program.

MR. CAMPER: Let me try to get you focused, if I may. Are you referring to, say, for example, page 1449 of the Federal Register Notice, where we talk about an item C 1, 2, and 3, when we say, for example, each applicant for a new license shall submit the appropriate NRC, blah, blah, blah, blah. Each existing licensee shall submit blah, blah, blah, blah. Are you saying that you're questioning the agency's ability to review a quality assurance program that is submitted and the adequacy of that quality assurance?

MR. SUNTHARALINGAM: We have concern about it, okay? And there were some earlier statements made this morning that you are out there also to try to help people out in the Boondocks who don't have, quote, the "qualified experts" or the expertise in-house to put together a state of the art minimum QA program.

Similarly, we in the field have some concern, and

therefore we will need NRC to identify and tell us, "Your concern is unfounded. These are the people that we have added to the staff. This is the level of competence of these individuals, and these are the ones who will be scrutinizing these programs." Then we, I think, as organized groups within our own associations, will feel a little more confident that this program will be reasonable successful.

What I think Dr. Svensson was trying to point out was the ACR and the other documents, even though voluntary in nature, have set the goal having been addressed by qualified experts, both physicians and physicists -- and I'd like to again also correct, if there's a misconception. There is no intent here -- this is not a physics program. This is not a physical QA program. This is a comprehensive QA program. So there is a tremendous amount of input from the physicians, as well as the physicists.

MR. TELFORD: Larry, can I make a suggestion that you kind of give these folks a thumbnail sketch of the people on your staff? But let me correct two things that you said.

You said that we said earlier today that we wanted to help those people in the boondocks develop a program. We're not helping them. We're going to require them to have a minimum program. There is a big difference.

Secondly, this is not a comprehensive quality-assurance program. This is a basic quality-assurance program.

In the fall of 1987, we published an advance notice of rulemaking for a comprehensive quality-assurance program. A couple of years from now, we may or may not be back talking about a comprehensive quality-assurance program.

But let me assure you this is not comprehensive.

MR. CAMPER: I think what's more important is that, if we look ahead and we see this rules becomes effective and we look at the fact that there are going to be license reviewers with NRC that will have to review submitted quality-assurance program, part of the process of doing that is going to be to develop what's called a Standard Review Plan, which our reviewers would follow.

The Standard Review Plans and implementing this program or any new program -- another one, for example, that comes to mind, coming down the pipe, is -- it's very controversial, far more controversial than this is -- is Part 20. Okay?

Anytime you develop a new program and you're going to have to expect to get into that program, then the agency will take whatever steps are necessary to get the training or the types of individuals that is necessary to review

those programs adequately.

Once this becomes a rule, if we assume that it does, we're going through the process, then, of developing inspection guidance. We're going to be developing a Standard Review Plan. And we will utilize the existing staff resources, which are extensive, in the current makeup of our Headquarters group and/or ACUI or consultants or contracts, whatever it takes for the agency to feel comfortable that it has developed an adequate Standard Review Plan and basis for evaluating quality-assurance programs.

Now, I can't sit here and comment to you, because you've had a bad experience with an inspector that you didn't feel was competent to do the inspection, but I can tell you that part of the process is to develop and pursue the kinds of things that I was just getting at. It's hard to be more specific than that.

Now, with regard to the point that John was making, we do have staff right now at Headquarters that has a fair amount of --

MR. SUNTHARALINGAM: It's a dialogue that I think we've already put on record as expressing our concern, and the way it goes from there, that's entirely left in the hands of NRC. But I think, we, as organized societies, some of us do have some serious concern, and that needed to be

aired in the discussion.

MR. TELFORD: Is there something that you would like to see us do?

MR. SMITH: It's the other way around.

MR. TELFORD: I mean is that your point?

MR. SMITH: Why don't we go on? Because we can't answer that question. You know, I don't know how we deal with that right now, and there are lots of important items on this agenda that we must get to.

MR. TELFORD: Okay.

Shall we go to the next paragraph?

MR. BRICKNER: Yes.

MR. TELFORD: What we're calling the "Audit and Evaluation Requirements."

MR. BRICKNER: What does "comprehensive" mean?

MR. TELFORD: We intend to say we'd like all parts of the program to be annually reviewed.

MR. BOGARDUS: How many parts is that? Is it down to every individual treatment or selective case histories, or how comprehensive is comprehensive?

MR. TELFORD: We used the word "audit," because we wanted to give the idea that you should sample the cases that you have, take a random sample of the cases you had over the last year.

MR. BOGARDUS: Wouldn't that be happening in our

normal QA process anyhow?

MR. TELFORD: It probably already is.

MR. BOGARDUS: And our QA minutes, wouldn't they be sufficient?

MR. TELFORD: They probably are.

MR. BOGARDUS: Should we not sort of mention something like that, instead of leaving as nebulous as an annual comprehensive audit, which sounds to me like counting beans in a large jar.

MR. SMITH: Well, "probably" is a difficult word to deal with, too. You use "probably" too often here. When there's a concern here about this, and you say "probably are" doesn't give us much.

MR. TELFORD: Well, I had to say "probably," because I don't know the details of his program.

MR. BOGARDUS: A thousand patients a year. That's going to be a big job.

MR. BRICKNER: We review 10 percent of our charts, which is 1,200 charts a year, or 120 charts a year, in some detail. We review those for the entire quality-assurance program, and we review them for peer review.

Now, I can't think of anything that's in this program that hasn't been looked at in that process, but a report has not been generated aimed at your QA program versus our QA program. But in the future, it could be. You

know, we could modify the review process of our QA program to include whatever else is needed.

Then at the end of the year, can we simply say at our annual meeting of the QA Committee, we have reviewed the 114 charts reviewed this year for many factors, including NRC approval, and we found 7 deficits, and they are blah-de-blah?

Now, does that constitute a comprehensive annual review?

MR. TELFORD: You're really bringing up two points here. One is what's the review program, and the second, how do you report on it? Let's keep how you report on it until the next step, until the next item we'll look at, which is 35.33. But I like everything I heard.

MR. BRICKNER: Okay.

MR. SMITH: You see, "comprehensive" could mean you have to look at every document. On the other hand, randomized selection could also be very accurate. But what do you really mean by -- there is a concern about the word "comprehensive" here.

MR. TELFORD: Give me your favorite word.

MR. SMITH: Random selection.

MR. BRICKNER: "Comprehensive," in this case, meant all aspects of the program, not all charts you have had.

MR. SMITH: That's what we're trying to really determine.

MR. TELFORD: Like if you had 1,000 patients, if you took 10 to 15 percent of those, just guessing, that would probably be a representative sample, and if you randomly selected those and you went through and you compared them, what's supposed to have happened with what did happen, and as Dr. Brickner says, you found 7 things wrong, you put those -- here, let's just stick to what we've got here.

You put that in the evaluation of the findings of this review, and you took those to your management, whatever that is, and there was a determination that the program was still effective, in the face of this, and you have done this. Or if you found two or those that needed modification and you made those modifications, then you've done what's asked for here.

MR. BOGARDUS: Now, let me put a wrinkle into your 10 percent then.

Very few of us run 100 percent of our business on Cobalt. In fact, I doubt seriously if there is hardly anybody left doing that. And you're talking strictly Cobalt and/or Cesium units, of which there are very few left. We do QA on probably 10 percent of our patients, but it includes Cobalt, Linac, the whole nine yards of it.

Do we need to do 10 percent of our Cobalt patients?

MR. TELFORD: Yes.

MR. BOGARDUS: So, it's 10 percent of all of your patients, and that may be only three or four Cobalt patients during the year, then, that have a review.

MR. TELFORD: Well, if it's just three or four, I mean you could do all of them.

MR. BOGARDUS: No, I mean 3 or 4 -- maybe we only treat 100 Cobalt patients in a year, so there's 10 of them.

MR. CAMPER: Well, let me just interject, if I may.

I would submit to you that as you're going to do with all aspects of this program, you're going to develop what constitutes a comprehensive audit.

MR. BRICKNER: Okay. Then, once again, that's another part of the program that, when we send you, if you accept it, then all we've got to do is what we said we were going to do. And if we say we're going to look at 10 percent of the Cobalt patients and you say that's okay, that's all we've got to do.

MR. CAMPER: I dare say that as this process unfolds -- getting back, as I said a while ago, to these things -- when you start getting into developing a Standard Review Plan and dealing with issues that come up in new

programs and what have you, certain things tend to fall out.

What will happen is there will be certain types of deficiency questions that will be developed, and if -- in the process, if the people look at this thing and they're seeing a certain standard being created by the licensees as a comprehensive program, those that are falling well outside that realm will be readily easily identified.

But what constitutes a comprehensive program is going to be something the licensee is going to be determining and will be variable from institution. It clearly wouldn't be the same in, say, a Sloane Kettering as it would be in, say, you know, XYZ Community Hospital in the middle of Montana.

MR. SUNTHARALINGAM: I think I need a point of clarification.

Are we talking about the audit identified as item B(1) on page 1449?

MR. TELFORD: That's correct.

MR. SUNTHARALINGAM: That's, then, different from whatever internal audit that might take place within the department staff for treating the patients. But the way I understood this, this has to be done by somebody not involved with the day-to-day care and treatment of these patients, and secondly, this has to be done at no less -- at a frequency not to exceed 12 months, and again, I want to

point out I think some of us are concerned -- and unless you have some new data -- whether this was included in the pilot study, I am not sure, but the NRC staff has not adequately studied the significant time commitment and the personnel required to do an effective QA or audit program.

Somewhere -- and maybe we are misquoting and misreferring to a statement made somewhere else, something about that this will only require an additional nine hours of effort per year. Somewhere in this document that we are reviewing, there was some statement pertaining to that additional documentation and that additional review process would require only an additional nine hours of effort per year.

So, we feel that something is missing, or we are misunderstanding each other in what is expected.

MR. TELFORD: Do you do quarterly reviews now?

MR. SUNTHARALINGAM: We do monthly reviews. We did it ourselves.

MR. BOGARDUS: Where are we going to get these people to do them from the outside?

MR. TELFORD: There is a misunderstanding. It's not outside.

All we were trying to say in the guide is that you shouldn't audit or review your own work. From a previous discussion with Dr. Brickner -- let me use that example.

He has 9 or 12 technologists, and he has -- you have a monthly review or something like that, where you may choose one or two of the technologists to review everybody's work. Now, if that person, as part of that audit, picks up something that's theirs, maybe so; maybe they are, in that sense, reviewing -- part of the audit is reviewing their own work.

But in the main, they are reviewing other people's work; they're not involved with all that. And if you're worried about that, you can have two people act like a team and use the buddy system, so that one person keeps the other person honest when they come to their own work.

But you don't want to review your own work, because you're blind to your own mistakes; you can't pick them up.

MR. BRICKNER: Well, see, as we understood it, it was to bring in -- I've got to hire something to come down to Tulsa, Oklahoma, once a year to look at 10 percent of my charts, which I'm sure would educate him and he could use it, but nonetheless, I can't afford him.

MR. TELFORD: If you would like to do that, that's probably okay. But we didn't have that in mind, that it would require --

MR. SUNTHARALINGAM: I that a change from what was originally intended? I mean if so, we'd like to know.

MR. TELFORD: No. No, it's not a change. It's what we intended all along. It's just, somehow, the message hasn't gotten across.

MR. SUNTHARALINGAM: Was it something specific in the regulatory guide? I mean somewhere we obviously picked this up, and I'm trying to flip pages.

MR. FLYNN: Regulatory Guide, page 4.

MR. CAMPER: The Reg. Guide does discuss that, and you're correct. Again, this is a guide, not required of people. But this guide will be changed. And the same comment you are making we have heard in the field, the problem of having a qualified expert.

The problem of having what is considered an authority in the field that would be able to come in and do this work can be a big impact on smaller institutions as well as large and big programs and small. And we have had that question posed, where -- what if we can't get somebody in to audit our program that knows what they're auditing? We're the only guy here that does the audit or does the work. And this may be changed, because I realize -- I think the staff realizes it is a problem, and it can be a big impact.

MR. SUNTHARALINGAM: On page 4, it clearly states the audits will be conducted following approved, written policies and procedures by qualified personnel who have not

been involved with the activity being audited.

MR. CAMPER: If you decide to accept the program. Don't forget, this is an option. You can modify any sentence in this page.

MR. TELFORD: We're a little too deep into discussion of the guide, but those words still don't say that. That says people who are not involved; i.e., don't audit your own work. If there's another person from down the hall --

MR. SUNTHARALINGAM: You are leaving certain things for interpretation that can be interpreted poorly by different people, including your own inspectors.

MR. TELFORD: That's a good point. We hear you. We'll fix that.

MR. BRICKNER: You might wish to consider that a great many of the institutions -- certainly not all -- will have quality-assurance/improvement hospital committees, and it would be perfectly rational for me to audit my department if I do it with the hospital's quality-assurance person at my side to, as you say, keep me honest. Here is a person who is trained in auditing quality-assurance work. They will need some guidance about doses and things.

But we could do our own charts ourselves with somebody outside of the department who understands the audit business, and you will have to clear up that we don't have

to bring somebody from out of town or another hospital, because that's the interpretation we have.

MR. SMITH: Almost everyone really believes that you're talking about an outside expert that you have to bring in to audit your program.

MR. SUNTHARALINGAM: I saw a draft of a state regulation, New York State, and they clearly indicate there that you need an expert from outside the institution to come in and audit or double-check their measurements. So, it will filter in if we are not careful about the wording. That was the concern.

MR. TELFORD: Well, we hear you. We even agree. We don't want somebody, necessarily, from outside your organization. Somebody from within the organization can do this annual review.

But just for this paragraph, what it say, an annual review to review all, audit all aspects of the program, a management evaluation of the results, a management determination that the program is still effective, modifications if required. What would you do with that?

My sense is that you're already doing it monthly or quarterly. To answer another one of your questions; no, you don't have to duplicate. If you're doing it monthly, just stack up 12 of them and you've got it. If you're doing

it quarterly, stack up four of them and you've got it.

MR. CAMPER: Your current mechanism by which you comply with -- well, not comply, but follow the guidelines of JCHO is very similar in concept to what could be as a possible mechanism by a comprehensive audit program, or if you had outside consultants coming, reviewing their audits, if you already have them, and compiling the data to show trends, to show how many errors you had on a certain frequency, annually.

Then you can look at mechanisms by which you can change your focus or your area of concern in that program. These quarterly meetings and this final documentation is already inherent in JCHO's peer reviews.

MR. SUNTHARALINGAM: Some of us may be having these problems, but I think, again, a word of caution: I don't think one has studied this carefully as to the impact of additional personnel and cost to any one licensee. I mean, we just heard earlier that you have to convince your own adminstration that you need additional staff.

Here's one example that he gave in his department where he has one full time technologist assigned as the QA tech. You have to go and justify. Now, that is additional cost to the hospital.

Then if one also requires as a complement later on, the reporting mechanisms to upper management, the

written report, all this takes time and effort and therefore, cost. Our feeling was, unless there is no information built in the pilot study, that this has not been carefully thought out, the impact of this program.

MR. CAMPER: The impact has been thought out, moreso than you think in regards to some of the preliminary information that we've collected and are currently documenting and analyzing regarding the pilot program itself, which does address cost elements and time which we will, I guess, eventually be able to discuss at a later time.

We don't have all that information in front of us, but we have spent a lot of effort looking at that and we have discussed this with each facility during the site visits. We have collected real numbers, not speculative, not theoretical, not projected, but real numbers. They participated and we have the actual dollar values.

I will leave it to John to finish.

MR. TELFORD: Let's see if we can dichotomize here because you're lumping both the performance of the annual review and the reporting of it, and we shouldn't be doing that.

MR. SUNTHARALINGAM: You see, to do the annual review, there's a lot of process and documentation.

MR. TELFORD: All right.

MR. SUNTHARALINGAM: That's before you can even get to reporting. The next phase is management evaluation. For the management to be evaluated, you have to have something in writing, okay, and additional meetings between management and departmental personnel. All this takes time and effort, even before we go to reporting outside the institution.

Some of those big centers may not have this problem.

MR. TELFORD: You said to go outside the institution.

MR. SUNTHARALINGAM: No, when we say we come back in the later steps of reporting, if need be, there are incidents that have to be reported and that's a different level of activity.

Some of those big centers may not have the problem and maybe you could get enough feedback from the smaller centers.

MR. TELFORD: We covered conducting the annual review. You're all familiar with that; you do it all the time.

Let me ask you this: where it says management evaluation of the audits, what aspect of management would you like to have active here?

MR. BRICKNER: Quality Assurance Committee in the

hospital.

MR. TELFORD: If there's not one of those?

MR. BRICKNER: Well, then they're not approved by the Joint Commission. You don't have to worry about it being a radiotherapy client.

MR. TELFORD: How about a private practice, a private teletherapy practice?

MR. PAYNE: You have a problem with the private practice, say, a nuclear medicine license, and to do it in an office practice, they are the management.

MR. BRICKNER: Bob says to just close them. We could use the business at the hospital.

MR. PAYNE: I don't know what you would say.

MR. BRICKNER: Board of Directors.

MR. PAYNE: It may just be a practice of two doctors and they run a nuke med office, one of the mobile nukes.

MR. BRICKNER: So that's the Board, the two guys.

MR. TELFORD: So that is the licensee management in that case?

MR. BRICKNER: Who is the licensee? Management is the licensee, the licensee is the management and there's a new --

MR. SUNTHARALINGAM: My understanding of NRC's definition of management, unless you want to change it, is

that because you have a licensee and there's a management overseeing this licensee, isn't that the current terminology of management within current NRC licensing procedures.

Is that hospital administrators who are the management?

MF. TELFORD: It's the licensee.

MR. SUNTHARALINGAM: No, no, who is the management, not the licensee.

MR. CAMPER: Management is typically, if I understand what you're getting at, management is typically is characterized in the licensing process, as an individual who is responsible for the licensee. It's an individual who is in a position to make decisions and commit financial resources of the institution.

This typically is the hospital administrator or someone in that type of managerial position.

MR. BRICKNER: Or partners in a partnership.

MR. SUNTHARALINGAM: Many have interpreted this as now the next evaluation is at the hospital administrative level and the hospital administration designates this to a QA committee within the hospital and that probably is acceptable.

MR. CAMPER: Again, the licensees will have to submit their individual qualification programs on a case-by-case basis and they will be reviewed accordingly. I would

submit to you that if an institution comes in and it's hospital management or its management partner identifies the fact that a management audit team, a quality control organization, if you will, has been set up to review these kinds of things, that is not uncommon at all.

It's happening all the time right now in the practice of medicine. I don't think the hospital -- in reality, I don't think a hospital administrator is really going to want you to bring up your radiation therapy department records and set them down on the desk and say, take a look at these. That's not going to happen.

There's going to be some management structure in place, a committee or something of that sort, that's typically going to involve the department head and what have you. There's going to be a management review process there.

MR. PAYNE: Hospitals shouldn't be a problem. Hospitals are going to -- our hospital has created a -- we call it quality management. We used to call it quality assurance and now we call it quality management. We're using the Deming model.

It's ongoing quality improvement. We would do exactly that. We would take our comprehensive audit and we would submit it to the Quality Management Department. That's not a problem. I would think that every hospital is okay there, or every clinic.

The problem you're going to have and the problem will be the private practices which are just physician groups; either one physician or a group of physicians. They'll just have to develop their own program, I guess, as to how they can conduct their audit. Then they are they, so they can just do it twice.

MR. TELFORD: Where we say on page 1449, Paragraph B1, where we say, licensee management, in Line 7, licensee management. Would you like to see something other than that? Would you like to see management or designee or Quality Management Committee or Quality Assurance Committee?

MR. BRICKNER: No. If you start designing it for us, you're going to screw somebody. Management means management.

MR. TELFORD: Or designee.

MR. BRICKNER: Yes. When you say management, management is whoever the boss says management is.

MR. PAYNE: Whoever owns the license. The license is given to a something. It's usually like a physicians' group, you know, for instance, Minneapolis Radiology, PA.

MR. BRICKNER: Management or designee.

MR. PAYNE: So, they're the owner of that license and they're responsible for it.

MR. BRICKNER: If you start defining it too narrowly, you're going to make an impossible situation for

some poor guy.

MR. TELFORD: Maybe in the preamble, we could say that it's okay for a designee. It's okay to use a Quality Assurance Committee. It's okay to use a Quality Management Committee.

What would you like to see changed in Paragraph B1?

MR. SMITH: The management would be the ones to implement modifications. The management will recommend modifications? The management will implement them.

MR. TELFORD: Require the implementation of?

MR. SMITH: Certainly, they'll not be implementing anything.

MR. TELFORD: Promptly require modifications within 30 days, something like that?

MR. BRICKNER: Yes, that's better.

MR. TELFORD: Okay, what else?

MR. BRICKNER: It says what you want. What you want is an audit and something done about it. If you say management or designee, you cut some slack on how specific it is and you've made it broad enough so that everybody can get in the tent.

MR. TELFORD: Dr. Suntharalingam, is there anything else you'd like to see changed here in B1?

[No response.]

MR. TELFORD: Dr. Flynn?

MR. FLYNN: I just see this word, prevent. I would but that as will prevent versus should prevent, but I'm not going to argue about that. It implies that it will eliminate -- by having institutions change, but that's okay; we talked about that before.

MR. TELFORD: Okay, this is after the fact, but the audit has found two mistakes that were made last year that can be fixed. So, modifications are made to the QA program with the thought in mind of fixing those two mistakes.

Those modifications that you make; aren't you making those with the idea that you would prevent those from occurring? In fact, they would not have occurred if you had had these procedures in place?

MR. SMITH: Actually, if you didn't put these things and you found the incidence in the first place, you're negligent, because you don't wait a year later to do this. If you found an error in something, you don't wait till a yearly audit, for Christ's sake, to do something.

MR. BRICKNER: Well, you could report it in the audit that these mistakes were noted and the program was modified.

MR. PAYNE: That is ridiculous and silly in the audit to find something that goes back to the beginning of

the year.

MR. TELFORD: That's a good point.

MR. BRICKNER: If that's your requirement, that's what we'll do.

MR. TELFORD: Good point.

MR. BRICKNER: You might put in there that corrective actions taken in the interim will be summarized in the audit.

MR. TELFORD: Yes, that's good.

MR. SMITH: You don't really want to recommend corrective action by checking a yearly audit.

MR. TELFORD: We would, of course, like to see happen what you said.

MR. SMITH: You don't want a system that's producing errors in place for a year before you take corrective action.

MR. BRICKNER: Moving right along to the fun part of the afternoon, --

MR. TELFORD: Is everybody willing to move to the reporting requirements?

MR. SUNTHARALINGAM: Can we just stop? Again, I address that particular concern. Can one just stop at saying the licensee's management shall evaluate each of these audits, including any corrective actions to determine the effectiveness of the basic quality assurance program,

period?

MR. TELFORD: You are in Paragraph B1?

MR. SUNTHARALINGAM: Yes, yes. Where it says, the licensee's management, and I have said, licensee's management or designee or whatever it is, shall evaluate each of these audits and any corrective actions implemented, to determine the effectiveness of the basic quality assurance program, period.

MR. TELFORD: That's good language. Then the licensee shall maintain records of audits and --

MR. SUNTHARALINGAM: And management evaluation. I have a problem with this phrase, in an auditable form. Is that defined somewhere? I mean, you already have an audit.

MR. TELFORD: Yes.

MR. SUNTHARALINGAM: Now you want it specifically in a form that the NRC can audit it?

MR. TELFORD: That means the records are available. They're legible and in a form that can be read.

MR. SUNTHARALINGAM: What does that phrase, in an auditable form mean?

MR. TELFORD: What I just said.

MR. CAMPER: It means it can be reviewed. You don't want it on microfiche.

MR. SUNTHARALINGAM: It says the licensee shall maintain records of each audit and management evaluation for

three years.

MR. TELFORD: Right.

MR. SUNTHARALINGAM: What does the phrase, in an auditable form, mean? It immediately then says, has NRC defined what form they want that in?

MR. CAMPER: Are your record that you maintain that an inspector can look at in auditable form?

MR. SUNTHARALINGAM: Yes.

MR. CAMPER: Well, then, what does that mean?

MR. SUNTHARALINGAM: Somebody raised the question that they can read our reports or they didn't say it's not in a format that agrees with what we can audit.

MR. CAMPER: Our inspectors go into institutions all over the United States and they see records and forms in every shape, form, color, creed imaginable. If you can review them and make a determination as to whether the records are thorough and complete and what have you, then they are auditable.

MR. PAYNE: I'll make a comment here and that is, if they're auditable, if the people are there -- we have surprise inspections. I have definite obligations on my life, my job, and when we have surprise inspections, the records may not be in auditable form because they may not say, this is the audit.

We're going to have to -- I'm sorry I interjected

this here, but the NRC is going to have to change its policy if they expect to get a good inspection onsite. They cannot just show up at 8:00 in the morning and expect me to drop my implant that I've got. I've got a 10:00 implant. I've got a iodine case at 1:30 and I've got a meeting offsite at 3:00.

I cannot stop those activities to conduct a surprise inspection. End of comment.

MR. CAMPER: Well, I would make a couple of comments. One is that for the inspection program to have credence, there is a need to have unannounced inspections. Secondly, I really don't think you want the NRC to tell you how to keep all of your records.

I really think that you'd have trouble with that. I think most licensees would have trouble with NRC dictating to you the form, format and style that you will keep you records in. I really think that would cause a lot of complaints.

It's kind of a no-win situation.

MR. PAYNE: True.

MR. SMITH: You have them all together in some place so that they can be read and understood when somebody looks at them; is that what you mean?

MR. CAMPER: Generally -- to try not be hung up on this term -- generally, this concept of auditable, as I

said, means to be able to be subject to review.

Is that fair, from an inspection standpoint?

MR. KLINE: There's a lot of time involved, I guess, during the inspection process, and this varies among individuals and based on facilities and what the inspectors look for when they inspect. But there can be a large involvement of time that is a waste of time because records cannot be retrieved because records are misplaced or lost or somebody took the computer disk home. So -- and there is a requirement which says you must have those records available within a reasonable time upon request for inspection. So this requirement is not new in that sense.

MR. SMITH: This is nothing new of us to do this. We can do this. This is -- this is easy, let's go.

MR. TELFORD: Does anybody object to taking a 5-minute coffee break, stretch a little bit?

[Short recess.]

MR. TELFORD: Okay, let's to back on the record.

Okay, next, do we want to discuss the reporting requirements, the 35.33 and the 35.34, these proposed reporting requirements. There's -- there's a page in your handout that's labeled "current requirements." I put that there to remind you what -- what's currently in 10 CFR. Hopefully you're already familiar with that, but when you see some of these repeated, we may have repeated it because

it's a current requirement.

But it's still open for discussion because part of our charter is to revisit the definition of misadministration. So, let's keep 2 things in mind here. Defining th e occurrences which would be a misadministration or an event or unintended deviation, and those things which ought to be reported some place and how those ought to be reported.

MR. BRICKNER: I would suggest to you that if we're going to use the word "misadministration," with its connotation of a grievous error, that that be limited to the first 3 items on your list. That is, the wrong source, the wrong patient or the wrong route. From that point forward, we're talking about variations in dose or variations in success of -- or variations in preciseness, and that's different to me.

The term misadministration is such a loaded term, at least in my mind, medical/legally, that I would not lik to refer to it now.

In the second category, starting with item 4, we need to probably talk about each of these. I don't know anything about radiopharmaceuticals and would leave that to anybody here that does. I don't know that 50 percent dose variation is important or not in a diagnostic environment, it would be in a therapeutic environment.

I should think if I were treating with P32 interabdominally or systemically or if I was treating with iodine for metastic thyroid cancer, at a variation of 50 percent, I'd want somebody to be -- I would think it would be legitimate for you to say somebody should be aware that you were off by that much, and if it happened very many times, we need to have a talk.

Now, whether we have to get on the phone and call you about it or whether it appears as a top line item in the manual audit for your inspector to look at, is something perhaps we should discuss or debate.

MR. SUNTHARALINGAM: I guess, so that we're all on the correct wavelength here, we are now addressing what is in 35.33, is that it?

MR. BRICKNER: Yes.

MR. SUNTHARALINGAM: Yes.

MR. TELFORD: It's summarized on this page.

MR. SUNTHARALINGAM: Yes, but there is somewhere earlier --

MR. TELFORD: No, no, no.

MR. BRICKNER: Oh, no?

MR. SUNTHARALINGAM: But there is --

MR. TELFORD: You made some good suggestions.

MR. SUNTHARALINGAM: Are we also commenting on something on page 1442. There are not specifically in there

when they put this out for public comment -- ask for the proper use of the term "misadministration," and the choice or use of the word "event."

MR. TELFORD: We're on the page 1447, the discussion of 35.33, or about the 5th page of your handout that's labeled "Reporting Requirements," 35.33.

MR. SUNTHARALINGAM: To get to those --

MR. TELFORD: Now, if you would, Dr. Brickner made some general remarks about the use of the term misadministration that I think carries across everything.

MR. SUNTHARALINGAM: Yes, but to get to those, wouldn't you think that we need to discuss a little about the use of the term misadministration and the use of the term events?

MR. TELFORD: Please, go right ahead.

MR. SUNTHARALINGAM: I think we tend to endorse what Dr. Brickner said in terms of what might be a serious problem, which was identified as item 1, 2 and 3 on the --

MR. BRICKNER: I was looking at the wrong page, but, still --

MR. SUNTHARALINGAM: Yes, but -- but it's some -- it's repetitious -- it's repetitious --

MR. BRICKNER: -- wrong patient, wrong isotope, wrong route.

MR. SUNTHARALINGAM: It's items 1, 2 and 3 of our

current requirements, still serious in nature, that they can be considered as misadministration.

MR. TELFORD: Now, with respect to 35.33, we've divided those into events and misadministrations. Now events are those things that get reported back to the licensee management, back to your -- to your department, back to your quality assurance committee or quality management committee, whatever licensee management designates. Those things are errors or mistakes that are less onerous than misadministrations, is the intent.

Now, do you find this concept useful at all?

MR. SUNTHARALINGAM: Well, again, somewhere earlier on you're throwing another distinction between misadministration and an event and say a misadministration is indicative of inadequate quality assurance on the part of the licensee, and then you say misadministration involves certain error in the administration of by bi-product material.

MR. TELFORD: What page are you reading from?

MR. SUNTHARALINGAM: 1442, in this description there. And then you go on to say, and other events that essentially involve deviations from procedures. So, you're making the distinction between a misadministration a an error in administering the bi-product material.

MR. TELFORD: We've attempted to list those right

here on this page.

MR. SUNTHARALINGAM: This is not reporting requirements. Yes, but first you need to define what is misadministration and what is an event before you go to what is reportable.

MR. TELFORD: It's all right here.

MR. SUNTHARALINGAM: It's all right there?

MR. TELFORD: Let me lead you through this. We've done 2 things at once here. We have an operational definition for what an event is. In other words, 35.33(A), 1, 2 and 3, those things are events. You make one of those mistakes, you have an event by definition. So that's what they are.

MR. BRICKNER: That's reportable in-house.

MR. TELFORD: The idea is to have those reported in-house. Is that concept useful to you?

MR. SMITH: Yes, it is. I think there was some confusion before of whether both events and misadministrations will be reported in the same way. Apparently they are reported both in-house -- they're all reportable events -- they're reportable incidents, let's say.

MR. BRICKNER: Events are reported to your QA and they will see it, NRC will become aware of it on an annual audit. A misadministration will be reported to the NRC as

well as to your administration and yet to be determined in this discussion. Hopefully outside peoples who don't have any business being reported to.

Misadministrations then diagnostically are items, as I mentioned: wrong patient, wrong pharmaceutical, wrong route, as well as a variation in dose of 50 percent. Does anybody have any trouble with the 50 percent variation? Do you concur that that's a misadministration in a diagnostic setting? I don't know anything about diagnostics.

MR. SMITH: Well, I don't know. I would say that you're talking about --

MR. SUNTHARALINGAM: That is what we are largely accepting today.

MR. BRICKNER: Have you spoken with nuclear medicine organizations, or what was the feedback from your pilot study on this 50 percent variation in diagnostic usage?

MR. TELFORD: The feedback that we're getting on thresholds, in general, like 50 percent is that, as was stated earlier this morning, we would like -- most licensees feel that those things that need to be reported to the NRC are those that both exceed some difference -- some percentage difference.

For example, administered dose is 50 percent different from what was prescribed, and it exceeds some

threshold level because what you're after is trying to capture those events that are threatening, that have the potential to cause harm, that are -- that truly mean something; whereas, in some cases, 50 percent might mean something, in other cases, it might not. So there's an additional threshold that's -- that's captured on the next page under (D), but these are current requirements.

What we're attempting to do is to solicit ideas for how to modify these thresholds. For example, they're 50 percent different currently it says and the organ dose is greater than 2 rem and the whole body is greater than a half rem.

MR. BRICKNER: Wait, there's no "and" in there, as I read this.

MR. TELFORD: Well (D) says that "the licensee will notify the NRC if you have a B missing."

MR. BRICKNER: (A) or (B)?

MR. TELFORD: (A) or (B), in other words, an event or a misadministration, if you exceed one of the following --

MR. BRICKNER: So you can be, you can have (B)(2) --

MR. TELFORD: (B)(2), yes.

MR. BRICKNER: -- and if it didn't meet any of the 3 criteria in (D), you wouldn't have to notify?

MR. TELFORD: Right.

MR. BRICKNER: Well, see, this is more complex than my mind was quite ready for.

MR. TELFORD: But what I want to offer for a suggestion is that we talk about these thresholds because that's, in our mind, the way that we build in some meaningfulness in the reporting requirements.

MR. SMITH: Well, I think you have to because most of those misadministrations ar diagnostic. Doses of more than 50 percent still would have meaning -- no meaning, in terms of injury to patients. I think you have to have these qualifiers in terms of (D). I think that's important.

MR. TELFORD: We have had suggestions from, I believe, the ACMP and the SMN that we rely on something like 50 percent different and it's clinically significant, or it causes harm to the patient. But my difficulty with that is -- is that if we use those words then, among the 2,000 licensees that are NRC licensees facilities, we'd have 1,001 definitions of those terms. So, we're attempting to use some sort of uniform -- think about using some sort of uniform threshold that would say, you exceed this dose.

MR. BRICKNER: I don't know anything about an organ dose greater than 2 rem or a whole body dose greater than 0.5 rem.

MR. FLYNN: I was going to ask the question, what

is the general public, in a hospital setting, allowed in a corridor? For example, a patient in a room next to a patient getting brachytherapy; what is the patient in the enjoining room allowed to get maximum -- unavoidable --

MR. TELFORD: That's where these doses came from.

MR. FLYNN: 500 MR?

MR. TELFORD: Yes.

MR. FLYNN: That's Y4?

MR. SMITH: That's a yearly allowable amount. These are entirely --

MR. SUNTHARALINGAM: It's going to change?

MR. TELFORD: That's out of the new Part 20, but this particular number -- I don't think it -- it's the half -- it's the 5 rem annual to workers that might change.

MR. CAMPER: Part 20 is occupational.

MR. TELFORD: That's -- we're saying that's where these numbers same from originally, but these -- these numbers are open for discussion -- open for suggestion for -- if you don't feel --

MR. PAYNE: I'll be a devil's advocate. I just got a call about 3 weeks ago from a physician. They did just what I told you earlier. A patient came in to this -- this was a hospital and -- north -- a small hospital -- community hospital outside of the metro and the Twin City and they gave -- they did a lung scan. They did -- they did

a technetium aerosol for the ventilation part and they gave technetium macro aggregate albumin for the profusion part and the patient really should have had a CT lung scan.

So the physician reading this said this was an inappropriate exam. They went ahead and did the CT exam. Then the patient happened to be a nuclear medicine worker -- I mean a nuclear reactor worker, he looked at Monticello, the nuclear reactor plant, so he knew about radiation and he said, "I want to know how much dose I got from that 'misadministration' of the lung scan."

So I got called as a consultant/physicist. I could handle the technetium albumin problem. That's -- there are handbooks, it's great. The aerosol, I couldn't handle. I found no data whatsoever on the aerosol. So I called Syncor, Syncor is a big nuclear pharmacy. I said, is the package insert? The radiopharmacist says, good look, there is no package insert for technetium aerosol. He said, "I'll get you some data." I'm still waiting for the data.

So there are going to be situations out there where even good physicists aren't going to be able -- then the next thing I'm going to have to do is I'll say, well now how did -- is this an old man? What was his ventilation rate? How many breaths did he take? What did it look like? Let me look at the films. I'm going to have one heck of a time deciding whether he got 2 rems to his lungs or not.

I'm just posing this as a pragmatic problem.

MR. SMITH: That was going to be my next question -- how in the hell are you going to ask us to interpret? It's nice to say this and it's compatible with other kinds of exposure levels but determining this but determining this in all relevance is going to be real problematic.

MS. PICCONE: The way you're doing it right now, this is a current requirement so for the most part if you use the product information there are some cases like that -- but I mean those are out of the routine as well.

Normally you can just use the package insert.

That's a current requirement now.

MR. BRICKNER: Well, what the current requirement then is that or what you proposed requirement is, if the dose varies from what you intended by more than 50 percent and exceeds one year's allowable dose, it is to be reported.

MR. CAMPER: No. If it exceeds five times or 2 rem to the organ or --

MR. BRICKNER: Yes, sir, I understand -- or five-fold or exceeds one year.

MR. CAMPER: Right, and let me just throw something else out too to add to the discussion.

As it turns out the 2 rem criteria encompasses about 90 percent of the procedures that are performed in nuclear medicine because of the bladder dose.

What you end up with is a number that if you look at (D) above, you go back to (A) and (B) then?

Basically what happens is it catches almost everything that takes place because of that criteria.

MR. BRICKNER: Well, then that obviously is not a very good number because you picked a number that's the normal expected result and it should be something significantly greater than the normal result. If the bladder dose from the normal, properly-conducted study is 2 rem and you are concerned about those that might have meaning to the patient, shouldn't we be talking about 10 rem to the bladder or 5 rem to any organ or something higher?

MR. CAMPER: Those are excellent comments and that's what we were going to ask you.

MR. SMITH: I was going to point up the fact, Ted, that these levels are levels that patients might receive in many diagnostic radiology procedures as a regular course of events.

MR. BRICKNER: Well, I would suggest to you that you follow line 2 in which you said five-fold error in dosage, that five-fold is significant and that certainly seems a reasonable thing to say -- five times your intention is an error, and just multiply 2 rem and 0.5 rem by 5 and say at those levels that is significant to the patient -- for lack of -- or get a consultation with a good radiation

biologist if there's one available and say what level does it mean anything? We know that 2 rem doesn't cause cystitis and doesn't cause leukemia and doesn't hospitalize the patient.

MR. SMITH: -- in the regular course of events, how could it be a misadministration?

MR. FLYNN: Because it has to be in error also.

MR. SMITH: Still doesn't make sense, if you use the same levels that people normally would be allowed to receive.

MR. CAMPER: Well, for example, certain things might -- I think that most people would agree that there are certain categories of these events, if you will, that would be fair to characterize as a misadministration: wrong patient, wrong pharmaceutical, wrong rather than misadministration without any kind of dose rate or criteria but then you start getting into things like, okay, well, it's so many times an error for the intended dose. Well, then, there ought to be perhaps some qualifier or some threshold if you will that is effect-related, for example, and then what constitutes an effect that you what to go with and things like that?

I think that's what we are really getting at.

MR. BRICKNER: I should the think the dose that would be expected in the average person to cause a reduction

in the white count or reduction in the platelet count is in effect dose and a biologist hopefully could give you a number for that observable effect like that.

MR. TELFORD: Like an observable effect like that.

MR. BRICKNER: Yes.

MR. SUNTHARALINGAM: But NRC reasoning, to jump from a 50 percent difference in prescribed dose to now a factor of 5 or five-fold as what is reportable to NRC.

MR. TELFORD: I don't follow your question.

MR. SUNTHARALINGAM: In (B)(2) misadministration, diagnosing and requiring a report says any diagnostic use that ever resulted in administered dose differing from the prescribed dose by more than 50 percent.

MR. TELFORD: Yes?

MR. SUNTHARALINGAM: Now I am just asking for what the pattern of reasoning to say that it now becomes reportable to NRC?

MR. TELFORD: Yes?

MR. SUNTHARALINGAM: If it involved a five-fold error in the dose.

Was there some relationship between the jump from 50 percent to five-fold? Did five-fold have a significance?

MS. PICCONE: It was an effort to reduce the number of reports, the number of misadministrations that you would report to NRC so that the first thing you're quoting

is the definition, part of the definition of a misadministration and then they looked at it and said, well, do we want to hear about all of these, so what can we do to limit the ones we hear about?

MR. SUNTHARALINGAM: Yes, unless there is some clinical significance to this five-fold error is my question.

MR. TELFORD: No, you are just sort of logically trying to encompass the ones that are meaningful.

MR. SUNTHARALINGAM: Yes, but earlier on if I understood the statement correctly it said if you had a 50 percent difference you already are giving an organ dose, bladder dose approaching 2 rem.

Is that what was said earlier on?

MR. TELFORD: No.

MR. SUNTHARALINGAM: That's not?

MR. BRICKNER: What he said was the usual -- the normal bladder dose for most isotopic studies is around 2 rem.

MR. SUNTHARALINGAM: So that would increase it by 50 percent so then item numbers 2 and 3 are vitally differing in their requirements.

MR. TELFORD: Understand that these are current requirements. What you are looking at is currently in 10 CFR. What we are asking for is how did you like -- first of

all, does the concept of saying it should be reportable to the NRC if it is X percent different and exceeds Y rem, does that concept appeal to you?

We're trying to capture --

MR. PAYNE: I guess the Y rem concerns me because we have never, the difficulty here is defining radiation that's acceptable.

I realize that this did not generate, potentially did not generate benefit -- you know, the risk benefit ratio and how much radiation can patients received and still be okay. I am not aware that -- we have never stated how much radiation. We have never fixed the natural dose and we probably shouldn't use rems in here. We probably should be in millisieverts or sieverts or SI units but that's just being facetious.

MR. SMITH: Any time you put down an arbitrary number which cannot be related to an observable effect you are going to have problems with it.

MR. TELFORD: Let's say we put down numbers that are related to observable effects.

MR. SMITH: Well, then, you are closer to home.

MR. TELFORD: Does that concept have an appeal to you?

MR. SMITH: Absolutely because --

MR. TELFORD: It's not arbitrary. If it relates

to something measurable then it is not arbitrary anymore.

MR. SMITH: These numbers I think are arbitrary.

MR. TELFORD: These are current requirements. We are out here trying to figure out what's better.

MR. BRICKNER: I would suggest you either multiply the third one by five or get biological evidence giving you some kind of a basis for a different number, that this number is far too low to be meaningful.

MR. TELFORD: Well, we are doing the latter.

MR. BRICKNER: If you can get a biological statement that has some meaning to it then you have a number that you can support and justify.

MR. TELFORD: Okay.

MR. BRICKNER: But it should be something that gives some indication of harm.

MR. SMITH: It bothers me that you would ever have a reportable misadministration, reportable to NRC at dose levels which in which there are no measurable effects whatsoever in the population. That's a real concern.

MR. TELFORD: I'm sorry -- that's what the current requirements are.

MR. SMITH: We know that but are still concerned about it.

MR. TELFORD: Okay, good, we're together on this.

Dr. Payne, was there something else that you would

like to see rather than saying X percent different and exceeds Y rem?

MR. PAYNE: No, I would follow up with -- you know, I'm not an expert in that area so I would follow up with what Al just said, something that is of biological significance.

MR. SUNTHARALINGAM: Would that be a problem in deleting the statement about dose?

MR. CAMPER: You're saying do not --

MR. SUNTHARALINGAM: Item (D)(3).

MR. CAMPER: -- do not include any dose related criteria is what you're saying?

MR. BRICKNER: In (D)(3)?

MR. SUNTHARALINGAM: (D)(3).

MR. BRICKNER: "Dog."

MR. CAMPER: Leave (D)(2) and eliminate (D)(3), is that what you're saying?

MR. SUNTHARALINGAM: Yes.

MR. CAMPER: So you don't want doses related to measurable effects?

MR. SUNTHARALINGAM: No -- but I am trying to get adequate biological criteria and arrive at a dose level that is reportable or meaningful may again keep you people working around for years.

MR. SMITH: We can't force them to do things but

we must ask them if they give us numbers they cannot be arbitrary and they must have some meaning in terms of biological effect -- sure, it's difficult but you must do it.

MR. FLYNN: For whole body dose -- and by whole body dose you need at least 15 rem to get the small chromosome changes and 50 rem to get the lymphocyte count depression, slight lymphocyte count depression.

MR. BRICKNER: So we are talking about a hundred times.

MR. FLYNN: Well, does it have a measurable effect? You need 15 rem whole body dose to get some chromosome changes. That's the minimum you need and about 50 rem for slight depression in lymphocyte count, whole body exposures.

MR. BRICKNER: So we are talking about 100 times.

MR. FLYNN: This is data from Oak Ridge and other places.

MR. BRICKNER: We sure do need to take those up with some kind of meaningful --

MR. BOGARDUS: Is not some of this set of numbers though related back to that neat little word you had a while ago about the theoretic cancer formation problem?

MR. FLYNN: Yes.

MR. TELFORD: Dose levels?

MR. BOGARDUS: Yes -- well, your dose levels were set and then it kept getting racheted down.

MR. TELFORD: Very minor -- what is it? Ten to the minus six per rad?

MR. PAYNE: But, see, these people are -- this is going to be a small group too. This is not every single person falling into this misadministration route.

MR. BOGARDUS: I fully understand that and even things like 2 rem as to which organ, you have got to figure out what organ you are talking about but even a technetium bone scan gives you probably more than 2 rem to the bladder because that is the end organ of excretion.

MR. CAMPER: There are very few procedures that do not meet the cutoff.

MR. FLYNN: It might be the whole body -- organ dose is meaningless, I think.

It's the whole body dose that has any significance at all, even for cancer.

MR. BRICKNER: If you happen to be dealing with an agent that was highly concentrated in the marrow space, for instance, it might be meaningful when you say organ dose rather than whole body.

MR. FLYNN: If they say whole body dose they mean whole body bone marrow dose is what's typically meant.

MR. BRICKNER: That's what the definition is, yes.

Let us say that a hundred times this much or a biologically supportable number is our recommendation to you.

MR. PAYNE: We've got to do some more work on this.

MR. TELFORD: We are doing that work. We will agree.

Would you like to move to the therapy ones?

I'm sure you can really sink your teeth into those.

You have been wanting to talk about these all day.

MR. BRICKNER: These are events or misadministrations and you haven't broken them into groups?

MR. TELFORD: We followed the same strategy here, all the things that are (A), these five things are events. You turn the page -- the four things that are labelled (B), those are misadministrations.

Okay?

MR. BRICKNER: I would suggest that Number 3 is --

MR. SUNTHARALINGAM: Item 5 --

MR. TELFORD: Let's take them one at a time.

MR. BRICKNER: You're saying that if you don't have a prescription and you haven't seen the patient, you shouldn't be treating them.

MR. FLYNN: Yes.

MR. BRICKNER: That's an event.

MR. BOGARDUS: No problem with that, that's an event.

MR. TELFORD: Okay.

MR. BRICKNER: You looked surprised.

MR. TELFORD: I'll take yes for an answer. How about No. 2?

MR. BRICKNER: Yes, it should be recorded daily.

MR. BOGARDUS: I agree.

MR. FLYNN: I'd make it 50 percent or throw it out. I'd make it a cumulative weekly dose, because I think quality assurance and weekly status checks are the thing of the future. I think that if it's a weekly, cumulative dose, it has more, and if a machine malfunctions or his patient vomits or a patient has too much pain or claustrophobia and you give one fourth or one half the treatment, is that an event?

MR. BRICKNER: Less than a dose for a physician-justifiable reason. If I justify it as a reasonable thing to do, then it shouldn't be an event or anything else.

MR. TELFORD: Also, too, when you get into things like machine malfunction, for example --

MR. SMITH: You treat one side and something happens and you don't treat the other side.

MR. CAMPER: One of the things we're looking as we

go through this for the future, is trying to come up with some language and what have you that would address this question of a machine malfunction not being a misadministration. It should be something that should be reportable, because we'd like to know about those kinds of things, but not a misadministration.

MR. BRICKNER: You could footnote that. I think that would probably be the best way. Doses that are less than those prescribed, due to mechanical problems related to the equipment or to illness on the patient's part, will not be considered an event, but if related to mechanical malfunction, would be kept as a separate, reportable incident, just a footnote.

MR. TELFORD: Keep a record.

MR. BRICKNER: Yes.

MR. SUNTHARALINGAM: Again, we are back to this whole definition of what is an error. In Item 3, you're talking about a teletherapy administration with whatever percentage you want to put in there, error. Again, define for me what is your concept of an error?

If it's a deviation or a mistake where a human error was made, a human mistake was made, that's one thing. But because a treatment couldn't be completed for equipment malfunction, is that an error?

MR. TELFORD: No.

MR. SUNTHARALINGAM: That is not an error.

MR. TELFORD: That's what we've been saying.

MR. SUNTHARALINGAM: So it's not, so therefore, I don't know whether you can -- you have to define the term, error somewhere in your definitions as to what constitutes an error.

MR. CAMPER: There are clearly things you can exclude from being an error, such as malfunction and what have you.

MR. TELFORD: What A(3) says is that if for any reason like inattention to detail, having no procedures, having no supervision; if any of those happens to result in the fact that the administered dose is 20 percent greater than the prescribed dose, that's an event.

MR. SMITH: You never know their arbitrary number here.

MR. TELFORD: Let's go back to Dr. Flynn's idea.

MR. FLYNN: I think that if we have physicists like at Mass General and we forget to put -- someone forgets to put a wedge in on one day because someone's inattentive, but they're really not inattentive if the physicist has picked it up and a second dosimetrist has checked the first dosimetrist's calculations. If that's done and the physics people here think that should be done maybe once a week, and that's something that you should aspire that the people out

in South Dakota should be doing.

They should have a quality assurance check on all the charts once a week, if possible. Then it would make sense to promote weekly quality assurance checks. You can't do it daily; you don't have enough staff.

Then you're promoting this concept of weekly quality assurance and you're picking up errors on a weekly basis, if they haven't been corrected when they were spotted before.

MR. BRICKNER: What are you going to say about that weekly dose?

MR. FLYNN: Well, I'll ask you. What do you think the weekly cumulative dose should be? We check patients once a week.

MR. BRICKNER: First of all, it exceeds what you planned, not if it falls below. Falling below is rarely a clinical problem.

MR. FLYNN: You can make it up.

MR. BRICKNER: If it exceeds, and by how much. Twenty percent seems awfully tight to me, but that I can't argue about that. That's one whole treatment.

MR. SMITH: One day.

MR. BRICKNER: Yes, that's one day. If it's more than 20 percent -- yes, sir?

MR. SUNTHARALINGAM: Here again, we are getting

into this question of fractional dose. Is it in the early part of the treatment, middle of the treatment or towards the end of treatment?

Even if it is a high dose in the first week of treatment, by a certain percentage, you can always, again, take corrective measures. That's a physician decision.

MR. BRICKNER: Biologically correcting for the patient's benefit doesn't change the fact that you screwed up.

MR. SUNTHARALINGAM: Yes, true, that's right, but --

MR. BRICKNER: What they're looking for is --

MR. SUNTHARALINGAM: The same reason can be given if you made a mistake on the lower side.

MR. BRICKNER: The low side, the only reason I exclude is that the low side is so frequently due to a machine or patient malfunction, not to an error in calculation.

MR. BOGARDUS: There are errors in calculations, though.

MR. BRICKNER: All right, make it up or down, unless explained by mechanical failure of the equipment.

MR. SUNTHARALINGAM: The other concern I have about this fractional -- unless we, again, define it as a daily, weekly or whatever it is -- is therefore, you have to

now establish a QA program that will detect these. ..ow will you go about detecting these?

That means now that if you sa_, fractional, yet there's something in place; that something is being scrutinized on a daily basis.

MR. BRICKNER: We're talking about doing it weekly.

MR. SUNTHARALINGAM: Weekly is all right, as long as we agree, are we going to weekly or are we staying at fractional dose?

MR. SMITH: Glen has an excellent suggestion.

MR. TELFORD: Say weekly cumulative dose differs from prescribed by some amount. You say 20 percent of total?

MR. BRICKNER: Get away from the total dose. Let's do it according to what was supposed to be done that week. When you start saying the total dose, then the difference becomes totally fallacious because in the first week, you're allowed ten percent of the total 6,000 which is 600 which is damn near the whole week.

But when you come up with the cumulative fifth week, the difference is nothing. Forget that.

MR. FLYNN: The physicians see the cancer patients once a week. That's standard in the United States, and more frequently if they're ill or require it. The patient must

be seen at least once a week. That's a standard weekly management check. It's call the weekly management check by the physicians.

MR. TELFORD: So we're going to compare the administered dose for that week to the prescribed dose for that week.

MR. BRICKNER: Planed or prescribed dose for that week, yes. What do you want to call it, one day's worth or 25 percent?

MR. SUNTHARALINGAM: Wouldn't that depend on -- we have been living with it, but we have been concerned about ten percent of total dose.

MR. BRICKNER: Let's get to that in a minute.

MR. SUNTHARALINGAM: Wouldn't this number depend on what number do you want to hang your hat on for total dose?

MR. BOGARDUS: Not really, because you're dealing with only a week's worth here. I think that 20 is a reasonable number. That's one day that has been a problem during that week.

Generally, if you have a massive foul up, it's hard to conceive that it would have gone longer than one day. One day's worth of rearrangement of dosage in a given week, regardless of your dose rate or delivery, is not going to create a major problem with the patient.

MR. TELFORD: Twenty percent or more?

MR. BOGARDUS: Differs by 20 percent. You just say the administered dose differs from the prescribed by 20 percent. You're talking about cumulative administered versus prescribed per week.

MR. SMITH: Let me ask you something, the therapist. Many times, these kinds of things -- what you're really interested in is the total biological effect. Most times, you can alter planned fractionation, daily doses and so forth, but yet end up with the same biological effect, which really is the bottom line.

MR. BRICKNER: There are two bottom lines: the bottom line that you're speaking about is what I want to do for my patient who has a name and has a disease. The other bottom line is that he wants to make sure that my department operates in a safe and sane fashion.

MR. SMITH: But there should be some correspondence between those things; shouldn't there?

MR. BRICKNER: There doesn't need to be any relationship whatsoever.

MR. SMITH: Are they disassociated?

MR. BRICKNER: Yes.

MR. SMITH: I don't understand that, but I'll take your word for it.

MR. TELFORD: Wait a minute, Dr. Smith. Let's say

that we're in events here. These get reported back to the licensee management or designee. This is a Deming idea.

You let this be reported internally without fault. It doesn't have to go to the NRC. We don't have to know about these things.

These are events. These are things that you need to know about that your department is not running as well as you want it to.

MR. BRICKNER: I want to know if that happens 3 times out of 6 weeks. If in three weeks there's an error of 20 percent, I'd like to know why that technician is smoking those funny cigarettes.

MR. SMITH: I'm convinced.

MR. TELFORD: Dr. Smith, could you bring back that question, though, when we get to misadministrations?

MR. SMITH: Yes.

MR. BRICKNER: Okay, what did we decide? Okay, we've solved all of that of No. 2. Number 3, not authorized; I don't know what that means. That's right, we're talking about isotopes; aren't we?

MR. TELFORD: Yes, it's not on your license.

MR. SUNTHARALINGAM: Item 5. How do you administer the lost source?

MR. BOGARDUS: You lose a source in the patient and leave it there. I assume that's an unrecoverable sealed

source.

MR. SUNTHARALINGAM: The statement is confusing there. Brachytherapy administrat w king source, with a lost source?

MR. BRICKNER: You have a footnote or a codicil there that permanent inte implants are not lost.

MR. TELFORD: Page 1448.

MR. BRICKNER: How much are we getting paid for this?

MR. TELFORD: This would be 35.34, paragraph (b)(4).

MR. SUNTHARALINGAM: I had a problem in deciphering that statement on that page.

MR. BRICKNER: What we're saying to you is that that's a lousy paragraph before, because lost or unrecoverable, you have to make an exemption for those that we intentionally put in, never to be recovered.

MR. TELFORD: Okay, we did that in the guide.

MR. BRICKNER: Lost, not lost internally, lost externally. For instance, we have seeds that fall out of the prostate and go up to the diaphragm. They're not lost.

They're lost out of the implant; they're not lost out of the patient and they don't threaten the community.

MR. SUNTHARALINGAM: I'm still hung up with that

phraseology or terminology.

MR. TELFORD: Phrase it any way you like, but the intention here is -- let's get past what the intentions are, because I'd like to know how you would fix this.

MR. BOGARDUS: Let's break it down into three things.

MR. TELFORD: Let's do that.

MR. BOGARDUS: It should be any therapeutic use not authorized.

MR. BRICKNER: Period.

MR. BOGARDUS: That's one thing.

MR. BRICKNER: Yes.

MR. BOGARDUS: A brachytherapy administration with a leaking source.

MR. BRICKNER: Period.

MR. BOGARDUS: That's another thing; that's a bad deal.

MR. BRICKNER: Okay.

MR. BOGARDUS: The third thing is the loss within the patient or the inadvertent leaving of a source in the patient.

MR. BRICKNER: Inadvertent being --

MR. BOGARDUS: Inadvertent leaving of a sealed source in the patient.

MR. TELFORD: That's unrecoverable?

MR. BRICKNER: It's not necessarily.

MR. BOGARDUS: It's not unrecoverable, but it's unintentional.

MR. BRICKNER: For instance, if you put --

MR. BOGARDUS: Nothing is unrecoverable.

MR. BRICKNER: If you put a tandem in a woman's uterus and the tip of it comes off and one cell falls out and stays in the uterus, you get the tandem back; you have lost one cell. It's not lost, it's in her uterus.

You did not mean for it to stay in her uterus. It is recoverable when you take her uterus out, but she's going to be quite irritated that you had to take her uterus out when you didn't intend to. Do you see what I mean?

MR. TELFORD: Okay, the operative word for the lost seed is?

MR. BRICKNER: Unintentional or unplanned or unintended or inadvertent; it's not part of the plan. It's not what you intended to do. This is in an intracavitary application to lose a source in a patient.

MR. TELFORD: It's reported lost.

MR. BRICKNER: Yes.

MR. SUNTHARALINGAM: This is still a report to licensee management. This is an event within the institution.

MR. TELFORD: Yes.

MR. BRICKNER: Yes.

MR. BOGARDUS: You really haven't lost the source because you're going to ultimately get it back. It is the inadvertent leaving of a source within a patient that you had originally intended to recover.

MR. PAYNE: How do we handle the Iodine 125, the prostate implant -

MR. BRICKNER: Intentionally left.

MR. PAYNE: I'm just saying where somehow a seed then goes up to the patient's lung.

MR. BOGARDUS: Now, that doesn't count. That's just --

MR. PAYNE: But it left the site that we put in.

MR. BOGARDUS: Not significant. It is not significant and is something over which we have no control whatsoever.

MR. BRICKNER: I meant for it to stay in his body and it stayed in his body. If you want to argue with me about the size of my implant, mine is this long.

MR. SUNTHARALINGAM: That is very common and we need to address how best to change it. Some people have interpreted this lost source as lost from the site from where it was implanted.

MR. BRICKNER: It should be clarified that a lost source is a source that was put into the patient and

intended to be removed from the patient and was not removed, due to some incident.

MR. PAYNE: I guess I'll raise it -- how will the NRC handle a situation where we do a prostate implant -- I'm hanging on this because we're doing eight of these a month now -- and our procedure is to strain the urine when the patient is in the room. So we do, and we strain the urine, and we find one or two seeds come out.

I had a situation where, when we strained the urine, the nurse did it in the room, and the seeds went down the toilet, and she refused to get the seeds out of the toilet, and she flushed the toilet. Now, are these seeds -- did we lose these seeds? Do I have to report to the NRC? Am I in non-compliance?

MR. KLINE: I think you are.

[Laughter.]

MR. PAYNE: If the patient went home, he can flush the toilet at home, and we're fine.

MR. KLINE: You still would need to notify the NRC. Seeds could go in the sewer system --

MR. PAYNE: Well, that didn't happen in our place.

[Laughter.]

MR. KLINE: Which hospital?

[Laughter.]

MR. SUNTHARALINGAM: If the patient went home and

flushed it down their toilet, that's all right.

MR. KLINE: No, it's not all right.

MR. SUNTHARALINGAM: Why? The patient is sent home. These are permanent implants.

MR. KLINE: Okay. Now, we have two different questions, right? We have one, what is a misadministration? The second is, what about those lost seeds? Could that be a threat to public health and safety? Could somebody possibly get exposure to that? That would be something on a case-by-case basis that the NRC would look at and try to discern whether or not those sources are recoverable, what their half-life is. I mean, this has happened.

MR. TELFORD: I think we're kind of far afield here. What we're talking about --

MR. BOGARDUS: What we're really talking about here is you have done an iridium ribbon implant, and when you're pulling out your sources, the last source in the ribbon snaps off and stays in the patient. Now, you have two choices. You can either ignore that piece of iridium, calculate what dose it's going to deliver, decide it was too much, and you may have to re-operate the patient just to recover that source. Is that what we're talking about?

MR. TELFORD: Yes.

MR. BOGARDUS: Because that's really the only situation where this happens anymore.

MR. SUNTHARALINGAM: If such an incident happens, we have to make a report of it?

MR. BOGARDUS: You've got to make a report.

MR. BRICKNER: Internally. This is an event.

MR. KLINE: And you might feel in that case that the benefit either outweighs the risk, or vice versa. But that's your decision.

MR. BOGARDUS: That's right. We make a medical decision. Do we leave the source in after the physics folks tell us what the dose is going to be, or do we run the risk of going after it?

MR. PAYNE: I have to go catch a plane.

MR. TELFORD: We are going to talk about the follow-on meeting at the end of the day.

MR. PAYNE: Right. I can check with the College staff on that.

MR. KLINE: Thank you for coming.

MR. TELFORD: Thank you.

MR. BOGARDUS: Does that make sense, though, on these lost sources?

MR. BRICKNER: Maybe we should come up with another word for lost.

MR. BOGARDUS: A retained source.

MR. BRICKNER: Unintentionally.

MR. BOGARDUS: Unintentionally retained.

MR. TELFORD: That has a nice ring to it. Unintentionally retained source. Do you like that?

MR. FLYNN: And what do you call the source that's flushed down the toilet or lost in the trash, a small source of no measurable hazard and can't be detected, you can't find it?

MR. BRICKNER: I call it non-existent.

MR. FLYNN: Is that a lost source, also, externally lost, unaccounted for?

MR. BRICKNER: That would be lost, I guess.

MR. TELFORD: You can't recover it at this point if it's down the toilet.

MR. KLINE: But that doesn't fall under lost source under some other section.

MR. TELFORD: That falls under another section and has to be reported for other reasons.

MR. KLINE: In other words, it could be part of this, but it could also not be part of it.

MR. BOGARDUS: That is totally getting astray, but since that is something that happens in I would suspect every prostatic implant eventually, it's not really something -- it's no more than the patient who's had a therapeutic dose of iodine and goes home with 29 millicuries in him and keeps paying in the john. Eventually, he's going to dump 29 millicuries down the sewer system. You're

talking here about half millicurie and quarter millicurie sources of radiation which are still sealed and can't get loose and do anything. So I don't think these are even significant. I think it's almost considered like a liquid source -- it's gone, it's gone.

MR. TELFORD: Well, of course, what we're talking about here are difficulties that you encounter when you go into the OR and when you come out of the OR, but they're still within your control.

MR. BRICKNER: If we go in there with 20 seeds and we put ten in the patient, and we come out with eight, we've got a problem.

MR. TELFORD: Yes.

MR. BRICKNER: And you think that ought to be mentioned to somebody.

MR. BOGARDUS: Yes. We would like to find out where they went.

MR. TELFORD: We think that ought to be reported back to the licensee management or designee to say that we lost two seeds in the OR.

MR. KLINE: See, that would lead to the second course of action, which should be either take another radiograph to see if those two sources are in there. If they're not, that means they could have been lost on the floor in the operating room. Then you have another sequence

that kicks in where you have to find those sources. So it can somewhat complement a follow-up remedial action that you have to take to find the sources.

If you can't find them at that point, then you make the best guesstimate where they might be. You assure that the area where people work that are unrestricted, they don't receive exposure -- the nurses, childbearing age, that sort of thing -- and then document it, and that would be a 20-year event. As long as you follow up on these things.

We realize that there are sources that are lost and are never retrievable and nobody knows what happened to them, but so long as there is some sort of a conscientious assessment made, not, "Well, gee, it's not my problem. I don't know where the source is." That's not the sort of way to address it, especially when the public finds out that that source is in your facility, and they don't know where it is, and you didn't address it.

MR. PAYNE: That's a little different from a 30-curie well logging source carried around in your hip pocket overnight.

MR. KLINE: Exactly.

MR. TELFORD: Shall we move to the (B) part, Misadministrations?

MR. BOGARDUS: Did we decide we were going to call it something other than "misadministration."

MR. TELFORD: There was a suggestion to call the things where you have -- like (B)(1), where you have the wrong patient, the wrong source, the wrong site, the wrong route --

MR. SUNTHARALINGAM: We said deviation from intended treatment.

MR. TELFORD: No, no. For (B)(1), Dr. Brickner suggested that we call those things misadministrations.

MR. SUNTHARALINGAM: Right.

MR. BRICKNER: Yes, where you have the wrong patient.

MR. BOGARDUS: That's clearly a misadministration.

MR. BRICKNER: Yes. That's a screw-up, and there's no other way to look at it.

MR. TELFORD: But the (B)(2) and (3) and (4) might be something like unintended deviation.

MR. BOGARDUS: Yes.

MR. TELFORD: I mean, that's what I heard.

MR. BRICKNER: Yes, sir.

MR. BOGARDUS: So there really ought to be a (C) starting with (2).

MR. TELFORD: Okay.

MR. TSE: What about in the case where large doses are given to the patient unintentionally?

MR. TELFORD: That would be one of these with the

large dose.

MR. TSE: But is he talking about whether that should be a misadministration?

MR. BRICKNER: You feel that there is some level that's greater than an unintended dose that gets into a gross error?

MR. TSE: The person may get hurt.

MR. BOGARDUS: Like 100 percent error in dosage, or something. Double the dose.

MR. FLYNN: The word implies harm to the patient, though. That's what I think the problem is.

MR. BOGARDUS: Yes. A misadministration means it's going to do something bad.

MR. FLYNN: I'm sure that NRC knows about nuclear phobia.

MR. TELFORD: If you incorporate the threshold idea that we were talking about in 35.33, if we put that into 35.35 in the (B) part, where we have the deviations that are -- the administered dose is X percent different from what was prescribed and it exceeds the threshold -- see, the question is how far does it exceed the threshold? If it exceeds a certain dose, then at some level you may want to say, "Yes, we report this to the NRC." At some level beyond that, you may want to say, "We may want to call these misadministrations because they may have, indeed, harm

to the patient."

Let's take like a B-3, where you have a radiopharmaceutical therapy, you're giving I-131, and you're giving -- well, not you, but the administered dose is greater than ten percent, ten percent greater than the prescribed dose with I-131. So if you've given -- you know, if you're prescribed five millicuries -- let me back up.

Say you've prescribed something small, like 20 microcuries, but you gave five millicuries. So the resulting dose to the thyroid is 5,000 rads, approximately. So that would probably exceed a measurable effect. You might come across a measurable effect at, what, 300 or so rads to the thyroid? Is that right?

MR. FLYNN: I'm not sure.

MR. TELFORD: Then 300, 500. At some point, you're going to run across a measurable effect, but at some point, probably around 2,000 rads, you might get --

MR. BRICKNER: You might call it a misadministration.

MR. TELFORD: You might get something that amounts to an impairment of that organ such that there's some measurable amount of hypothyroidism since that thyroid now got that dose. So once you exceed that, do we want to call that a misadministration?

MR. BRICKNER: That's an interesting thought.

That's probably reasonable. It gives us a whole bunch of different things we have to do. I mean, what are we going to call this threshold? Are we going to start dealing with each organ system? Are we going to say, for the thyroid, the threshold is 2,000 rads? For the pelvis, the threshold is 1,000 rads? One approach is to list each organ.

MR. SMITH: That's very problematic because when you get to teletherapy in particular --

MR. BRICKNER: That's what I'm talking about.

MR. SMITH: -- the biological response is also volume dependent, not just dose dependent.

MR. BRICKNER: Yes. There's a tremendous difference --

MR. SMITH: We don't even know the dose response for most normal organs to within 20 percent either way.

MR. TELFORD: Do you know those dose levels that produce a measurable effect?

MR. SMITH: Not for partial organs, no. For whole organs, we might in some cases know, but not within 20 percent in most cases, no.

MR. FLYNN: It can be very difficult.

MR. SMITH: It's very problematic to get --

MR. TELFORD: Well, you can be liberal within 20 percent of the dose to the organ.

MR. FLYNN: It's not well defined. The dose to

the organ is not well defined. Lung tolerance, liver tolerance, the kidney tolerance, the changes you might see is not well defined, and the doses are very high.

MR. SMITH: We don't know the normal tissue tolerances even for whole organs, much less partial organs within ten, 20, 30 percent. It's just not there in the literature. I would say get away from the idea of tolerance to the organs.

MR. TELFORD: Even for teletherapy?

MR. SMITH: Yes. Absolutely. It's very problematic.

MR. FLYNN: I think you were right in the Federal Register to get away from it. I think you were right. You get 1,000 rads delivered, and some patient might get a widely elevated liver enzyme; in another patient, you may not. It's just hard to predict. You can't predict it. And those are extremely high doses.

MR. SMITH: You really should stay away from the concept of tolerances.

MR. FLYNN: I think you were right in the Federal Register to stay away from those. You rejected them the first time they were proposed.

MR. TSE: Right. Somebody suggested that and we considered it being proposed that way. But the question is, under certain circumstances, when the doses are so large,

should that event be considered as a misadministration? I think that for thyroid, it's very easy to say, but for teletherapy, it's difficult.

MR. FLYNN: For teletherapy, it's very difficult.

MR. SMITH: Well, then you have to talk about organ functions and things. That's very messy. Do you really want to get into that? You have to deliver enough dose where you have a measurable change in organ function, then you're going to describe the function and the testing.

MR. TSE: It is very difficult.

MR. FLYNN: It's going to be very infrequent, also. I suggest when you have these very odd incidents, that you present them to the ACMUI and ask them to make a judgment. I'm confident that whoever is on that committee in the future will make a judgment with you if it's significant or not, and that person's license could be suspended if they are giving possibly harmful doses to patients and not having a good QA program.

MR. TELFORD: Well, what we're after, though, is to try to define reporting thresholds such that we capture the departures that are significant departures from what was prescribed.

MR. SUNTHARALINGAM: We are coming to reportable dose levels in Item 3. We can address that. Now we are faced with a situation based on whatever we agree for Item

3, then what might fall into a misadministration as different from what would be a deviation. So you can come back to that.

MR. TELFORD: Okay.

MR. SUNTHARALINGAM: Let's see whether we can arrive at some numbers.

MR. TELFORD: (B)(3).

MR. FLYNN: Another thing you can do, you could have the serious deviations go before the ACMUI and have them decide whether that serious deviation could bring harm to the patient, and therefore be classified on a case-by-case basis as a, quote, "misadministration."

You take the monkey off of everybody's back and being held accountable to people who may have a nuclear phobia.

MR. TELFORD: The problem with that is that the makeup of the ACMUI will change. We're going to rotate members on and off, so that, you know, in one year you have one decision, and then five years later, you may have a different decision.

MR. FLYNN: You may have a -- the serious deviations will be relatively few in number, and you'll have precedent established and a record established of serious deviations. It wouldn't be that many, I don't think, to cause severe harm or death of the patient.

MR. TELFORD: Well, let's look at (B)(3)(i). This is a total teletherapy dose, has 10 percent difference.

MR. SUNTHARALINGAM: Shall we go to (B)(2)?

Ted, are you still satisfied with 10 percent for (B)(2), even though that is existing?

MR. BRICKNER: I don't know what that is.

MR. TELFORD: That's radiopharmaceutical therapy, (B)(2).

MR. SUNTHARALINGAM: It's radiopharmaceutical, but it's practiced by radiotherapists, also.

MR. BRICKNER: Not this one.

MR. SUNTHARALINGAM: Not this one, but in some departments, the radiotherapist may.

MR. BRICKNER: I don't know enough about it. I think 10 percent might be a little narrow.

MR. SUNTHARALINGAM: Ten percent, I think, is narrow to be a misadministration but even to be an event that is reportable to the NRC, which we later come to.

MR. BRICKNER: That is not reported, then.

MR. SUNTHARALINGAM: You have to be careful, because all these items in (B) are reportable to NRC, but we classify them as misadministration or deviations. I mean, to me, my concern is whether the dosages can be measured, first at 10-percent accuracy; that's a separate problem. But assuming that their measurement technique is the same,

now the question is: Is a 10-percent difference in dose activity delivered to the patient -- does that become a reportable event?

MR. BRICKNER: I don't think so.

MR. SUNTHARALINGAM: But I think you may have to get some feedback from the nucs, people who are doing more of these studies.

MR. BRICKNER: I would say 20 percent.

MR. FLYNN: I would say 20 percent.

MR. SMITH: Let me bring up my own lung case again now. Anytime you give Cobalt therapy to a lung tumor --

MR. BRICKNER: We're talking about radiopharmaceuticals.

MR. SMITH: I thought you were on (3).

MR. BRICKNER: No, (2).

MR. SMITH: I'm very sorry.

MR. SUNTHARALINGAM: Let's go on around and see what the reaction is from some of the others in the field.

MR. BRICKNER: Are you going to be talking to them?

MR. TELFORD: Yes.

MR. BRICKNER: See what they have to say about that, because I should think you would have a lot of trouble determining 10 percent.

MR. TELFORD: Don't forget, this is a current

requirement.

MR. BRICKNER: Just because it's current doesn't mean it's --

MR. TELFORD: Well, I mean, if you use a dose calibrator and you were supposed to give 100 microcuries and you gave 110, it's 10 percent.

MR. SMITH: Some of the calibrations are -- you can't have anything less than 14 percent, because the calibrations are that uncertain.

MR. KLINE: There were comments from -- nuclear physicians regarding dose calibrators, current errors in the dose calibrator, current errors in sealed sources.

MR. SMITH: I looked that up in the responses to the public.

MR. KLINE: This was noted. And they are errors which, in Part 35, current Part 35, have been revised to allow a little more tolerance in the testing of this dose calibrator to give you the latitude where there is more inherent error.

And the question came up: Is that latitude given there reasonable in respect to this? Okay? Meaning this tolerance of 10 percent, is that reasonable considering you have an error with your dose calibrator, an error with your sealed sources as to the true value of what you're getting, of maybe 10 percent or more.

But that has been brought up, and we're looking at that.

MR. BRICKNER: Consider it brought up again.

MR. SUNTHARALINGAM: To go along, we are recommending 50 percent. Let's take it from there and see where it goes.

MR. KLINE: Twenty or 30 percent?

MR. SMITH: I'd vote 30, because if the uncertainty in a basic calibration was 14 percent, that gives you 5 percent.

MR. KLINE: Where did that 14 percent come from?

MR. TELFORD: You can't use that, because it's the same before and after. I mean if you've got -- it's whatever it is. Whatever your inherent error is in your dose calibrator, that's what it is. But it's consistent.

You measure it, and that's what you think it is. So, that's what it is. That's the way you're behaving.

So, if you're supposed to give 100 microcuries and you gave 120 -- let's say that the window was 20 percent and you gave 125, or if it's 30 percent and you gave 135.

MR. SMITH: Well, see, again, we get into this thing about error. We know that the stated error is an error from the delivered dose by at least 14 percent, because there is that inherent error in the calibration.

So, let's don't get back into that.

MR. FLYNN: In the Federal Register, you saying errors in exposure time and in calibration. What if you recalibrate and find out that you were 9 percent off the last time? The other physicist calibrated it. He made a mistake, and he calibrated --

MR. TELFORD: You're in (B)(3).

MR. KLINE: You're talking about teletherapy. We're talking about radiopharmaceuticals.

MR. TELFORD: Yes. We're on (B)(2).

MR. FLYNN: What if what he was using to calibrate the weld chamber, whatever it was, was 9 percent different when he recalibrated this device?

MR. KLINE: That's an error in calibration.

MR. FLYNN: And that's supposed to be included in the errors in the -- errors in calibration, exposure time, and geometry is supposed to be included.

MR. KLINE: Exposure time and geometry -- you're talking about teletherapy again. We're talking about radiopharmaceutical therapy.

MR. TELFORD: Are you thinking about -- you go back and you check on your dose calibrator, and you find out the calibration was off by 9 percent.

MR. FLYNN: Somebody else calibrated it, and they made a mistake. The calibration is off by 9 percent. So, all your previous -- the treatments you've been giving are 9

percent off; I mean some of the isotopes you've been missing may be 9 percent off.

MR. TELFORD: Yes. But when you were using the dose calibrator --

MR. FLYNN: The physician was administering the dose properly, because he was basing it on a calibration that --

MR. TELFORD: Yes. I mean you've got a problem with your calibration of your dose calibrator.

MR. CAMPER: You've probably got a misadministration there.

MR. KLINE: Yes. You have to go and look at that.

MR. SMITH: Come on. If you make a mistake and calibrate something wrong and use it, then that's a misadministration.

MR. KLINE: That's correct. The equivalent would be if you had your --

MR. SMITH: It's got to be.

MR. KLINE: And you're treating these patients based on that chamber factor, the output of your machine, and they're misadministered to; that's a misadministration.

Now, the root cause -- because you sent your instrument out to be calibrated; it was not calibrated properly -- that would have to -- that's a specific situation where the NRC would have to sit down and say okay,

now who -- what are we going to do about this? Okay. How are we going to address that? Because ultimately, you are responsible, and it was your patient, but you had a contractor who didn't fulfill his obligation.

Now, if you look at a dose calibrator, the same thing could happen. You could have a miscalibrated machine. You're given a certificate by somebody who is supposed to be qualified and says this thing is calibrated. The machine is not; it's off by 9 percent. You administer in excess of 10 percent. That would have to be addressed.

That would be a good example of how the committees, the organizations we have at our disposal, would look at that.

MR. SMITH: It's not often that a physicist would have a calibrating service; he would calibrate his own dose calibrator.

MR. KLINE: That's correct. You do a secondary check, and you should, and that's good physics.

MR. SMITH: But that's still subject to --

MR. KLINE: Well, there is some error there, and I guess the point that we need to say is what is -- the NRC realized back in the '80s that there was a problem with the regulatory guide, the plus or minus 5 percent required for somebody that does calibrator testing, and they came back with a prescriptive -- that said 10 percent.

Now, we're going a little higher. And the question is what is reasonable and what's not, and I think John's point is that if you have an error, it's reproducible all the time.

Ninety percent of the time that's correct, unless you get, for example, P-32, which is a pharmaceutical therapeutic radiopharmaceutical drug which cannot be measured in 90 percent of the dose calibrators. It has to come from the pharmaceutical people, which will tell you what that activity is.

You can only double-check it, like you would a chamber -- like a Strontium 90 source for the chamber, to make sure that that number is a number that is possibly consistent with, maybe, a standardization you set up on that dose calibrator.

So, the bottom line is that dose in pharmaceuticals are very difficult to measure in the field. Syncor, Malaprop -- you can even sit there and say that we know, beyond the fact, that we know that this thing is 5 percent off what it should be.

MR. SMITH: Let's make sure John understand this.

John said that if a physicist made an error in calibration, say of 15 percent, and then he used all those, and they were consistent, that's not a misadministration. I think you'd have to call that a misadministration. Think

about it.

MR. KLINE: Well, I think what John was saying was that if you have an acceptable error in the NRC of 10 percent for a dose calibrator, you don't know exactly what the true number is. So, as long as you're within that 10 percent, you shouldn't be adding errors on top of errors on the high or low end in order to go in the misadministration range.

MR. CAMPER: Well, this is when a mistake occurs. I mean there is no question when you measure these isotopes in these dose calibrators, you've machine, electronic noise to deal with. You've variance in the assay dose. You've got variance in seal sources, you know, 3 to 5 percent, roughly. You're right. We're in the range of 10 to 14 percent variability.

This is when an error occurs. Now, if you go back and you discover that an error occurs because you have improperly calibrated a machine, that's a misadministration.

Similarly, in the case in Maryland, there was a therapy unit that was involved and a calibration factor was not changed, and they subsequently dosed 35 patients or something. You had 35 -- well, you had more than that, probably. You had how many times it occurred.

But what this says is that this is when a mistake occurs and it has a threshold of allowability, if you will,

of 10 percent. Now, the question is is 10 percent a reasonable number?

We've heard 20 percent. We've heard 30 percent. We've heard 10 percent. You know, what is a reasonable margin of error for it to be a misadministration?

MR. SMITH: In this particular case, you're probably asking the wrong group.

MR. FLYNN: For isotopes, it might be 30 percent, but for teletherapy, it might be 20 percent.

MR. SUNTHARALINGAM: That would be item (3).

MR. TELFORD: Yes. Let's go to teletherapy.

MR. BRICKNER: Ten percent is an event; 20 percent is, in my opinion, a misadministration.

MR. TELFORD: And why is that?

MR. BRICKNER: I don't think 10 percent is a great threat to the patient. It's not good, and I want to know that, and I want it corrected, and I don't want it to happen routinely, but it's not a big threat to the patient. It's common as hell, and you're going to get a lot of paperwork. And it's easy to do.

MR. TELFORD: If you have a total dose of 6,000 rads --

MR. BRICKNER: And you get 6,600, it worries you; you don't like it. And you get 5,400, it worries you; you don't like it. Double that and you're getting into a place

where patients are going to get complications, and tumors are going to recur.

MR. CAMPER: What if we're lured outside of the defined target volume?

MR. BRICKNER: That's a whole other problem.

MR. SMITH: Yes, that's different, because 10 percent to the target volume be even give you a higher probability of cure.

MR. KLINE: What if you have a case where you have, let's say --

MR. BRICKNER: If you're outside the target volume and you happen to be on a sensitive organ, if you working -- for instance, you're treating 6,000 or 7,000 rads to a primary lesion in the brain and you're outside the target organ and you have the lens and the visual cortex at the eye, you're going to get a problem at 50 percent of the dose.

Well, is that important? Yes, it's important; the patient is not going to live long enough to get the cataract. But it's still tacky. It's not good. It's a mistake, you know. It's an error. But some of these things are important.

There are times when you will treat spinal cord to a dose that you know, if the patient lived three years, they'd probably get a myelitis, but the fact is they're not

going to live three years; they're not going to six months. And they're in severe and excruciating pain.

So, you treat to a dose that you know is a toxic dose to the organ you're treating, to relieve the pain, knowing the patient won't live long enough to see the complication and that if you're very unfortunate, some guy will live long enough to see it and sue you. But those are the kind of things you get into.

So, when you get out of sight of -- did you miss the target? That's a whole new ball of wax, and I don't know that you want to get involved in that. That's part of the quality-assurance program we're looking at.

Did you take port films twice a week on all these ports? Did you review the port films? Are those port films signed? Do you know that you were on the treatment point? That's what our QA program in radiation oncology is about.

MR. FLYNN: If it's bad enough, though, it's covered by (B)(1), the wrong patient, the wrong source, the wrong group, or the wrong treatment site.

MR. BRICKNER: Yes. Well, for instance, if you treat the right kidney instead of the left kidney or the right lung instead of the left lung, that's the wrong site.

MR. KLINE: What about situations -- let me pass this out amongst you -- where you do large dose fractions, let's say, a hemi-body or a total-body fractionation that's

a quite large number of rads administered at one time, with this sort of error? What are your feelings on that?

MR. BRICKNER: Eight hundred rads and you made a 10-percent error? You may or may not get in trouble. Twenty percent, you probably would.

MR. SUNTHARALINGAM: Even there, I think, under your example, again, there is still a lack of acceptance of what is the dose limit to be used. Some people are a little cautious and go slow, some people are going to high doses, and it's a mixed bag.

So, if I am intended to deliver 800 and give 700, now to call that -- that may have been because of some mistake that was made, but what we want is, certainly, identify what that mistake was. Now, whether that whole thing is reportable in the sequence of things and to whom reportable, that's a separate question.

Certainly, if somebody made a gross mistake in doing some calculation or double-checking something and, instead of delivering 800, gave 700, that's certainly an event or an incident that needs to be reported and followed up in terms of what caused that error to happen.

MR. BRICKNER: Because something -- because I say 10 percent is an event, that doesn't mean that's acceptable therapy. That means that it should be looked at, evaluated, and corrected on a local level; that is, within the

institution.

It is not acceptable to say that all my treatments will be plus or minus 10 percent. That's not satisfactory treatment. But when it gets as high as 20 percent, it's more than an institutional problem. It gets of such a magnitude there must be some really gross error going on, and it's beginning to get dangerous to an individual patient, or more, and probably you all should be brought into it at that point.

I'm just making the rule in my mind how do we discriminate event from misadministration. And it's kind of, to me, is there a high probability of injury to the patient. Does this require kind of a crisis correction? Because, if we have to call you and tell you about it, you know we're going to be running around like little rats trying to get the thing fixed this week.

MR. SMITH: Ted, there are numerous cases. And you can think of them. They happen to us everyday , when you have a treatment plan that has a ten percent hot spot. Think of any breast treatment. Any breast treatment using -- in the cephalad cold bed areas of the breast you are going to have hot spots, because there's less tissue there.

Those are about in the order of fifteen percent. But those recur routinely, daily, and in a lot of treatments we do.

MR. TELFORD: If you're treating the larynx.

MR. SMITH: How does your language preclude that?

MR. BRICKNER: The language to me says -- and this is how I'm running my department and will continue -- that, if I make a statement that I want to have X dose at that point, and I deliver X dose at that point, they're satisfied.

And if there's a 20 percent hot spot back by the cricoid that's my problem. But I have accurately delivered the dose to the point specified.

MR. SMITH: That's the way you prescribe it. How do you supply your prescription?

MR. FLYNN: Or, if I circle the 80 percent isodose and sign my name, which I often do, and the dosimetrist does it to the 60 percent isodose, then that's a problem. That's an error.

MR. BRICKNER: That's a problem, yes sir.

MR. FLYNN: I circled the 80 and initialed my name, and showed it to him. But he made a mistake and he did it to the 60 percent. So, he may have overdosed by 20 percent, or underdosed, whatever.

MR. BRICKNER: If I'm satisfied with inhomogenicity in the field, that's my medical decision.

MR. FLYNN: Right.

MR. BRICKNER: But, if I said I was going to do it

30 times and each time a certain event was going to happen at a given point, and I don't do that --

MR. SMITH: Let me ask the question differently, because it's all the same question really.

What if you have a distribution that does not correct for tissue inhomogenities, and you circle the 80 percent or 90 percent isodose line. But in actuality, the administered dose, because of tissue introgenerities, is higher. Then how do you count for that?

MR. BRICKNER: I'm aware of that, and that's what I intended to do, that's perfectly all right. That's my medical decision. His concern is only if I don't do what I intended to do with his machine.

MR. SMITH: But we found the language in here I think someplace that said delivered dose, measured, delivered dose. Not calculated. But actually delivered dose of -- something. He found it before, earlier today.

MR. TELFORD: This language talks about administered dose.

MR. SMITH: Oh, you didn't say calculated. You said administered dose. That's what I'm getting hung up on here. Because we know that the administered dose is many, many times -- more than ten or fifteen percent -- more than the prescribed dose.

MR. SUNTHARALINGAM: Maybe some of us are reading

too much into that language of the administered dose.

MR. TELFORD: I think so.

MR. SUNTHARALINGAM: But it then points out again the need for some clarification.

MR. BRICKNER: That's true. You do need some clarification.

MR. SUNTHARALINGAM: It essentially points out the need for some clarification in your opening verbiage as to what the intent of this deviation is.

I mean, if the deviation is from what the physician intended to do, then that constitutes an event.

MR. TELFORD: Dr. Smith, what phrase would you like us to use instead of administered dose?

MR. SMITH: I would feel better if you said calculated. Because the physician makes his decisions based on the calculations that are given him.

MR. TELFORD: You want it called calculated dose? Calculated administered dose?

MR. SUNTHARALINGAM: No, deviation from intended dose.

MR. TELFORD: We know that. We know it's the prescribed dose. But his point is, is it what you calculate to be delivered, or what is actually delivered?

MR. BRICKNER: It's what you calculate. You don't know what's delivered.

MR. SMITH: Physicians make judgments on calculations that are given to them. What is administered often, in fact always, is different from what that.

MR. BRICKNER: But you never know what's administered.

MR. SMITH: I would like the word administered because, not only do we not know, it's always different than what is calculated.

MR. TELFORD: What if we use the calculated administered dose?

MR. SMITH: What does that mean?

MR. BRICKNER: That's fine.

MR. SMITH: The calculated administered dose. Okay, I can live with that, I think.

MR. BRICKNER: Back to my original point. When we talk about total dose, I still hold the contention that 10 percent should he studied in house, 20 percent calls for talking to you all. That's this individual person's opinion.

MR. SUNTHARALINGAM: Well, that may give the authority. In a room of 20 people it could be highly debatable. I know we are living at this stage with 10 percent. As a result, even though I've been told many times you have ways of finding out, it is my serious concern that many events are not being reported because of this reporting

requirement of 10 percent. Therefore, people are using their judgment.

I think we have raised this concern in the past that only those who have some Q.A. programs, have some review process, are going to identify their errors or mistakes. Ninety percent of the people who don't have this staff or don't have a Q.A. program, if we don't look we won't find.

MR. TELFORD: Yes. Dr. Flynn made that point most eloquently in his letter. Dr. Brickner gave some rationale for why it should be 10 percent and 20 percent. Namely, that for most total teletherapy total doses, 10 percent is probably not clinically significant. But 20 percent extra almost assuredly is.

MR. BRICKNER: Yes sir, that's correct. I agree with that.

MR. FLYNN: I agree with that.

MR. SUNTHARALINGAM: Again, will you classify 20 percent as misadministration which is different from reporting to NRC?

MR. BRICKNER: yes.

MR. SUNTHARALINGAM: I mean reporting to the patient also?

MR. BRICKNER: No, I do not believe that under any conditions NRC has any right to tell me to report anything

to a patient. How I deal with the patient --

MR. SUNTHARALINGAM: So that's a separate issue. You have to be careful that all these get --

MR. TELFORD: Let's get to that in a minute.

MR. BRICKNER: That's a different matter.

MR. TELFORD: That's B(3)(i). Can we go to B(3)(ii)

MR. SUNTHARALINGAM: How about B(3)(2)?

MR. TELFORD: Yes. Double i. How about that?

MR. SUNTHARALINGAM: Oh. Factor of two error in any -- can we now change that to weekly fractional dose?

MR. FLYNN: Weekly cumulative dose?

MR. SUNTHARALINGAM: Weekly cumulative.

MR. BRICKNER: What do you think about that, Flynn?

MR. FLYNN: Is that factor of two too high?

MR. BRICKNER: No. I think within a week -- you know, normally you're going to give a thousand.

MR. FLYNN: So, fifty percent? My problem is, can you make it up the next week without harm to the patient, is the key question.

MR. SUNTHARALINGAM: He said 20 percent earlier as an event. Now we are talking about what is either --

MR. BRICKNER: Wait. Where are you coming from?

MR. SUNTHARALINGAM: On page B-A, item 3. We say

that teletherapy with greater than 20 percent error in any weekly cumulative dose.

MR. CAMPER: Are you talking about an event or misadministration?

MR. BRICKNER: No, an event is greater than 20 percent.

MR. SUNTHARALINGAM: Greater than 20 percent weekly dose. So now whatever number we have to come up with has to be somewhat consistent with that previous thing of 20 percent.

MR. BRICKNER: Okay. That's not unreasonable.

MR. FLYNN: Fifty percent weekly accumulated dose?

MR. BRICKNER: Now you're talking about 1500 instead of 1000 in most cases. That might --

MR. FLYNN: Yes. I'd call that a deviation. Fifty percent weekly cumulative dose a deviation. And 20 percent weekly cumulative dose an event.

MR. BRICKNER: Yes.

MR. TELFORD: What would you call a misadministration?

MR. FLYNN: See, I wouldn't use misadministration except for part B(1), because I would let a committee decide if there's significant harm to the patient. A committee of cancer people, cancer experts and physicists who work with cancer patients on a case by case basis. Because there will

be many patients who are not harmed, but there will be a lot of law suits. And it will cause people in the boon docks not to report and to cover up in their Q.A. programs.

MR. BRICKNER: We do have to go to the end, a little bit beyond. Because if you're going to say you will notify the patient and use the word misadministration, that is a tremendous flavor on --

MR. FLYNN: Your lawyer will call you.

MR. BOGARDUS: That's going to really be difficult. If we're not talking about having to send out that required notification to a patient calling it a misadministration, let's just talk about what's good medicine and bad medicine and what sloppy medicine and what's not.

MR. FLYNN: If someone is doing bad medicine you're going to take away their license anyway. And the patient has the option to sue through the normal process if they're harmed. If they're harmed they go to another physician, yes you were harmed, and they document that in a court of law.

MR. KLINE: Do you have a problem with that message being relayed to the referring physician, that there was a misadministration?

MR. BRICKNER: I'm not keen about that. But, no, that's acceptable. Because I can talk to him and he

understands what I'm saying, more or less.

MR. FLYNN: Yes. I think there would be less objection to that.

MR. BRICKNER: But to the patient, I think you're opening up Pandora's box for a great deal of unhappiness.

If we're going to do it that way, if we're going to limit this to NRC and perhaps the referring physician and the institution, a weekly cumulative dose that varies by greater than 50 percent I would be willing to accept as a misadministration.

MR. FLYNN: Or -- well, okay. Deviation or misadministration?

MR. BRICKNER: Misadministration. By more than 20 percent I would call an event, which we did a while ago.

MR. TELFORD: A typical weekly cumulative dose might be a thousand.

MR. BRICKNER: That's the usual dose. Eight hundred to a thousand.

MR. TELFORD: So, a 50 percent difference would be five hundred.

MR. FLYNN: And if you found that in your first week you would give less dose the second week.

MR. TELFORD: But if I go back to your logic on total and if you were giving five thousand and you were off by ten percent, then that's the same five hundred.

MR. BRICKNER: Yes, but that five hundred is spread over five weeks, not over one week.

MR. FLYNN: Right.

MR. BRICKNER: See the difference?

MR. FLYNN: There is a thing that has not been addressed in here. Well, I guess you really can't.

If there are interruptions of treatment it totally -- you would just write a new prescription, I guess.

But if you interrupt treatment for a week or two weeks because the patient had to go to grandma's funeral or they got bad diarrhea, or they had to be operated on for another problem, and you come back.

You had originally prescribed five thousand rads to the pelvis, there is a two week or three week interruption, and when you come back you're going to have to go to a higher total dose. Well, you write a new prescription, I guess and that makes it legitimate.

But time is a critical issue in radiation oncology. These doses we talk about all are meaningful as long as they're given at the regular intervals we intended. Once a day, five days a week, week in and week out.

If they're interrupted due to a snow storm or something, you may have to throw an extra treatment in at the end to compensate for three days off for a snow storm. That kind of thing.

We wish we could do it scientifically. It gets a little esoteric at times. What do you make up for three days off for snow? I don't know. How about one treatment? That's about as scientific as it gets.

But if we do that knowingly, intentionally with a reason, then that's not a change in dose or an error in dose or anything else. But if we thought we gave a thousand this week and on Friday we find out we gave 1500, I should think that's a significant error and probably should be reported to you just if nothing else to make us get busy.

If we were off by 200 that week we ought to know about it. I don't think it's quite as threatening. But we ought to investigate anyway.

MR. SUNTHARALINGAM: We have already addressed that 20 percent as an event that'll be --

MR. BRICKNER: Where we are is I had made the suggestion that the total dose be considered an event at 10 percent and a misadministration at 20 percent.

MR. CAMPER: To make sure I understand what you're saying here, do I hear you saying then --

MR. BRICKNER: Let me back up for Carl's sake. We have said, then, that anything under 20 percent, between ten and 20 percent, you made an in-house correctable error and you should be aware of it but it doesn't threaten the patient's life.

At 20 percent you've made a big enough mistake we ought to let them know.

MR. BOGARDUS: This is with the total dose, not the --

MR. BRICKNER: Yes, sir. Total dose.

MR. FLYNN: I agree with that.

MR. BRICKNER: We're talking now about the fractional dose. What we've done is we've changed, as Flynn said earlier, talking about daily doses doesn't make much sense because we do everything weekly. We've already said a bit earlier that a 20 percent weekly variation is an event, not an misadministration.

I have suggested that a weekly error of 50 percent probably represents misadministration.

MR. FLYNN: A factor of two is much too high probably.

MR. CAMPER: That's what I want to make sure of. In other words, we're saying that a factor of two for weekly --

MR. FLYNN: Weekly. For weekly.

MR. BRICKNER: We've suggested you get rid of fractional terms.

MR. FLYNN: So we've actually tightened up, but made it more logical.

MR. SUNTHARALINGAM: Yes. It's 50 percent either

way. I mean, a 50 percent error, plus or the minus side.

MR. BRICKNER: Yes, it's almost the same thing.

MR. TELFORD: So you're wiping out two, B(ii) and (iii) with this weekly cumulative?

MR. BRICKNER: Yes, sir. Also, your (iii), that's the strangest thing I've ever heard of and I just would never bring that up in here.

MR. FLYNN: That's a tough one. That's a tough one to monitor, even.

MR. SUNTHARALINGAM: Item 3, I don't know. Maybe it should be deleted.

MR. FLYNN: Yes, it should be deleted if we've got the weekly cumulative dose.

MR. FLYNN: Yes. Triple i.

MR. BRICKNER: Delete triple i, it's meaningless.

MR. FLYNN: Because you know you have the weekly cumulative dose.

MR. BRICKNER: Right.

MR. TELFORD: Okay.

We got off on a tangent here for a moment about reporting to the patient because that's been brought up several times.

On page 1449 of the notice --

MR. BRICKNER: 1449, I'm not going to like this, am I?

MR. TELFORD: Now, start on line 9 of the first column.

MR. BRICKNER: Line 9 of the first column.

MR. TELFORD: "The licensee shall also notify..."

MR. BRICKNER: ..."referring physician --

MR. TELFORD: Right.

MR. BRICKNER: -- and the patient area responsible." I don't think that's wrong.

MR. TELFORD: Now, skip to the comma.

MR. BRICKNER: "Unless the referring physician agrees to inform the patient or believes, based on medical judgment, that telling the patient would be harmful to the patient or to the relative, one or the other," it says.

Now, this is a current requirement. It's currently in the regulations this way. Our Office of General Counsel advises us that we may have a legal obligation to keep this. This is a current requirement; we didn't add this.

MR. TELFORD: No sir, I understand that. I found your counsel's suggestion interesting, I hope he's wrong. I hope that he will seriously reconsider it. It's fraught with a whole lot of problems.

MR. BOGARDUS: This is for a misadministration only?

MR. BRICKNER: Yes, sir.

MR. BOGARDUS: Not an event?

MR. BRICKNER: Yes, sir.

MR. FLYNN: This is where I think you should change the terminology to deviation. This is the reason why.

MR. SUNTHARALINGAM: Do we hear that there is an escape clause that the physician's have; because in their medical judgment, if they feel it's not proper to inform the patient, they can so do, but they have to document why they didn't inform the patient?

MR. TELFORD: There is an escape clause, in that the referring physician can say no, I don't want you to tell the patient, because it would do more harm than good. I think, in the report to the NRC, you have to say that the patient was not informed for that reason. You have to have the referring physician's agreement. I don't think we say that the referring physician has to document that.

MR. BRICKNER: You can just assume that it would be a rare event in which there is justifiable reason not to tell the patient. You're going to have to assume that the patient is going to be informed 99 percent of the time that there is a "misadministration."

MR. TELFORD: Okay.

MR. BRICKNER: My problem is that the timing on this is such that, as I understood what I read, is they're

going to be informed within 24 hours. It may be more than 24 hours before we know, number 1, that it really was an error of that magnitude, there really was a misadministration; and it may well be more than 24 hours before we realize whether there's any harm to the patient or not. We may be scaring the daylights out of them before we're prepare to have a realistic evaluation of what possible harm has been caused and be able to sit down with them and go over where they are and what we need to do.

MR. BOGARDUS: Well, I think that's a very valid point. You know, if the machine falls on the patient, then obviously, that's an obvious event and you know that. But some of these things are a lot more subtle and you may not pick it up for awhile and you may want to reinvestigate it -- a very intensive investigation before you come up with your answer; and 24 hours does not give you enough time to do a meaningful assessment of what might have happened.

MR. SMITH: Even though we know something has happened, it often takes -- in fact, almost always takes us 24 hours to determine -- to quantitate what has happened -- to go back through the calculations and sometimes even the measurements requires it. So 24 hours is really not enough time.

MR. SUNTHARALINGAM: Isn't it again -- it's the wording -- isn't that an -- sort of an escape clause. It's

24 hours after the group establishes that there is a therapy misadministration, to say --

MR. TELFORD: Discovers is the operative word.

MR. SUNTHARALINGAM: Okay, discovers -- but I mean, that question is -- is that -- I mean --

MR. TELFORD: No. Dr. Bogardus' point is still -- still valid. You discovered it; within 24 hours you're supposed to go through the referring physician and notify, unless told otherwise. How long would you need? What's the reasonable time for -- for doing a thorough investigation before you --

MR. BRICKNER: What difference does it make? It could take 4 to 6 weeks.

MR. TELFORD: No, no, no. I'm not saying that. I'm saying 24 or 48/72, there's not a big rush. You can't get the radiation back out of the patient. So I would say that I would want at least 72 -- I should think within 1 work week we should have a good definition of the incident, exactly what happened, what the dose was and what the risk to the patient is and we should be able to sit down with the patient and inform them of the situation.

MR. BRICKNER: You're point is, there's no rush.

MR. TELFORD: There's no rush because there's nothing you can do about.

MR. FLYNN: There's nothing you can do about it.

There's no action to take.

MR. SMITH: Often times you have to go back and do a completely new treatment plan. If there are multiple fields involved --

MR. BRICKNER: You may have to simulate it on a dummy, you may have to do a lot of things to get an accurate estimate of the dose. Then you've got to sit down and perhaps look up some literature and say, okay now, here's the dose we had to this part of the body. What is the probability of injury? What injuries are we looking for?

Then -- because those are the things the patient is going to want to know the minute you say there's been a misadministration -- you've been hurt.

MR. BOGARDUS: We are obligated, after you tell the patient, look, we screwed up, we did something wrong. The next question out of the patient's mouth is of what consequence is it to me? So you need to be able to follow up immediately and tell them, it's probably of no consequence or it may give you this or you may have some dire problems from it.

MR. CAMPER: So, it's really not so much the reporting of, it's the time?

MR. SMITH: Yes, sir.

MR. BOGARDUS: It's the time that's the problem.

MR. BRICKNER: I don't even like the reporting;

but if your attorney says that it's necessary for some reason -- but we certainly need to have enough time to get all the ducks in order; know where we are and to be able to say something meaningful -- you know like, don't buy long-playing records or something.

[Laughter.]

MR. BRICKNER: You've got to have something you can tell them. Many times, what you'll tell them is, the chances are 99 out of a 100 that you'll never evan know you had that extra dose. We're very sorry about it. It was an error, but it's very little chance that it's going to hurt you, let's go on with your treatments. That's fine. But if they say, what are you talking about? What happened? What did you do to me? That's going to be the term that's used. You say -- I don't know, we haven't figured it out yet. Well, that's --

MR. FLYNN: Boy, that would destroy everything.

MR. BRICKNER: You just call your attorney immediately.

MR. SMITH: A work week really is more reasonable.

MR. BRICKNER: It takes time. I've been through this before and it's a -- it takes 1 day just to get yourself prepared to sit down and have this conversation. There's no way around it -- you have to do it, and the only way that you can continue to practice safely in your

community is if you always do that. You sit down with the patient and say, here's exactly what happened, and I'm sorry it happened. Here's where we are and here's what we can do about.

MR. FLYNN: Are there circumstances where they would like to have the phrase added, "unless more immediate intervention would result in some action which would result in less harm for the patient?" For example, if it's a radioactive isotope, they can hydrate the patient and give him some lasix and get the iodine out much faster.

MR. BRICKNER: Very good point -- or if it's a subcutaneous infiltration of an isotope, it might be worthwhile to lay that open.

MR. FLYNN: If someone is not --

MR. BRICKNER: Unless immediate medical intervention is required to minimize the injury to the patient.

MR. FLYNN: Right okay, that's it. Unless -- right, that's it.

MR. BRICKNER: Yes. Because you can't stall around a week -- you know, yes -- you've seen -- we've all seen the medical oncologists that infiltrated and didn't do anything --

MR. FLYNN: Right.

MR. BRICKNER: -- and then come back --

MR. FLYNN: I think that then you're covered over this end then.

MR. KLINE: Well, also there could be incidences where you have a -- as a -- like John had talked about earlier -- equipment malfunction. The NRC needs to know so we can notify the -- the distributor of that equipment -- that there could be a problem.

MR. BRICKNER: This doesn't delay notifying you, we're just delaying notifying the patient.

MR. KLINE: Okay.

MR. BRICKNER: This is -- no request to delay notification to you.

MR. KLINE: All right.

MR. BRICKNER: We just want to have -- we want to know what we're talking about before we start talking to patients, because the patients are going to be very interested in a lot of answers fast.

MR. TELFORD: Okay. Now let's go to (B)(4), if you're all willing?

MR. BRICKNER: Sure. Oh, I hate that one.

MR. TELFORD: Okay. This is -- "administered dose is 20 percent from prescribed dose for brachytherapy."

MR. FLYNN: I'd like to agree with something -- said a long time ago -- maybe it should be 20 or 30 percent of source strength and for removal sources within 20 percent

of the described time. Then that would satisfy me because it would also address, in the Federal Register, all the serious brachytherapy reports that you've gotten to date, which have to do with incorrect source strength and wrong number of sources.

MR. TELFORD: You mean, if the loading were different by 20 percent or if the time were off by 20 percent.

MR. FLYNN: But for removable sources, if the time -- plus for removal source -- if the time was off by 20 percent, because then it would address every single serious brachytherapy incident that's been reported to you to date. All the serious ones -- to go back to your Federal Register, were primarily -- all the serious ones, and the most numerous was incorrect source strength; one was incorrect number of sources. There was one incorrect site. I'm not sure what the heck that was -- if they implanted the left breast and not the right.

MR. TELFORD: The current one in brachytherapy like this year, have been high dose rate remote afterloaders, where they have input the wrong treatment distance and greatly over dosed some patience.

MR. BRICKNER: I don't know about those things.

MR. TELFORD: Those things are almost like teletherapy. Well there's another one, that's the

gammaknife.

MR. KLINE: Those devices are becoming more and more prevalent and they're going to be load dose rate after-loading devices which still might be effected -- a high dose rate by 20 percent.

MR. SUNTHARALINGAM: Again, you may have to separate out a brachytherapy procedure, low dose rate, and a brachytherapy procedure high dose rate.

MR. FLYNN: Right. I had that in my letter to you back in March -- separate those out.

MR. BRICKNER: That's true. Again, a change in dose, with a high dose dosimeter -- for instance, if I do a 72-hour application and make a 20 percent dose error in the standard treatment of cervix cancer and Bob does one on his machine in an hour and a half and makes a 20 percent dose error, I think your error is going to be more significant than my error; is that right?

MR. BOGARDUS: Well, it's going to be worse because what I'm doing is say delivering 700 rads in a matter of 3 or 4 minutes, and a 20 percent error can change that significantly.

MR. SUNTHARALINGAM: I think we should coordinate with the ACR for the future.

MR. TELFORD: How about the second week -- the second week in December?

MR. SUNTHARALINGAM: Through ACR?

MR. BRICKNER: Second week in December?

MR. TELFORD: How does that sound.

MR. SMITH: We should have somebody make the calls.

MR. TELFORD: Well, yes, but I have to ask you first. I mean, does that sound reasonable, or is it totally out of the question?

MR. FLYNN: Towards the end of the second week?

MR. TELFORD: Towards the end of the second week?

MR. BRICKNER: Do you gentlemen work Saturdays?

MR. TELFORD: For you, we will.

I don't know about you guys, but it would be a hell of a lot better for me if I could fly up hear Friday afternoon. I don't mind spending a Saturday. My partner doesn't like my spending Monday.

MR. BOGARDUS: Bear in mind that you're beginning to cut into Christmas weekend, which will make your wife vigorous unhappy with you.

MR. TELFORD: December the 15th -- that's a Saturday? Dr. Flynn, you said December the 14th is a Friday, right?

MR. FLYNN: Right. Not all of us are so fortunate, Al.

MR. TELFORD: Sunthy? The 15th -- December 15th?

MR. SUNTHARALINGAM: That's right, it's a Saturday.

MR. TELFORD: Dr. Smith, is the 15th all right?

MR. SMITH: Sounds clear for the moment. As far as I know.

MR. TELFORD: Dr. Bogardus?

MR. BOGARDUS: Probably won't work, but let me check and see.

MR. FLYNN: Perfect for me, actually.

MR. TELFORD: Who should we get back to when we get home with our calendars?

MR. FLYNN: The ACR -- Brad Short, I believe.

MR. BRICKNER: Shall we quit?

MR. FLYNN: You notice that the physicians have more staying power than the physicists.

MR. TELFORD: It looks that way. It looks like it is true today.

MR. TSE: May I ask a question about your suggestion about time -- to use time? Time is calculated. Somebody calculated to deliver certain dose and maybe 72 hours. But if you say that deviation deviated from that time, suppose somebody calculated wrong and the 72 hours is not really 72 hours -- should be, if you deliver certain dose, you should be 48 hours? Now how do you compare -- which time are you going to compare to? How do you know

that original time is the correct time?

Your dose is the correct dose because the physician you said gave 5,000 rads, so the physicist -- they're not here -- they take this number and go do their calculation and come back to tell you 72 hours. But suppose before -- instead of the 72, because the computer program, whatever made an error somehow. Now, how do you compare the time? Which time you compare with?

MR. FLYNN: I'm not sure if I can address that question. I looked at the plan myself. I don't let the physicists tell me how many hours. I look at the plan myself. I want to see an isodose plan. I have reference points or -- volume, whatever I select, 50 rads per hour as the target volume I'm giving and I know that if I want to deliver 3,000 rads, I want a 60-hour implant. If the resident puts it in at 6:00 and I come by a half hour later and check to make sure he put it in right, I want to make sure he put a note in the chart that he takes it out at the right time because sometimes they may, in their heads, be 12 hours off and make sure that they don't make that kind of a mistake.

MR. BRICKNER: We both feel on brachytherapy difference of 20 percent is an event and 50 percent is a misadministration.

MR. TSE: Dose or time?

MR. BRICKNER: Dose -- dose, time, it doesn't matter, it's the same thing.

MR. TSE: We were just discussing how does the time relate to the dose?

MR. BRICKNER: Well, once you've got an amount of radioactive materials present, dose is determined by time.

MR. TELFORD: Yes both -- the answer it both.

MR. BRICKNER: They're the same thing.

MR. TELFORD: They're the same thing.

MR. FLYNN: There are some people who are still using milligram hours, like M.D. Anderson, still using milligram hours. Some people might be using a .A as a reference point, or .B.

The closer you prescribe the dose to the source over a high dose gradient area, the more perilous you are.

MR. BRICKNER: The sillier it is to use a point that's close to the source, because millimeters make huge differences. That's why milligram hours is probably the best way to do it.

MR. BOGARDUS: Milligram hours are less likely to screw it up.

MR. FLYNN: In the Register, when they have summarized all the serious brachytherapy events that they have knowledge of, all the serious events reported to date have been incorrect sources, 6 events; incorrect number of

sources, 1 event; incorrect site implanted, 1 event.

The other ones, the ovoid broke off as they were pulling a device out -- that's going to deliver a millirem dose to the -- I mean, all those are --

MR. BRICKNER: It was wrong sources.

MR. TELFORD: By the way, I think that was as of December of '89.

MR. BRICKNER: It hasn't changed. Except now you got this damn high dose thing.

MR. TELFORD: There have been -- there were 12 misadministrations in 1989 in the therapy range; there were 20 so far this year. I think that's -- isn't that -- aren't most of them high dose? Do you know?

MR. FLYNN: Of the brachytherapy ones, yes.

MR. TELFORD: My opinion is that if you talk about conventional brachytherapy, I would be satisfied that 20 percent is --

MR. FLYNN: Conventional low dose rate brachytherapy.

MR. BRICKNER: Yes. Conventional low dose rate brachytherapy. 20 percent is an event, 50 percent is a reportable misadministration. I think you need to handle high dose rate remote afterloading as an entirely separate horse.

MR. BOGARDUS: Well, with it, if you have an

error, it's going to be hundreds of percent; it's not going to be a 20 or a 50 percent probably.

MR. BRICKNER: Then the 20 and 50 would be fine with me.

MR. TELFORD: Yes, right. It's going to be 120 -- 100 --

MR. BOGARDUS: It's a magnitude change, if somebody calculated at a centimeter, instead of a half a centimeter. You know, the guy didn't look at the isodose before he ran it.

MR. BRICKNER: It's 4 or 500 percent then?

MR. BOGARDUS: Yes, and you're talking, instead of 500 rads, 10,000 rads.

MR. TELFORD: Okay. But if I follow that logic then a 50 percent difference is what it's going to be anyway.

MR. BRICKNER: It's all 20 and 50. Can we go home now.

MR. TELFORD: Well, we may be to a breaking point. We've gotten through the therapy reporting requirements. The next thing that we could have -- yes?

MR. TSE: Did you say that 20 and 50 for conventional low dose rate?

MR. BRICKNER: Yes, for all of them. I just changed my mind with what Carl Robert has said, is that by

the nature of the beast, the errors are so gross for all --

MR. BOGARDUS: The errors are so huge with the high-intensity stuff that these numbers --

MR. BRICKNER: What were your intentions for the next one?

MR. TELFORD: The next topic -- the next topic on the agenda was the regulatory guide and that might -- this might be a good breaking point.

MR. BRICKNER: The regulatory guide is what?

MR. TELFORD: The latter few pages of that notice -- that notice package.

MR. BRICKNER: Okay. This thing.

MR. TELFORD: Yes.

MR. BRICKNER: I need another one of these I haven't drawn on. Do you have one?

MR. TELFORD: Sure.

The way to look at guide is that we have gotten a lot of feedback from our volunteers. And we have some questions that we would like to ask you-all, because you are the experts, that are based on suggestions that our volunteers have given us.

So if you find a lot of things that you don't like about the guide, do not be alarmed. We know about almost all of those.

MR. BRICKNER: Do you want to ask us some of those

questions that we'll just shoot at right now?

MR. TELFORD: Well, for instance, in Section 4.3, if you open this thing here to Page 6.

MR. BRICKNER: Yes.

MR. TELFORD: You're in brachytherapy. We're looking for a good way to check the sources or the source strengths and the loading sequences, or what we should be checking or should be asking for to be checked. So we're looking for a recommended list of things to check and ways to check.

MR. BRICKNER: Okay. Qualified person under the supervision of an authorized user. So what you're saying is there are going to be two people look at the sources, and you have left open, obviously, the most useful one, because reading the serial numbers is not practical. Using clearly-marked storage spaces is good. But you've left one out. And I think it's one that you are in a position to implement, that we cannot, and that is an industry-wide standard of color-coding for sources.

MR. FLYNN: It's not uniform yet, because some of the old sources have different color codes.

MR. BRICKNER: Fine. But from now on.

MR. FLYNN: Right.

MR. BRICKNER: So that in the future, we don't have this problem.

MR. FLYNN: Right.

MR. TELFORD: Well, let me give you a list of our, let me give you some of our questions, and I don't expect answers now.

MR. BRICKNER: I think that paragraph is fine.

MR. TELFORD: So we're looking for things to check and methods of checking.

And in 4.5, on that same page, Page 6, we're looking for acceptable methods for determining position of sources, so the dose calculation can be performed. Secondly, we're after the special considerations for what devices to include here, that may be exceptions, like high dose-rate afterloaders, gamma knife, implants, et cetera.

MR. BRICKNER: Well, as has already been pointed out to you in the letters that were sent to you, dosimetry radiographs are normally made with dummies in place and all the afterloadings. So it goes without saying that radiographic films should be taken for dose calculations, but you don't have to wait until you load them. Preferably, you don't.

Now, high dose-rate afterloading. I assume that you do, don't you do the same thing?

MR. BOGARDUS: Yes, we do. We do a dummy run. Because obviously you can't do it with a real source in there. So you have to do it on the dummy run. Then the

real source, you assume the machine puts it where you wanted it.

MR. BRICKNER: I would assume radiographs is right, because even if you were satisfied with your fluoroscopic examination, you need to document it for future reference.

MR. TELFORD: Or maybe we're also looking for exceptions.

MR. BOGARDUS: Well, the exception would be in 45. After implanting the sources, radiographs be obtained. You can't do that in remote afterloading.

MR. BRICKNER: Exceptions.

MR. TELFORD: Like eye implants.

MR. BRICKNER: That might be an exception.

MR. BOGARDUS: Black dose, blacks for melanomas and things.

MR. BRICKNER: Yes, that's an exception.

MR. BOGARDUS: Yes, you can't tell anything about that.

MR. FLYNN: There's also fixed geometry implants, where you have maybe 150 sources and a fixed cylinder, some kind of a perineal implant, or template. And of a physicist is going to calculate, he's not going to be able to discern 200 seeds would have leaked films. So the fixed geometry implants can be done.

MR. BRICKNER: Yes, but you probably need to take a film of that anyway to document where they are in relation to the bladder, the rectum, and some other anatomic site.

MR. FLYNN: Yes. But as the basis for calculating the delivered dose. There are other bases.

MR. BRICKNER: Yes, okay. Yes, that's a legitimate exception. There will be devices in which you can't do it radiographically. When there's 500 seeds in there, you can't pick them out.

MR. BOGARDUS: You can change that and say, and used to assist in the calculation of the delivered dose, because that's really what you're doing with it. It is not the sole basis, many times. It's used only as an assist.

MR. BRICKNER: In that case, you just consider each of those tubes to be a linear source, don't you?

MR. BOGARDUS: Yes.

MR. BRICKNER: And eye implants. What else? Everything else you pretty well want to take films of.

MR. TSE: Could you use CT instead of radiograph?

MR. BOGARDUS: No. CT's worthless. You get so much artifact from CT you can't see anything.

MR. BRICKNER: Just a good X-ray.

MR. BOGARDUS: Yes. Orthogonal films taken at the appropriate geometry are the best way to go.

MR. BRICKNER: Well, some people still use stereo

shift. I think it's dumb. But if they've had good luck with it, I guess it's all right. ?ppropriate film. But no, scanning them doesn't help.

MR. TSE: How about templates?

MR. BOGARDUS: Yes, templates in fixed geometry.

MR. KLINE: Do you feel that there are any oncologists or physicians that are practicing medicine that are using the fixed geometry concept with an afterloading device for brachytherapy implant, intercavitary, and can justify a dose delivered without taking radiographs?

MR. BRICKNER: No.

MR. BOGARDUS: Yes.

[Laughter.]

MR. BOGARDUS: The exception being in that is the GYN remote afterloading, because that applicator is a tandem and a ring, and you place that visually. I see where I put it. You lock it into place. And two minutes later, the patient has already been treated. You don't need a radiograph.

MR. BRICKNER: You don't need a radiograph to memorize the bladder and the rectum and calculate the dose?

MR. BOGARDUS: You can do that one time out, if you want to. But after that, the geometry is fixed. You're doing this eight, ten, 12 times.

MR. BRICKNER: Okay.

MR. BOGARDUS: We do it the first time out, on our planning. But beyond that point, each day, we set up the geometry the same and treat them the same.

MR. BRICKNER: I bow to Dr. Bogardus's superior wisdom, since he has one and I don't.

MR. BOGARDUS: But there's always these wierd little exceptions that get thrown in there.

MR. TELFORD: Okay. We have some on Section 4.8, of the timing of these checks, and the methods for doing the checks.

MR. BRICKNER: That's always an interesting problem. We tried, when we did the American College of Radiology, all these years, the program design, when the checks had to be done. We tried to say, by the second treatment. And problems came up with that. By 10 percent of the dose. Problems came up with that. We finally settled on 72 hours.

That meant you weren't going to, in most situations, you weren't going to get more than three doses in before the check was in the chart, which is normally early enough. It took care of long weekends. Treat on a Friday and you don't come back until Tuesday, and that kind of thing.

MR. TELFORD: This is brachytherapy.

MR. BRICKNER: Oh. I'm sorry. It should be done

immediately.

MR. BOGARDUS: Sometimes you can't, though. You do one of those site implants, that physicist will screw around with that thing for 24 hours before they come up with the final numbers.

MR. BRICKNER: Yes, but they should start immediately.

MR. BOGARDUS: Yes, well, they do. But they won't be done, maybe, until the next day, and then you know, you pull out sources and rerun it again and pull out a few more sources and rerun it again.

MR. FLYNN: You can say before the treatment is completed, if you make the error that you don't get --

MR. KLINE: You're re-running your prescription, also, aren't you?

MR. BRICKNER: Should you say before half of the treatment is completed?

MR. BOGARDUS: That's what we've got down here now. That's aa reasonable number, probably.

MR. BRICKNER: Because if you're going to say well, I'm going to put it in for 72 hours, have me the answer by the morning, and I take it out, you know, you may have already flubbed the dub by then. 50 percent of the dose would be reasonable.

MR. BOGARDUS: That's reasonable.

MR. KLINE: What about, have you had any problems with, as I say, combined teletherapy, brachytherapy treatment for a total dose? Do you have any comment on how this --

MR. BOGARDUS: Well, they need to be added appropriately.

MR. KLINE: Right. So then you have the addition, but yet you've got before 50 percent of prescribed dose has been administered.

MR. BOGARDUS: Well, you're talking brachytherapy only.

MR. BRICKNER: Fifty percent of the brachytherapy dose you intend to deliver.

MR. KLINE: Okay.

MR. TELFORD: Okay. You have to separate that, separate teletherapy and brachytherapy.

MR. BRICKNER: No, but there are some people who would object to adding rad, for rad, brachy, and tele.

MR. TELFORD: There was a 24-hour needle implant brought up at one of our workshops. Do you still think 50 percent is the right number there?

MR. BOGARDUS: Yes. If you are doing a 24-hour needle implant, that's probably a fairly simple thing, and they should have had that precalculated, or get the numbers pretty quick on that.

The thing that takes so long are some of these massive template implants, which do stay in a long time.

MR. BRICKNER: Yes, a 24-hour one, that's the one that you really should have it, because, you know, a little bit of time makes a difference.

MR. FLYNN: You have an approximate idea before the implant how long it's going to stay in, roughly. You know, 24, 72, 48. You have a rough idea. So you know how fast you need to move.

MR. BRICKNER: The biggest problem is interstitial implants. When you go to put seeds in, you say well, I hope I get a doss between 1,000 and 5,000. Let's see how good I am today. And you go and you do it, and it's all over, and you can't get them back, and you get some films, and then you have to live with what you did. And that gets very interesting.

Now, what's an error there? I've got two patients that have permanent colostomies now, unfortunately. When I go back and look at the numbers on the computer runs, I still don't know why they have colostomies. But they do.

You say, I want to get such and such a dose. But you don't know what you're going to get, until it's done. Now, if you're way off, I don't know what you do. You can't go in and get the damn things back, so you have to try to safe-side it to the low side. But if you don't get enough

dose, then it wasn't worth putting the patient to sleep to do it.

I don't know what you call an error in that situation. When I know what I would like to accomplish, but I don't know what the dose is going to be until I've done it, what's the wrong dose?

MR. TELFORD: As we discussed earlier, the prescribed dose is after implant so after you went into the OR and you made the implant and then you determined location and then you calculated how long -- no, no. Then you calculated the dose that was going to be delivered but in this case you calculated there was a dose that was going to be delivered to an organ unintended, not in the treatment volume.

MR. BRICKNER: Oh, even the treatment volume. I may come back out and say, god, those are lot closer together than I meant for them to be -- my god, what is the dose going to be? And it is going to be 7,000 and I only wanted about 4,000. How do I determine the -- how can I say to you I did or didn't make a mistake?

Well, when the guy comes in with an ulcer this big in the back of his nasal pharynx, we can say it wasn't too slick a treatment but you know that's a very difficult one.

I don't know how to deal with that one.

MR. KLINE: Wouldn't that get more into the

clinical prescription, which is more your line of work than ours, whether or not you prescribe properly to begin with or even if you didn't if there are questions, whether or not that person's tolerance -- because tolerance varies, I would think.

MR. BRICKNER: Probably we ought to forget that I brought it up because there isn't an answer to it.

MR. TELFORD: I guess the answer is that the authorized user has to prescribe after the implant.

MR. BRICKNER: At that point you have to look at the isodose curve and you make the conscious decision that, yes, it probably is going to get 8,000 or 10,000 there but we cannot redo it. The risk is worth the benefit that is potentially going be gained by doing the implant.

I will agree that we'll leave it in for 8,000 at that spot and hope he doesn't ulcerate too bad.

MR. TELFORD: I mean you have to make a medical decision at that point to either leave him there or not.

MR. BOGARDUS: And we'll tell him usually, these are the patients we talk to later on and say, well, you know, it was pretty hot back there in the back of your throat and you got spot there but chances are we may have cured you.

MR. FLYNN: On these patients we have gotten informed consent. These are unavoidable. There is

absolutely no way we could correct this type of situation but hopefully you have gotten informed consent from the patient upfront, what the potential complications are.

They can not be treated at all and have 100 percent chance of having a complication due to the progression of the tumor or take a chance with our treatment and accept a certain level of treatment complication.

MR. BRICKNER: Did you have some more?

MR. TELFORD: Oh, yes, I've got more.

I thought what I was going to do is run through these questions and let you think about them.

MR. BRICKNER: Oh, grand, especially if you have them written down so we can think about them later.

MR. TELFORD: Let's see, we've got 4.8 timing in methods, special considerations or exceptions.

Let's move to teletherapy, 5.2.

We have used treatment volume here and we've used treatment plan.

MR. BRICKNER: Oh, well, you've defined it here. Perhaps you ought to -- yes, okay.

MR. TELFORD: But we have used treatment volume and some folks have objected to the treatment volume and some folks have objected to saying treatment plan.

MR. BRICKNER: No, that is a treatment plan. Is that a prescription? Yes, it's a prescription too. What's

the difference? I don't know the difference.

What is the question?

Is this a good definition of treatment plan? It includes the treatment modality, the treatment volume, the portal or field arrangement, the total dose at a specified location and the dose per fraction or the number of fractions.

That is an excellent treatment plan.

Those are the things that should be in it, no more, no less.

MR. TELFORD: You would use treatment volume rather than treatment site or treatment point?

MR. BRICKNER: I would, but then other people like site. Other people like --

MR. BOGARDUS: Volume is an understood thing and treatment volume to me is the area around the cancer or the area in the pelvis.

MR. BRICKNER: Is it the volume you're treating?

MR. FLYNN: It says here total dose to a specified location. By treatment volume did you mean the field sizes? Because in the next one is portal or field arrangement, field sizes, the treatment field sizes should be -- is that standard? That is in the chart for external beam treatment?

MR. KLINE: Portal refers to field size.

MR. BRICKNER: Well, treatment volume and

statement of the portal or field arrangement is going to be what you define it to be in your quality assurance plan.

In my plan it is not going to be centimeters of the field. Treatment volume in my plan is whole pelvis, left hemisphere of the brain, mediastinum and left hiler mass.

MR. FLYNN: In your charts, I mean in your plan you would tell a technicians how large to make the field.

MR. BRICKNER: Not on the treatment plan. That is in a different place.

When we simulate the fields and paint them on the patient and everything, then the field size is stated as a descriptor at the top of the column of daily treatment.

I just don't think size is part of the plan.

You could write it your way. It doesn't make any difference, just whatever you think is proper in a plan, just so you define it and stick to it.

I should think that's what they want.

MR. TELFORD: Then in 5.5, what things do you check weekly? If you could tell us about that later.

MR. FLYNN: It ties in well with our definition of event and misadministrations in terms of certain limits that are acceptable on a weekly basis.

MR. TELFORD: Your weekly check here.

MR. BRICKNER: Let's see, we started out with 4.8.

What was before that? 5.2, 5.5, 4.3 and what?

MR. TELFORD: 4.5.

MR. BRICKNER: 4.5.

MR. TELFORD: 4.8, 5.2, 5.5, 5.6 -- these are methods in timing for these calculations in 5.6.

MR. BRICKNER: 5.6.

MR. TELFORD: And also special considerations.

MR. BRICKNER: Special considerations?

MR. TELFORD: Yes, like small number of fractions or amount of dose given or something like that.

In 5.7(2) this would be methods for these checks, for these full calibrations. We're checking full calibration measurements.

Then there's 5.8, recommendations for measurements that you'd make at the time of annual full calibration.

5.9, we have heard some recommendations to rely on the inverse square law if we are outside the distance, the distances, or the distance range that was used at time of annual full calibration or they're saying that the used square field sizes and then what do you do about rectangular field sizes? Is this something that we ought to address?

Measuring transmission factors or beam modifying devices that have not been previously measured -- in 5.9.

Then in 5.10, we'd like some recommendations on what we should specify for checking out computer codes, both

on first use and then after the source change or what things should we list here as good things to do after a source change.

That is probably enough food for thought.

MR. BRICKNER: You would like us to drop you a line on those subjects?

MR. TELFORD: We would like your considered opinion and suggestions. Yes, indeed.

MR. BRICKNER: And where would you like that information sent?

MR. TELFORD: Well, how about the next meeting?

Is there something that you all would like from us in the next meeting?

I guess my point of reference is the agenda here.

We have left a blank spot for any of the associations to talk about their model programs or standards that they would like to get our --

MR. BRICKNER: You have copies of our program, do you not?

MR. TELFORD: Yes, but maybe if you wanted to discuss that program and to tell us that certain parts of it are eminently applicable to what we are trying to do here, you know, these parts are and these parts are outside your scope, because some parts of yours really are outside our scope, but you know, we would like to listen to that.

MR. BRICKNER: I'll try to do that for you.

MR. TELFORD: If there is some feedback that you want, just let us know.

MR. FLYNN: Probably the feedback that the physicists would like would be if either on the record or off the record you could give sort of a summary to date as to the key information you have -- somehow if we could know a little bit about the data that you have accumulated in the pilot study since it's over now.

If you have asked the wrong questions or if you are misinterpreting the results of some small section of that pilot study, we may best see where the pitfall might be.

You may make some major decisions based on that pilot study.

MR. BRICKNER: So, as much as you can give us on the pilot study and if you can, a synopsis of what you thought you heard today. We recommended a lot of changes. Now, whether we institute them or not, I, for one, would like to know what you thought you heard suggested for change and the reasons given. Do you follow me?

MR. TELFORD: A summary of recommended changes?

MR. BRICKNER: Yes.

MR. TELFORD: Okay.

MR. BRICKNER: I want to know that you heard what

we said and that we got the message across. Now, whether you institute all the changes or not, is a different matter. That's up to you when you go to the smoking room and write the rule.

MR. TELFORD: Okay.

MR. BRICKNER: It would help to know that we all understood each other when we were here. I can't think of anything else you can tell us, unless there are any new parts to the regulations or changes in the regulations that you are allowed to tell us will probably go through or you're recommending go through that would give us any additional information or flavor for where things are.

MR. TELFORD: Okay. Let's adjourn the meeting. Thank you very much.

[Whereupon, at 5:21 p.m., the meeting was adjourned.]

REPORTER'S CERTIFICATE

This is to certify that the attached proceedings before the United States Nuclear Regulatory Commission

in the matter of:

NAME OF PROCEEDING: Meeting with AAPM, ACMP, ACR, AES, and ASTRO, Proposed QA Rule and Reporting Requirements

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were held as herein appears, and that this is the original transcript thereof for the file of the United States Nuclear Regulatory Commission taken by me and thereafter reduced to typewriting by me or under the direction of the court reporting company, and that the transcript is a true and accurate record of the foregoing proceedings.

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