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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

OFFICE OF NUCLEAR REGULATORY RESEARCH

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QUALITY ASSURANCE PILOT PROGRAM

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POST TRIAL WORKSHOP

Airport Hilton Inn

Salon C

10th and Packer Streets

Philadelphia, Pennsylvania

Friday, August 17, 1990

The workshop convened, pursuant to notice, at 8:35 a.m., JOHN TELFORD presiding.

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PROCEEDINGS

[8:35 a.m.]

MR. TELFORD: Good morning. Welcome to the second day of the workshop.

I'd like to do a little preview of the agenda for today. This morning we will go through the Regulatory Guide and we will have the same approach as we did with the proposed regulation 35.35 -- that is, we will talk about your suggestions -- you will talk about your suggestions to whether or not you would retain or delete or modify section of the Regulatory Guide and in particular we would truly appreciate some suggestions for additions to the Regulatory Guide because I think those would be most valuable, if we had several alternative ways to address each objective that's in the rule and give a greater variety to licensees for ways to meet this rule.

This afternoon we'll talk about the reporting requirements -- first, the diagnostic reporting requirements and second, the therapy reporting requirements.

We will go through these at the speed that you want to go through them. We will take all morning on the Regulatory Guide, if that is what is effective and take all afternoon on the reporting requirements or as long as you want to talk about them.

For the Regulatory Guide, Dr. Tse is going to lead

you through that discussion, so at this time I will turn it over to him.

MR. TSE: Thank you, John.

This morning we will be talking about your comments or suggestions on each element of the Regulatory Guide. Before we go on to discussion, I have a few general notes I want to mention.

One is that we have quite a big discussion yesterday about the proposed 35.35. Whatever the revision we are going to make on the proposed 35.35 will be incorporated into the Guide because the Guide is the guidance to implement 35.35, therefore we will be modifying the Guide, which would meet -- which will follow the 35.35 changes, usages.

Second point is that we plan based on the comments and suggestions you made, we plan to meet with the professional associations in the medical area like JCAHO, AAPM, ACR, or ASTRO to discuss with them their suggestions and to look at, discuss with them on what they have in terms of QA. Then we will try to match or incorporate or adopt what they have or similar kind of wordings, just like you mentioned yesterday, so we plan to do that in the future.

Third item --

MR. KEARLY: Is that before any regulations would be implemented?

MR. TSE: Oh, yes. That would be considered to formulate the final regulation. Those discussions will occur before we finalize the final rule.

As John mentioned, if you have any suggestions on how to achieve certain objectives other than what we said in the Guide, please let us know because some volunteers indicated certain states or certain people may use the Guide as a regulation, so if we put more alternatives to satisfy the 35.35, that would be a better Guide because it would be more ways they can, licensees can use to achieve the objectives.

If you have any suggestions of how to achieve those objectives, please indicate to us.

Now we are going to go to the discussion and we'll try to see whether we'll go through each section and we'll obtain your suggestions on whether to delete, modify or retain this element or any additional for that particular program area.

Okay, everybody have a copy? I did not prepare viewgraphs for some many items.

Everybody have a copy of the Reg Guide? Okay.

I think we can skip the first three pages, unless somebody have specific comments he wants made, otherwise we start with page 4.

Does anybody have comments or suggestions on the

first three pages, which is the general discussions?

[No response.]

MR. TSE: If not, then we go on, to page 4. Page 4, on Item No. 1, is responsibility, authority and audit. We have discussed quite a bit yesterday on the items related to audit. Whatever we are going to adopt in the final regulation will be reflected here, as I indicated before.

Other than that, anybody has any suggestions on the 1.1?

I understand from yesterday's discussion your suggestion is to change the word "Management" with "Review."

MR. STRUBLER: I will just reiterate what I said briefly yesterday regarding that point, and that is Management as defined here is the licensee's management, which means Administration, and they are not qualified to review the efficacy of the program and they are going to rely on us or other people in the organization, so I think that should be changed, and perhaps either you should say the Committee or the Chair of a particular department or something of that kind might want to have/be the overall review based on a submission from more qualified individuals.

MR. TSE: Right, but does that have to be the Management who delegate the responsibility to certain departments or certain Committees? Maybe there's several

different committees could review --

MR. STRUBLER: That is possible, but the way you have it here it says the Management will review.

MR. TSE: I agree.

MR. STRUBLER: So if you want to delegate the authority to review --

MR. TSE: Management or delegate to certain -- yes?

MR. STRUBLER: Yes.

MR. KEARLY: I would also like to see it possible for you to say something like "The review will be done by a qualified individual" -- not by someone who is not involved with the process. There's only so many people to go around in this business and those of who are involved in using the program are just as capable of reviewing it, I think, as somebody from outside.

It's always nice to have an outside person look at what you are doing but I don't think for a review procedure like this -- you just take a look at your program and see if it's being effective.

MR. TSE: That's true. Always to have an outside review of it would be more satisfactory. But we do not really say it, because that is sometimes very costly and so on.

MR. KEARLY: You say somebody who is not involved

with the activity?

MR. TSE: Right.

MR. KEARLY: The only people in my hospital who could view our program are people in our program. So --

MR. TSE: We say in all activities direct, like if you are doing the calibration --

MR. KEARLY: I'm the only physicist there.

MR. TSE: Right.

MR. KEARLY: And to review this program, you are going to need somebody with a background similar to mine. We have go get somebody from outside. But they hired me to do that sort of thing at the hospital. Now, you are going to require that they also hire somebody else to do it. I don't think it's necessary.

MR. TSE: Okay.

MR. KEARLY: Not for review; I don't think so.

MR. TSE: The problem is that if I did my own calculation, I formulate my own program --

MR. KEARLY: But this is not a double check on a calculation. This is a review of a massive program.

MR. TSE: Review of audit of those programs. If I develop the program, if I audit myself, the efficiency would be low.

MR. KEARLY: It would be low both ways. Somebody reviewing it from outside who does not have a real

familiarity with what you are doing can take an extra long time to no benefit whatsoever. I might be able to see much more effectively that here is a dead spot in the program that ought to be removed, and maybe we ought to add something over there. So it could go either way.

MR. TSE: So your --

MR. KEARLY: I think it is completely unnecessary to have an outside, a non-involved person do a review like this. I think it's just --

MR. TSE: So your suggestion is that management could decide the qualification of the qualified person to review it, instead of having to have somebody who --

MR. TSE: I don't know if management is the right person, the right word to use there. But the department, my department can certainly decide that we can review our own program.

Again --

MR. STROBLER: We're kind of getting into the 1.2. But that's okay. I'll add my comments.

I basically concur. Ideally, I think we would all like and welcome an outside review of a program. But to insist on a yearly basis, number one, for a qualified person to do this outside review of a rather massive quality assurance program is probably not cost-effective. And most places, I would think, would be, as in Frank's and certainly

in mine, where you are compelled to go to an outside source to get a qualified person to review the program.

And also, once the program has been established and has been reviewed by a number of parties perhaps within the organization, that, on a yearly basis, I would question whether you are going to really be picking some defect up in the procedures, particularly since you have internal regular reviews to check on trends. To do it every year seems excessive.

But I also question the problem. I don't question the degree or the ideal, perhaps, of having an outside review, because you don't like to review your own work. But the cost involved and the time involved, if I were to review someone else's program, it would take me quite a considerable time, because we all do things a little bit differently. To do an appropriate job, and a thorough job, it would take quite a bit of time.

MR. TSE: But would that be the time more likely to catch somebody's error?

MR. BUKOVITZ: I don't think that the point is much different now from having us audit this QA program and us auditing other internal programs which we would report to the RSC on a routine basis.

We certainly don't need an outside authority to come in and say hey, you did something wrong, then report it

quarterly to the RSC. I personally feel we would be doing more than an adequate job.

And if, upon inspection, you find it is not being done, you can mandate an outside individual come in and then review the program.

MR. TSE: So what you are suggesting is that if the word stands, then some licensees will have to have outside auditor, even if we do not say so, because they don't have another person which is not involved with the work.

MR. BUKOVITZ: Right.

MR. STRUBLER: I would suggest most. I wouldn't say some.

MR. TSE: Oh, most.

MR. STRUBLER: I would say most.

MR. TSE: Most will have to have that.

MR. STRUBLER: If you're going to stick to the qualified persons who are not involved in the activity.

So all qualified person in the location are generally involved in some form or another, and also, to be really qualified to review the program, you would have to have probably some people with credentials similar to those in this room.

MR. TSE: Yesterday you mentioned about JCAHO and other organizations. When they mentioned audit, what do

they suggest?

MR. BUKOVITZ: Internal.

MR. TSE: Internal.

MR. STRUBLER: I can tell you my experience with JCAHO was very brief. Other people have much more detail, because of who may come. A physician would come to our facility and they may have some expertise in radiation oncology, or they may have zero. Most likely, zero.

Or some, you know, sense of what is going on. And since our facility had been accredited by the American College of Radiology, that was great for them, because they knew another outside agency had come in with expertise and a team, and spent many days, and that is all they were really looking at. I mean, that would satisfy them, completely.

And so they didn't even go beyond that. I had all this wonderful documentation that I was going to show them, and a QA program that I spent a great deal of time preparing. And they said no, that's all right; I don't need to see that.

So for the most part, I think it is internal audits, particularly JCAHO. They want a review of the quality assurance program, a review of the reviews, basically, as Frank was discussing yesterday.

MR. TSE: Any other comments on this point, or another area related to this section?

MR. KEARLY: In other regulations from the NRC, there are statements like a qualified person shall do such and such. You don't say a qualified person who is not involved with the department or something like that.

I think this just falls in that same category. We have been trained to do what you are asking us to do, so let us do it.

MR. TSE: Okay.

MR. KEARLY: That's what I think it comes to.

MR. DORING: I want to agree with Ken and Frank on that, on what they are talking about there. I totally agree that we can take care of things, we can take care of things internally, and we have been doing it right along.

MR. TSE: Okay. Yes.

MR. KAPLAN: So it is the consensus of the group to change this? And if so, how? I was just curious?

MR. BUKOVITZ: Well, the sense that I get is to change the "qualified personnel who are not involved," to just have "qualified personnel" period.

MR. DORING: You could theoretically leave that sentence the way it is and use the Radiation Safety Committee as the qualified personnel, so to speak, that is not directly involved with the activity being evaluated.

MR. KEARLY: I think the Radiation Safety Committee doesn't have generally enough expertise in therapy

or even generally in nuclear medicine, the whole thing. I don't think they would want to get involved in that sort of thing.

MR. STRUBLER: Yes. I think it is hard for a committee to review the program, because then you say, all right, you give every document to every member of the committee, and you have an administrator and you have someone outside the functions of radiologic science. And to do it on an annual basis I think creates also the burden for the committee.

MR. TSE: This word here says that the hospital or institution would be able to decide how they want to do their own.

So that leaves open for the institution to decide whether they want the Radiation Safety Committee or department or individual or whoever, as long as they are qualified. Then they will be, or could be doing such a review.

MR. STRUBLER: I'll make one final comment --

MR. TSE: Yes.

MR. STRUBLER: -- on these two sections, regarding the intervals not greater than 12 months.

I have mixed feelings about it because I understand the basis for it and agree with it. But again, what we are doing is not a static review process. It is a

very active one. On a continual basis, things are being reviewed and monitored. And then you are saying at the end of a 12-month period, or no greater than 12 months, to do that all over again, or to see if there is something that you are missing.

And I would think that a 12-month audit by internal personnel would be a very perfunctory one. The person who may be doing that, let's say ourselves, is very familiar with the program, and with the ongoing process.

So we would say all right, let's re-read it quickly and review it, and then write some kind of a statement into the minutes of the Radiation Safety Committee or however we choose to satisfy that requirement.

So again, I have some mixed feelings about a 12-month period.

MR. TSE: I think yesterday we touched on the question and the discussion went like, if you have quarterly review, and that certain satisfies this requirement because it's less than 12 months, and the idea is that if this becomes a final recommendation -- actually, this is in the regulation, in the proposed regulation, the 12 months.

If it becomes a final regulation then people should not, the institution should not have no review within like two years or greater than 12 months but any time less than 12 months, certainly should be satisfactory. I think

that's the discussion yesterday.

Ed, I want to clarify one thing. We are trying to look for comments, suggestions from individual volunteers for us to consider for changing the rules and the Guides, but we are not really per se looking for, say, the consensus of everybody -- we want to listen to the comments, the rationale and we want to consider carefully how to modify the final rule and the Guide.

Any other comments?

MR. KEARLY: Maybe just the last sentence. I am not quite sure what it means to distribute the report of this review to an organization.

What does that mean?

MR. TSE: Like the departments, nuclear medicine departments or therapy departments if there is any followup they have to do.

Do you have any suggestions on this item?

MR. DORING: This is just the internal institution's communication process.

MR. TSE: Right, right. Is there any clarification, modification you would like to suggest on this?

Frank?

MR. KEARLY: It's just a funny statement. Somebody will review the program, write a report and

everyone who has a stake in that report will get it -- that's what you're saying?

MR. TSE: You make the audit. If you discover anything you write recommendations, corrective actions, modifications of your QA program. Then somebody has to implement those and probe it. You may want to notify your managers, maybe the Chief Tech, we should change certain procedures and so on, or the physicians.

That's what this means, the sentence means, but if it is not clear to you, if you would like to make any suggestions how to make it clear so you really understand what the sentence means, then please let us know.

Anybody else have a problem with this last sentence?

MR. BUKOVITZ: Just the word "organizations."

MR. TSE: Organizations -- because it tends to be outside organizations?

MR. BUKOVITZ: Right.

MR. TSE: How about use like "within the institution."

MR. BUKOVITZ: That would be fine.

MR. KEARLY: It's still a funny word to use. You're talking about the departments involved --

MR. TSE: Right.

MR. KEARLY: So the Department Chairman will be

given a copy of the report for implementing changes, is that what you are trying to say?

MR. TSE: Right, but it may be sent to other people, the committees and so on for the organizations, so if you just say "department" there would be -- anybody have suggestions?

MR. KEARLY: It's getting vaguer.

MR. TSE: I understand your point.

MR. KEARLY: It's getting vaguer. I am not sure what the intent is.

MR. TSE: Well, just like you said, the Department Chairman, if anything, recommendation from this review needs to be followed up, then the involved persons or Chairmen should get a copy so that they can see it will be implemented.

MR. BUKOVITZ: Could you say "should be given to the appropriate personnel for institutional review and follow-up" -- that keeps it internal.

MR. TSE: Yes, that could be considered as a modification, so that the problem is the organization is not clear, whether it is an internal organization or an external organization outside the institution.

MR. BUKOVITZ: Right.

MR. KEARLY: For instance, we have, well, how many different committees in the hospital involved with problems?

There's an overall safety committee, there are subcommittees to the safety committee, there's the radiation safety committee, there's a quality assurance committee in the hospital.

MR. TSE: Well, that's true.

MR. BUKOVITZ: If we don't send a report to some of these things -- it's just not clear who needs to see such a thing.

MR. TSE: Well, that I imagine will be depending on the institution and depending on what kind of follow-up people have to do.

MR. BUKOVITZ: Basically it's just going to go through the radiation safety committee and they will distribute it from there because that is who the onus is going to fall upon anyway.

MR. TSE: That is why we use the word "appropriate" there -- meaning you may or may not want to send to all the departments or other committees, but send the ones with action involved or needs to have a copy, who have a need to have a copy.

MR. KEARLY: So do you think you ought to just say "radiation safety committee" and leave it at that? You are then assigning the radiation safety committee a new duty. You have assigned the radiation safety committee lots of duties before.

MR. STRUBLER: I would rather have it as Andy said, just "appropriate institutional committees or personnel."

MR. BUKOVITZ: I don't know if you'd have to change the RSC charter. That has a snowball effect.

MR. STRUBLER: This leaves it open to the institution to determine what is appropriate.

MR. TSE: That is correct.

MR. STRUBLER: It will be departmental chairmen in many cases and that's all it needs. It doesn't need to go further than that.

MR. TSE: Right, also depending how extensive the problems involved.

Okay. Any other comments on this section?

MR. BUKOVITZ: How is that last sentence going to read now?

MR. TSE: Oh, that? I'm not sure yet but I understand your suggestion --

MR. BUKOVITZ: Okay.

MR. TSE: -- is that the organization perhaps would indicate, not clear whether it's external organization or associations or internal associations but we meant within the hospital, so we are trying to modify it like that, but I am not sure exactly how to do it.

Okay. Then let's move on to Section 2. Section

number 2 has four elements, and those are the general elements, and they're applied to all program areas: diagnostic, radiopharmaceutical therapy, brachytherapy and teletherapy. Let's still go one-by-one. I think we have time to go one-by-one.

2.1 is -- its records has to be legible to minimize the likelihood of misunderstanding. These are the really motherhood area -- the motherhood statement. Anybody have a suggestion on this one; whether to delete, modify or retain?

MR. DORING: I just have one comment in regard to 1.

MR. TSE: Yes.

MR. DORING: And that's the comment that I made yesterday about electronic media. You were stating written in 2.1 twice, and that may infer you actually have to have a written document.

MR. STRUBLER: The statement I think though, if you delete the parenthetical phrase, "records relating to medical use should be legible and written clearly." So, "written clearly" means in good english and it doesn't have to be handwritten. That would be my interpretation. So that deleting that one parenthetical phrase, it would still qualify and be appropriate for electronic communications.

MR. TSE: Actually, the reason we put in the

parenthetic is just to explain what we mean by the word "record."

I think you have a good point for the future use. Maybe many of them may go electronic. But could I ask you a question first? If it's in terms of therapy of or radiopharmaceutical therapy, if its large doses involved, would you still go back electronically without actually seeing a physician's signature?

MR. DORING: No, you wouldn't.

MR. TSE: You wouldn't?

MR. DORING: No.

MR. TSE: What you are talking about is only related to diagnostic?

MR. DORING: What I'm talking about -- diagnostics.

MR. TSE: Yes, okay, diagnostics. Okay.

MR. BUKOVITZ: I have a question, just to back up for a second. This is for the field inspectors. As many institutions now are using computerized data-keeping systems in nuclear medicine, whereby most of their data is entered into the computer via keyboard and it's stored on floppy disk.

MR. KLINE: Is the question, are more facilities doing this?

MR. BUKOVITZ: No. I know a lot of facilities are

doing it. But how do you look at this when you inspect it? I mean, you can get a hardcopy print-out, but it's not written and their may be initials, or there may not be initials for that daily record, but you know that record was in there. Now, do you consider that a written record? How are you personally handling it?

MR. KLINE: Typically, certain records -- the -- if you're talking about the part 35 requirements, the radiation safety officer part assigned; often an institution will collect the raw data, enter it into the computer and then spit it out and then have the RSO sign that document and then file it.

I haven't seen too many people not keep current records in a print-out form. They might have records from 3/5 years back that are in a folder -- let's say, for example, since the last NRC inspection -- not in a folder, but in a medium -- a disk -- something of this nature, that's stored. But, typically, unless there are some reasons that are not conventional, I don't think most NRC inspectors would be going back that far to look in the records.

MR. BUKOVITZ: But I mean, just some of the institutions. Well, I'm familiar with two institutions right now that just bought computerized systems, like the Dupont system.

MR. KLINE: Right.

MS. PICCONE: Yes.

MR. BUKOVITZ: What are you doing with that?

MS. PICCONE: I've just recently seen a couple of those come in as well. And to be honest with you, so far in my experience, the one facility was because they weren't real sure of it, they were still maintaining written records in that regard. And the other facility, I didn't have any problem in -- in the computer output.

But maybe Larry can add to this, because I tnink this question is being considered in the revision to 35.

MR. CAMPER: It is an emerging issue, obviously, that we're looking at. In our regulations right now, if you look at them, there is nothing that prohibits people from computer storage of records.

Interestingly enough though, the thing that we find is that some states will not allow computerized records to be sufficient for purposes of inspection. In other words, they shelve presenting any hardcopy. Their rationale is that they don't want to find themselves in a position, where when an inspector comes in, only Joe or Mary or Susan, whomever knows how to operat he computer system is not available that day, and therefore, the record are not readily retrievable. That's there rationale.

But, it is an issue that, as Joe just pointed out,

that we are looking at as we look at revisions to regulatory guide 10.8 and perhaps even revisions to part 35. But I would reiterate that in our records -- in our regulations right now, there's nothing that prevents that from happening.

Now, generally speaking, in reality, what does take place, as the two inspectors are pointing out is that people, more times than not, will write copy back-up, even with the Dupont program, which I'm rather familiar with.

In my experience as a consultant on the outside, going in and out of many, many hospitals, they were more times than not keeping hardcopies as well. I never saw -- in fact, I never saw anybody rely upon the computer only and say, take a look at our CRT here, to look at the records.

So I think, to summarize, we are in a period of transition, we are in a period of regulatory review. And I think that in the future, this idea of electronic storage will be a bigger issue to deal with.

MR. BUKOVITZ: All right.

But what would you do in the case of -- if an inspector went into Tom's institution and for the last three months everything was on a floppy disk? Now --

MR. CAMPER: Well, again, getting back to what I said a moment ago. I don't -- the inspector's can correct me if I'm wrong, but I'm unaware of anything in our

regulations that says that you can't sit down at a computer screen, showing records to inspectors; the inspectors can then verify on their checklist by looking at a CRT that records have been maintained.

Now, you get into some problems with certain documents that must be signed by the RSO. But if I wanted to maintain linearity records on a computer system on a floppy disk, and I sit down and I show the inspector months and months of data, they could satisfy their requirements. Now again, signed documents are a problem.

Also, you could produce a hardcopy of need be, under such a scenario. But I would caution though that that's not true throughout all the agreement states. There are certain states that I know require a hardcopy period.

MR. KLINE: I think the question still falls back to the documents that require signatures.

MR. BUKOVITZ: Right. Those you can't do anything about.

MR. KLINE: The other documents seem -- facilities to pull them up and have them printed out on the spot. And as Larry has iterated, there's no requirement that says you cannot do that. There is mention of it, as a matter of fact, in the Federal regulations, that it is permissible to use that sort of storage medium, and I wouldn't think there would be a problem.

MR. DORING: I just wanted to point out that there's such a thing as an electronic signature that doesn't have to be in ink. So --

MR. CAMPER: Is that electronic --

MR. DORING: -- that issue becomes moot -- or a key. Just one key that puts a certain person's signature on there.

MR. CAMPER: Is that -- that a -- identifying initials, or are you talking an actual signature that's prerecorded and then is activated by punching of key?

MR. DORING: Yes. You punch a key or a few sets of keys -- a set of keys; and that individual's signature can appear on a document.

MR. CAMPER: Could anyone access that key and impose your signature on a document?

MR. DORING: Well, theoretically, anybody can hack a computer. Once you get into your -- once you use your password and get into the system, then you can use whatever security measures have been developed for you to do anything you want.

But anyone can --

MR. KLINE: Theoretically, anyone can get on, using your name. But if a password or some sort of fail-safe mechanism were to incorporated by the licensee for entering into that file an pulling out that data, I believe

the intent is being met.

If you are deliberately trying to circumvent and get around a rule, you can be creative and think of a million and one ways to do that.

I don't know, I find it hard to believe, that getting back to your question, an inspector would doubt. He might question well, does this person or anybody else have access to that file. He might question how you have your security system set up. I don't think he would go beyond that unless there was some reason to doubt.

MR. DORING: The reason for the concern, and it is obvious over the last day, and the first however long we've been here today, we are really, as a group of users of these regulations, are zeroing in on words or small phrases.

And the reason why we are doing that, I believe, and I may be wrong, but we have all been burned at one time or another because of a word or a phrase. And I bet everybody can give you an example. And I won't waste the time to do that right now. But that's what we are dealing with here.

That's why I'm bringing up "written" as a word.

MR. TSE: Tom, I think it is correct you need to bring out your concerns, even with words and phrases, especially in respect to regulations.

On this Regulatory Guide, it would be much less,

because it is not a requirement.

MR. KEARLY: Well, in my state, I know, it probably would be.

MR. TSE: Yes.

MR. KEARLY: But along those same lines, I just happened to think, how are you going to inspect against minimizing the likelihood of misunderstanding?

MR. TSE: Well --

MR. KEARLY: Maybe that's a silly point, but -- .

MR. TSE: -- I think that the intent of why the records have to be legible is to minimize the likelihood of misunderstanding. That is just added on to explain that you should write more clearly. And people have been mistaken before, like "6" becomes "8," and so on.

MR. STRUBLER: Well, I'll add to that, too, since it was brought up. Because I know at our institutions, we have technologists, and physicians, as you all know, are notorious for their scripts. And I'm amazed at how pharmacies and nurses and others can fathom what is being written.

But in terms of therapy, for example, where things are relatively straightforward and you don't have too many things to interpret, and you just look at some people's handwriting, and we have tried to say all right, if you are going to write a "7," you put that little hash mark through

it. And to try and get everybody to do that is something else again.

But I have badgered some of our physicians, and I showed them their 200 or 200 rads or centigrades, and I said looked, how would you read this; because this could be read either of two ways.

And you are not going to change a personality or a way they are writing things out. So while we are all in agreement these things should be legibly written and clearly understood, if an inspector comes out, there could be a matter of again interpretation, saying well, this is a guideline and therefore I'm going to make the interpretation that this is illegible.

And we're kind of a little sensitive to the issue of an inspector making this interpretation, well, this prescription is not legible to me, and it's a violation.

So I think that's where some of our comments are also coming from. In all of this section I agreed with everything here and I feel that it is appropriate for each of them. But again, some of the questions we have in the guides are, are inspectors going to make the interpretation that this is regulatory. And I think we have all had some experiences in that regard where a guidelines is interpreted as a regulation, and therefore one might get cited for it.

This is clearly an appropriate statement to make.

But the evaluation of whether the institution is meeting this record is not so easy and straightforward.

MR. CAMPER: Let me address that for just a moment.

We are certainly sensitive to the concerns that you are raising. But a couple of points I would make.

Number 1 is, this is a Regulatory Guide that we are talking about. A Regulatory Guide. This is not inspection directions. An important point not to lose sight of, although we recognize your sensitivities.

Number 2, that the inspection issue, there is a lot of concern being expressed here, I think, about what I perceive to be as fairly detailed concerns, I will characterize them as.

The inspection criteria, when we start looking at these things out in the field, in the future, if this should become a rulemaking, is going to focus more on programmatic issues, breakdown in management control, things of that type, as opposed to an inspector looking at a script and saying I can't read this, therefore I consider it to be illegible, I'm going to cite you. It's not that kind of thing.

We are acutely aware of developing inspection guidance for our people to use in the field, should this become a rule, so as to have consistent and appropriate

inspection criteria.

So If just throw this out. I recognize your sensitivity and your concerns, but I would not react as strongly or be as concerned as you appear to be at the language in the Regulatory Guide. I don't think that, when it is all said and done, that we are going to be, in fact, I know we are not going to be inspecting for that kind of detail. We're more programmatically oriented.

A quality assurance program, in the first place, is a difficult thing at best to inspect against. We all recognize that in the agency. And we are going to be far more concerned about programmatic issues and management control issuss that we are whether or not Dr. so and so wrote a script that inspector A or B viewed as being legible.

MR. STRUBLER: Well, I think, just a final comment for me is that I appreciate your comments and I understand that, and I have no doubts, because I have no problems with this section.

However, the agreement states is another matter. And you can't really speak for them. And I understand from what has been going on over the last two months that that is the thrust of this, that we are looking at program deficiencies here.

But now that we are getting, today, into some of

the details, these are some of the things that are welling up in some of us, and that there are these concerns, be;cause we have had inspectors in some of the states that are adopting programs from the NRC as this filters down, or who have other programs for major medical equipment that are driving us and administrations crazy, literally. And very harsh words are being thrown out by our administration; and inspectors are coming in and saying I want to see your billing procedures, professional billing. And we say that has nothing to do with what your inspection is. And they say, well, we think it does. And they do into that kind of detail.

So I'm not trying to nitpick on something like this, because I realize it is very difficult to perhaps inspect and review. And I do understand, and I am sure that you are sensitive to that. And throwing that one little example out was a very simplistic one. But it still could be made that interpretation, when you get down to other levels.

I'm not suggesting that that be removed in any way as a guide. And I realize that it is only a guide.

MR. CAMPER: Let me address that.

Ken, you make some excellent points. And again, from a realistic and pragmatic standpoint, your points are quite valid.

Again, though, on the QA rulemaking, should it become the final rule, it will be an area of compatability for the agreement states and it will be an are that we will spend a great deal of time and energy working with and instructing and guiding the agreement states personnel.

Now, in the final analysis, you are right. We can't exercise great control over how the agreement state inspectors go about conducting their inspections. But I assure you that we will make an effort to see to it that the agreement states understand the issues as we see them and the important areas as we see them, and so forth.

MR. KEARLY: Can I raise one more issue here? My feeling is that every item in the Regulatory Guide is probably something that ought to be covered by a check list in the department, so that a record of deficiencies in any one of these things is always kept.

Is that the intent? You put it in there, that means that we've got to keep track of it.

If we find -- it's the question I have with everything we've been talking about. If we find that something is not being done, do we need to document that for further review?

MR. TSE: First of all, each institutional licensee will have to create his own QA program.

If the QA program included this element, say that

the record is illegible, then you have to monitor that.

MR. KEARLY: So the answer is yes. If someone adopted your Reg Guide then there should be records kept of Item 2.1.

MR. TSE: No, I did not say "records kept." I said the management should monitor the carry-out of this objective in your QA review audit and so on to see whether people have any writing which maybe misled people or because it is not clear and if so, what action you want to take to correct such action.

I think the record is -- many people would be concerned. Yesterday already discussed it and John said essentially unless we specially specified in the regulation you have to keep certain records then it is not necessary for the regulation for NRC to keep a record like "illegible." It is difficult to keep a record of -- read how many pieces of paper which is illegible, so that's -- at least my thinking is that if you adopt this element in your QA program then you should follow up with the element.

MR. KEARLY: Let me give you an example. Dr. A has written his prescription. Dosimetrist B is confused about one number in the prescription and goes back to Dr. A and says please tell me what number you really mean here. It is not clear.

Is that the end of it or then does Dosimetrist B

have to write into Document C for Management D to review that they found one instance of an illegible prescription in order to audit the program effectively?

If they are saying that they are going to adopt your Reg Guide for the QA program, are you -- is that what has to be done or are we free to adopt this as a department policy which is not going to be documented?

MR. TSE: I think it is -- at least there is no requirement that you need to document it --

MR. KEARLY: But if you say it's going to be reviewed by somebody later?

MR. TSE: Yes?

MR. TELFORD: Go ahead with your answer -- well, this afternoon we'll talk about the record-keeping requirements.

For example, prescriptions. We're saying the record-keeping requirement is that you should keep a copy of those. You should keep those on file, a record of the dose administered.

What we are really after here is, what you could think we're after the source of the problem. If the inspector wants to come in and say, let me see a sample of your prescriptions, a sample of your records of the doses given they can look at them.

Now they may be semi-legible to the inspector but

unless they give rise to problems within your department, they're no problem.

You know -- I mean just like Ken said, the pharmacists are very good at reading prescriptions. It works for them. It's no problem, but if your review, your quarterly review or whatever reviews you do, turns up the fact that somebody's directions are really hard to read and causes confusion in the minds of folks and they don't know what to do and they are not really -- they don't really do 2.2 -- all we are saying in the Guide is we think it's a good idea if your records are understandable and secondly in 2.2 that people ought to ask questions.

In answer to your question about do I have to document this every time, no. There's going to be sufficient records there that an inspector could come in and look at that and the inspector might wonder, you know, how folks can read this and carry on with their work but if it works then certain the inspector is not going to cite any licensee for saying, look, I can't read this prescription therefore it's illegible, therefore I am going to cite you.

What Larry is saying is that's not the thrust of the Quality Assurance Program.

If a directive can be given and the administration can carry it out correctly, f it works for you, it's okay but, you know, this is some massive generator of records

here.

You are going to see exactly the records we are asking for. We are going to go through those this afternoon.

MR. TSE: Frank, if like the question you just mentioned arises actually, some technologist comes to you and says I cannot read his writing and he asks one time but next time still cannot read it, what would you do in those cases?

MR. KEARLY: Well, you can talk to the physician and you ask him to try to do it more clearly.

It does happen.

MR. TSE: I think that's probably the intent of the Guide also.

MR. TELFORD: Maybe for these points like on records or 2.1 and being legible and 2.2 for seeking clarification, what we would like to hear are alternative ways to say this, equivalent ways you are comfortable with.

This is not too amenable to giving different alternatives, as when we get over into sections 4 and 5 where there is more than one way to do something.

The same objective, though, is valid here and the objective is that we would like alternative ways that we can put in here such that even an agreement state that wants to rigorously use this Guide, the Guide would still contain

enough ways that it would be suitable to all licensees, so that the licensees can use this Guide the way it is intended and almost make it unusable to an agreement state as a prescriptive regulation.

If you have modifications you want to suggest or additions that can go into this, then I think we'll both be getting to the same goal of where we want to go.

MR. TSE: If you have any suggestions, please say so. I think that 2.2 is to -- if anybody has a question, they should ask, instead of continuing the medical use. This is similar to 2.1. It's a general statement. Does anybody have any suggestions or comments on this one?

In terms of records, everything else would be the same as discussed in 2.1. If there are no comments, we go to 2.3

MR. BUKOVITZ: I have a question on 2.3. Is emergent a real word?

MR. TSE: Yes.

MR. BUKOVITZ: Okay, I wasn't sure. I was assuming --

MR. TSE: Emergent -- in addition, it says, in a situation which may not be an emergency, but you've got to do it, essentially.

MR. BUKOVITZ: Okay, thank you.

MR. KEARLY: I have a problem with 2.2. This

means that we'll have to define a therapy event to our staff who must -- or diagnostic event to the staff who must then make a choice as to whether or not what's going on may result in such a thing. I don't know if they can actually judge that.

MR. TSE: First of all, I think that the word, "event;" we need to change that because event -- this afternoon when we discussed misadministration modifications -- proposed modifications of misadministration rule, we have the word, "event," used there. In here, if they discover something which is not right, then they need to stop.

If there is a discrepancy: the numbers don't match or the numbers are not right in their view, they should stop and then ask for trying to resolve it, including all the workers like physicists, technologists and so on. Depending on how -- what's the problem area which may go to the physical resolution, may go back to the physician for resolution.

MR. KEARLY: This is very potentially troublesome, I think. You should strike out that last phrase because we're not sure how event is going to be defined yet, and we'll talk about that later. You should not exclude other things that may not be, quote, unquote "events," because there may be something unclear and would not be an event if it were continued, but you still would like to stop and

clarify.

I think it's very clear if you would say that all workers should stop the medical use and get guidance if there's a discrepancy in their records and observations, period.

MR. TSE: That's a good alternative.

MR. STRUBLER: Then you don't get into the problem of defining what is an event and what is not. Also, those things that are not technically events, still could be discrepancies that should be resolved.

MR. TSE: Right, that's a good alternative from what you think of --

MR. KEARLY: I think that makes it a lot clearer as far as implementing it. It still bothers me a little bit. What you're putting down here is what every technologist is trained to do. Your technologist goes through a training program and they are told: this is the procedure you follow. If you don't understand what's going on, you don't treat.

I'm not quite clear, and that's why I was asking questions about how this was going to be inspected against. I'm not quite clear what the purpose is to include into a regulatory document, things that people are taught during their training.

MR. TELFORD: You're not going to be inspected

against the Guide. You're going to be inspected against your license conditions.

MR. KEARLY: But if you adopt the Guide as your QA program, then you're going to be inspected against it.

MR. TELFORD: If you adopt it totally, yes. But that's going to be a little hard to do because there's going to be -- back in Section 405 for one of those things, there might be four or five ways to do something. You can't possibly do them all; you're going to have to pick one, so you're going to have to make your -- this is like a big menu.

MR. KEARLY: Nobody is going to say they're not going to adopt something that says, my records should be clear. I mean, they're going to adopt that.

MR. TELFORD: If you come across a problem later and you look for the source of the problem and if it's due to records that are not readable, or it could be that some institutions don't instruct their personnel the way you just described it.

These are things that we have to say because all the workers should be instructed this way. If it leads to problems, then we want to be able to go back and say, here's our guidance; we think you ought to follow this. Or we'll ask you what you're going to do to prevent the problem from reoccurring.

It's not as if you are going to be inspected against these in total, but, I mean, it's like an analysis of a problem that has occurred. It's like a post mortem. What's the source of the problem and what went wrong? How do we fix it?

MR. BUKOVITZ: You say you're going to adopt the guide or if your guide has a menu selection later, you would adopt Section 2.1.B.3 or whatever -- just being facetious -- and you find out later that it does not work for you. Can you make a ministerial change, or does that require a license amendment?

MR. TELFORD: We said in the rule itself that the licensee is to make modifications to their regulation which is needed to prevent reoccurrence of, let's say, misadministrations, and may make any changes that do not decrease the effectiveness of the program. If it looks like it's going to decrease the effectiveness of the program, then you have to have an amendment.

So, if you found something that didn't work for you and you wanted something -- to put in something better; in my mind, that's increasing the effectiveness of the program and you should do it.

MR. TSE: That's in the section -- proposed regulation section 35.35(c).

MS. PICCONE: 1449.

MR. TSE: As you recall, yesterday when Josie presented the results of site visits, we do have that kind of problem -- question/suggestion, is that this is a professional understanding and professional people would do so automatically. But events, misadministrations do occur and sometimes they're not quite sure how to go about it -- trying to emphasize those problems.

MR. KEARLY: Are you saying that some of the problems that you've seen reported to you were caused when a technologist or someone on the treatment staff went forward with a treatment that they knew did not agree with what was supposed to be done; is that what you're saying?

MR. TELFORD: They couldn't understand.

MR. KEARLY: No, but I'm talking about the discrepancy right here. This one issue right here.

MR. TELFORD: Yes, yes. I showed you two or three of those yesterday, where the technologist could not -- misunderstood what the referring physician had written in the chart?

MR. KEARLY: Misunderstanding is different. If there's a discrepancy in the records, that means that someone recognizes that what they're trying to do is different than what's written down. I'm not arguing with this as a goal, but I was just asking the question, because that's what you were implying, that each of these is related

to a problem area that you'd seen -- and I don't -- I'll bet that that's not true.

MR. TSE: Not every case, but in many cases.

MR. CAMPER: Let me ask, if may, Andy or Frank, in particular, since the two of you brought this up. What is it that is troubling you about the phraseology? Is it something that you could put a handle on specifically? You've expressed some concern. Could you be a little more specific so we could take that away with us, to look at at a later time?

MR. BUKOVITZ: You're going to have to refresh me now -- on what particular aspect?

MR. KEARLY: My -- my first general question was documentation that John had addressed. What are we going to be asking? What kind of records we'll be asked to do? These are sort of philosophies of how we teach people to behave in the department.

You have some very specific instructions elsewhere in the regs that say, if the door interlock does not work, don't treat. And you must go into the room with a meter if the room monitor isn't working. This is an instruction similar to that. Now you're saying, if there's anything at all different between what you see in the treatment room and what you think you ought to see, then you don't treat. It's a much vaguer thing. I guess that's what bothering me about

this.

MR. STRUBLER: I'll add just quickly because we may want to be moving on. But I think -- we're all in agreement with this statement. It's again -- comes under the professional understanding that was raised many times yesterday, and commented on, and that it should be part of the educational and professional conduct of everyone.

And my sense of some of the things that John showed yesterday regarding misadministrations, was that there was a lot of sloppiness involved. And things that you showed were very disturbing to all of us. And we perhaps didn't appreciate some of the sense of the -- of what has been going on around the country. And then we start wondering ourselves, well could this happen at our institution? Are we missing something?

And I realize the focus of some of these comments -- and that's why some of these things are obvious to us -- saying that there is a professional understanding basic to this and that you have to state the obvious. And whether stating this in the guideline is going to prevent some of the sloppiness that resulted in some of the misadministrations we saw on the screens yesterday, I don't think so.

It may be that we're just -- you're just trying to emphasize and make sure that when it's in a guideline,

you're not just going to be taking these things for granted as a professional conduct, but say -- emphasize, this is part of your professional conduct and we expect you to review instructions as to their clarity, so that it will be a point of emphasis. And I'm sure that was going to be helpful to all of us, to perhaps state the obvious every now and then, rather than make any presumptions that may not be carried out.

But, other than striking that one phrase, I would -- I have no problem with that -- and I think, as guide only, it is an appropriate statement to be there, so that we can also emphasize the importance of it.

MR. KEARLY: Well, I'd like it a log better if we take the therapy event or diagnostic event part of it out too.

MR. TSE: Frank, are you talking about thinking that you wouldn't -- in a misadministration event, that the technologist looks at the picture and then the patient says, hey, it looks different, and did not go on to say, maybe I should stop and check before going on. Anyway, I understand your point. So, let's go on then, because the timing.

2.4? Which is before medical use -- the person should check, in accordance with the referral or prescription, which is similar to one of the objectives in the regulation. And anybody have any questions on this one.

[No response.]

MR. TSE: If not, then we go to Section Number 3.

Section 3 is those additional elements for the institutions who have either therapy, radiopharmaceutical therapy, or they have diagnostics which might involve more than 30 microcuries of iodine.

Perhaps we can lump these together, just please, instead of one by one, because of timing.

For those five elements, does anybody have any suggestions, changes, or modifications, so on?

MR. STRUBLER: For 2.2.

MR. TSE: 2.2.

MR. STRUBLER: I have a note here regarding, as we have talked yesterday, that there may be times when an occasional oral prescription is necessary.

MR. TSE: This is therapy, large doses.

MR. STRUBLER: Yes.

MR. TSE: Do you still think oral, sometimes oral prescription would be necessary?

MR. STRUBLER: Yes.

MR. TSE: For --

MR. STRUBLER: The example that I gave --

MR. TSE: For radiopharmaceutical therapy. This is ont teletherapy, not brachytherapy.

MR. STRUBLER: I see. This is

radiopharmaceutical.

MR. TSE: Right.

MR. STRUBLER: Yes. I guess I misinterpreted that. All right. I'll back off with that statement.

MR. DORING: Can I get this made clear? Can we assume that what we discussed yesterday would also --

MR. TSE: Will be reflected here?

MR. DORING: -- be reflected here? So you don't have to be redundant --

MR. TSE: You do not have to be redundant.

MR. DORING: Okay.

MR. TSE: That's the first point I made. Anything we discussed yesterday, if we are going to modify the proposed regulation, then the guide will follow.

MR. DORING: Okay.

MR. TSE: They have to be --

MR. DORING: Thank you for that clarification.

MR. TSE: Thank you.

Any other questions?

MR. KEARLY: I just have a general question for the entire Reg. Guide.

MR. TSE: Yes.

MR. KEARLY: It is sometimes not clear which item, which of the QA objectives an item refers to.

It is also not clear that every objective is

covered. So I would hope that you could point out in the guide, this is how we are accomplishing Objective 1 for this area, and so forth.

MR. TSE: Yes. We, in the site visit criteria, program criteria, we did that.

MR. KEARLY: You had that problem also?

MR. TSE: Right. We have that same problem. So we are going to revise that.

We have to consider to review it perhaps towards the same way.

Any questions, comments, suggestions, or any additions in terms of radiopharmaceutical therapy?

Last time I remember somebody mentioned about the hipporem, like 30 microcuries. Hipporem generally is like 200 microcuries.

Do you have any comments on that one, Tom?

MR. DORING: No.

MR. TSE: No? Okay.

So, maybe we, in our schedules, 10:00 O'clock to 10:15 has the break. And now it is about ten minutes before 10:00. But we have finished discussion on Section 3.

Yes.

MR. BUKOVITZ: One question on 3.5.

MR. TSE: Right.

MR. BUKOVITZ: Where you say you will record the

agreement or lack thereof.

MR. TSE: Right.

MR. BUKOVITZ: Does that mean to say you intended to give 100 millicuries and you gave 98, and you can say well, 98 given, or you say 98 was given, therefore the difference is 2?

MR. TSE: This item also was discussed earlier.

MR. BUKOVITZ: Right.

MR. TSE: Last workshop. And I think we understand the point. And the agreement, if it is within certain plus-minus range, essentially is agreement, or disagreement, if it is large differences.

And we, I think the suggestion is that if you have written down the two different doses, and they are close, and you don't have to write, and the chart saying this is agreement or not agreement, if you can compare with the two doses.

So we are going to, this is the same guide we discussed previously. The comments you made, we are going to look at them and see how to modify.

So it is good you raised it again.

So maybe we could start break, and then, John, can we start break now?

MR. TELFORD: Yes.

MR. TSE: And then we can come back 15 minutes,

and continue. So it will be somewhere --

MR. TELFORD: Five after.

MR. TSE: Yes. Five minutes, ten minutes after.

MR. CAMPER: Then we return to Section 4?

MR. TSE: Then we can start Section 4.

MR. TELFORD: Five after 10:00.

MR. TSE: Five after 10:00.

MR. TELFORD: Yes.

[Brief recess.]

MR. TSE: We will resume the discussion of the regulatory guide, and we are in the section for brachytherapy.

Brachytherapy has seven elements, and we already discussed some of those elements. We heard your comments from last workshop. And in trying to save time, again, I would ask for anybody have concerns or suggestions or problems or modifications, deletions, and so on, of the whole Section 4. You may make any suggestion on any of the elements you have a problem with.

MR. KEARLY: You know, of cc in 4.5, that we don't put the sources in.

MR. TSE: Right. You mentioned that last time, and we're trying to modify this -- the next version.

Take your time to read.

Yes?

MR. STRUBLER: I guess I have some notes here, and again, 4.2, as I mentioned, one of the remarks that I have sent in, often times brachytherapy is a complex process and during the treatment planning stages, where one is using a variety of sources, it may be such that you're not -- because of the timeframe under which you're dealing, it may be difficult to write a detailed, specific treatment with the source activity, for example, and the exact source loading prior to administration, and it may be the decision of the physicist, finally, what the source loading on the approval of the physician may be, and I could conjure up some scenarios where it would be very inconvenient to have a written prescription prior to administration.

It's, perhaps, a soft matter; it's not a difficult one, perhaps, to overcome, but often times, a generalized prescription is made, and it would be suitable -- the details would be worked out at the time of the application.

MR. TSE: So, the problem is that -- the word "prescription." If, for example, you use the word "general prescription" or "preplanned" --

MR. STRUBLER: Yes.

MR. TSE: If this "prescription" is replaced by "general prescription" or "preplanned," then we resolve your problem?

MR. STRUBLER: Yes.

MR. TSE: Okay. Any other comments?

MR. STRUBLER: A comment on 4.5: The one comment is made appropriately, and radiographs ordinarily would be taken, would be a suitable substitution, because there are some situations that are very simple interstitial implants, where a radiograph may not be required for single linear sources and single-plane implant, and I think there was an exception -- I don't see it in this one -- in the others, where you make the comment about a topical applicator would not be necessary to have. Yes, it is here.

MR. TSE: Yes, it's here.

MR. STRUBLER: "This may not apply to sources used for surface application." It also may not apply to some other more rare situations, as well, meaning it may be interstitial, but it may be such a simple implant that radiographs may not be required; they may be more for documentational purposes only.

MR. TSE: Well, how do you determine the doses if you are not --

MR. STRUBLER: Well, if you see -- let's say it's a breast implant, single plane, there's just a few line sources, and you see what you're doing, and it's almost visual, and you know where the insertion of the sources are, and you're not going to look at them in reference to any other anatomy, because there is no other critical

structures, and I'm saying that would be ideal not to take, but I could see that it would not be necessary, in some situations, to have radiographs, because it's a geometric arrangement, you know exactly what the geometry is, you've measured it, and you've inserted it that way, and you can re-measure it, virtually, and the radiographs would not be used for the final calculation.

MR. BUKOVITZ: Or if we use a template.

MR. TSE: So, how would you modify this element?

MR. STRUBLER: I would just say "ordinarily." I know that's very good for -- of course, these are just guides. I would say just, ordinarily, radiographs will be taken, because I'm just saying, as we spoke yesterday in private, that there would be exceptions to many of these situations, and you have to leave room for the exceptions, and if there's a problem with the exceptions, then they'll come out in the program or under inspection.

MR. TSE: Maybe "template" or "visual"?

MR. BUKOVITZ: Maybe we can go over the situations. There are cases where you put in single line sources or you put in a single source or you may use a template and then certain situations where if you just put in I-125 ribbons you can put in a loop, and these are cases where you know what the geometry is going to be before and after it's put in, and there's really no reason to take a

radiograph.

Now, I didn't hear quite what Frank had said, either, about brachytherapy sources, but a lot of cases, if we do after loading, you take a radiograph of the applicator, and then after you're sure of the applicator position, then you take a radiograph of that, and then the source is put in.

MR. TSE: That's what Frank said. There was discussion about that last time.

MR. KEARLY: May I make a comment?

MR. TSE: Yes.

MR. KEARLY: This requirement differs from all the others. I mean, we are ordinarily left to do medical dosimetry as we have been taught to do it and as it is required to do.

Why are you telling us how to do it? That's what this is right here. You're telling us that we must obtain certain information in order to do our dosimetry properly.

MR. TELFORD: Would you agree with Ken's suggestion? What if we reworded this to say "ordinarily radiographs will be obtained"?

MR. KEARLY: I'm just asking why it's there.

MR. TELFORD: Because it's a good thing to do.

MR. CAMPER: It's an acceptable guideline.

MR. KEARLY: It's another one of those things that

says how you do it. I mean, that's what we've been taught to do.

Do you think we're not doing it?

MR. TELFORD: We would be remiss if we didn't say it.

MR. KLINE: Frank, let me comment on that.

Yesterday, when I was talking about some of the onsite evaluations that you performed and how these proposed elements were a living document, meaning as time went on, we found that there were different ways to do things, I don't know if you recall, but one of our, one of the graphs I put up, or overlays, on treatment planning, talked about radiographs or other comparable imaging modalities like CT or nonograms or other equipment methods.

And I think the intent is not to much to tell you that you need to take radiographs, as the intent is that you need to have a method by which you can calculate dose, whether it be standard geometry using a template, where you have no dose distribution, and it is known to all the people involved, or whether it be specific with a radiograph or CT where you are doing a treatment plan and getting an exact distribution for the source alignment arrangement.

So I believe that -- is that alleviating some of your concerns? Would something to the effect that other equivalent method or something of that nature, would that

satisfy your concerns?

MR. KEARLY: But once you start saying those things, why put it in there at all?

We are supposed to determine the dose being delivered to the patient. That's our job. And you are telling us here, determine the dose delivered to the patient properly. I guess that's what you are saying. Which may vary with technology and characteristics of the particular treatment. But somehow you want to tell us in one particular type of case how to do it. That's what we're trained to do.

MR. STRUBLER: Frank, that comment could be made virtually for all of these statements. And so I think we've conveyed that before.

There is a fine line between intrusion into medical judgment versus a regulatory process that is designed to prevent mistakes and to make sure people are scrutinizing their programs adequately.

And so I think from a quality assurance guideline approach, you are probably obligated to put a statement of this kind in.

From the more general questions about are many of these statements even necessary, I think we have kind of gone through that before, and I don't think I need to comment further on that.

It is an appropriate question from our point of view, saying are you telling us how to do our jobs that we are trained for.

But from my point of view, I don't have any problems with it, other than changing, saying "ordinarily radiographs," or something.

MR. TSE: You must have some way to identify where the sources are, so you can make your dose calculations. Correct?

MR. KEARLY: As Ken was saying, depending on the situation, you do what you need to do.

MR. TSE: But necessarily a radiograph. But in many cases, like the case which the source was stuck in the catheter, and their response is that they want to take a radiograph to ensure that source is in the proper location.

MR. BUKOVITZ: Another question about 4.3.

MR. TSE: Yes.

MR. BUKOVITZ: Sealed sources. Is iridium wire a sealed source?

MR. TSE: Iridium wire, according to the device, sealed source device category, those are considered a sealed source as well.

Do you use iridium wire?

MR. BUKOVITZ: I use iridium ribbon. But I know some people who do use iridium wire.

MR. TSE: We are working on a petition related to whether to put iridium-192 wire in 35.400 or not.

Any other questions?

MR. STRUBLER: Can we move on to some of the other areas here?

Again, I think the same comment could be made on 4.7 regarding "this person will record the agreement or lack thereof."

MR. TSE: That's the same.

MR. STRUBLER: That's the same as before.

MR. TSE: Same comments we have heard.

MR. STRUBLER: And 4.8, again, many institutions don't have other qualified persons to make an assessment or review of what was done. And I have problems with that whole section 4.8, 1, 2, and 3. To have someone, I think it is important, as stated earlier, to have a check, perhaps of the computer input on the computer printouts. But someone who did not make the original calculation is I think a difficult circumstance in many institutions to have that person qualified to come in. Or they may not be there, because of vacations or sick or whatever the case may be.

For example, I'm here right now. And there may be things going on at the institution that I have approved. But there would not be a review of it.

MR. TSE: In the Q&A program review criteria, we

developed earlier, this was considered. We suggest that perhaps you can either have independent person to make calculation. That's the best way, because it's easier to catch somebody -- it's difficult to catch one's own error. Or, if you do not have another person, then you can make a separate calculation by yourself, or make a rough check.

That's -- we're thinking to incorporate these things, just to avoid somebody have to have another person qualified to make additional calculation. So what would you suggest this, perhaps make a same person make a separate calculation?

MR. STRUBLER: Well, allow that -- that possibility. I mean, I know it sounds like we're checking ourselves, and therefore, not likely to do a good job, because we all think we do it right. But we all, in the field of therapy, in particular, we all recognize that we can make calculational mistakes, and that's why we have redundancy in all of our programs; particularly with external beam therapy.

With brachytherapy it's a little bit more complex and difficult, because the understanding of what the computer is doing and sources, is not necessarily something that a technologist or dosimetrist or physician would fully understand and -- and when you're talking about moving one millimeter from a linear source is a 10 percent change in

dose, that's not often appreciated by the physician's either, in terms of making a prescription. And it just raises the complexity of the entire area of intercavetary interstitial applications.

MR. KEARLY: I have a problem with the -- whenever you put numbers like 50 percent down, as to when a check is to take place, I would like to be able to allow for the occasional time that we're invited to an NRC workshop, so we could have a little bit longer to do our doublechecks.

The -- the therapy summer school that they just held -- one of the people did a study of how long it took to do double checks of regular calculations at their institution. And there was a spread, and generally they got it done within two treatment days, for instance, for that institution.

I would like to see the rules be flexible, to the extent that says the goal is to do it within 50 percent. Because again, I have the question, all right, we've been invited to the NRC workshop and there's nobody there to do the double -- the doublecheck, until they get back on Monday. We've just broken the law, as I see it. What do we do about that?

MR. DORING: So, if we inserted the word, "normally" before "50 percent" of the prescribed dose; would that suffice?

MR. KEARLY: That probably changes it -- changes the regulatory aspect of it considerably when you do that.

MR. TSE: Yes, but one question. Should the doublecheck be completed before the completion of the treatment?

For example, brachytherapy. Suppose you initially say 48 hours, should the doublecheck be completed before the 48 hours expires, or you could do it afterwards? Which way would you normally do it?

MR. STRUBLER: The point is, it should. And there's a difference, of course, between the should and the shalls. And it should be agreed that these things should be done, but there are many, many situations where it cannot be done because you don't have the qualified person, or the qualified person is -- is out of town, or sick or whatever it may be.

And there will be instances where there will be a completion of the brachytherapy procedure without an independent check, other than the individual who did the original calculation will review it.

MR. TSE: Of course, we could supposedly accept that?

MR. STRUBLER: Yes.

MR. TSE: Then should you check it before the completion?

MR. STRUBLER: Yes.

MR. CAMPER: Just a question for clarification. Is that customary at this point? What are you doing now as far as someone double checking at some point?

MR. KEARLY: This is close to what we've tried to do. We have never articulated it. But the treatments are very short -- it's a three or four-day treatment. And the doublecheck is done within say two days usually. But that may not be 50 percent -- it may be 67 percent, or something like that.

It depends on the accumulation of the information, then the dosimetrist has to sit down and do the plan, and then I'll have to review. And it's a long planning process, because there's a lot of information to gather together and evaluate, on her part. And then you have to reevaluate that. Her schedule and my schedule are different.

MR. STRUBLER: For my institution, we have not be fortunate enough to have a dosimetrist full-time, because when we're short of technology staff, they're the individuals that get pulled to the machines for treatment for external beam therapy.

So it's left for me to do the brachytherapy, since I'm most knowledgeable and familiar with all the aspects. And I generally am the one who communicates with the physicians because I can make recommendations. And

therefore, I'm the only one that's doing it, and the other individual may not be fully trained on because they're on the machines, would be difficult for them to be pulled off and to do a check.

So I have to rely, unfortunately, on myself for the duration and --

MR. CAMPER: Is this customarily occurring before the 50 percent criteria that we're talking about here?

MR. KEARLY: I don't think so. I think it's right at the cutting edge there. I think there's a reasonable distribution on both sides of that 50 percent, is the way it happens.

MR. BUKOVITZ: You have to also keep in mind there are certain gynecological applications where it's relatively standard to put in a particular source or sources for a specified amount of time. And the physicians don't necessarily worry about rads. They'll put in a -- they'll put in some Haman capsules and they'll just say, well, we have 50 milligram equivalents of radium, so we'll just put it in for 10 hours or 20 hours.

And then what happens is you find out it was done after the applicators are back out. And this is something some of the oldtimers just do for years -- vaginal applicator -- you put in so many milligrams of cesium for so many hours.

MR. KEARLY: We don't have the luxury of being able to do these calculations and plans prior to treatment with brachytherapy. It's a different -- significantly different situation from teletherapy, where we can go ahead beforehand and see everything that the patient's going to go through before the treatment even starts.

And because the treatment course is so short, 50 percent, maybe overly restrictive. I've forgotten that there are shalls and should -- may a should word is more appropriate -- is appropriate for this. I like that idea.

I just think it's going to be very tough to meet 50 percent.

MR. TSE: The suggestion then would be normally 50 percent, but would not -- will not be exceeded -- or would be -- should be before the completion of the therapy.

MR. KEARLY: Can you use shoulds and shalls in a -- in a guide? Or have you folks done that? NCRP does that. Do you also? I can't remember.

MR. TELFORD: Yes, we can do that, but -- but in this case, you gave the example of -- to do with the check within two days for a three-day treatment. What we're after is that the check be done in some reasonable amount of time. We've put in 50 percent, because that looks like a good number to us. What we're asking is what's your good number?

MR. KEARLY: I don't think 50 percent is a bad

number, as long as you're allowed some leeway, when circumstances dictate.

MR. TELFORD: All right. We could either put in some -- some weasel words that give us -- give you some leeway on the 50 percent, or we could increase the number to two-thirds or something.

MR. STRUBLER: I like weasel words.

MR. TELFORD: Do you like weasel words?

Well put.

MR. TSE: Any other questions or comments?

[No response.]

MR. TSE: If no, we could go to teletherapy.

Again, we're trying to not element by element. We lump the elements together for example from 5.1 to 5.6 on the first of this page 8.

Anybody have suggestions, comments?

MR. STRUBLER: For 5.2 I have a note here saying delete the treatment volume. I'll have to re-read that but make it --

MR. TSE: I think you said --

MR. STRUBLER: Have I already commented on it?

MR. TSE: The last workshop said treatment site.

MR. STRUBLER: Treatment site.

MR. TSE: Right, that's the one we plan to use.

MR. STRUBLER: In 5.4, the same thing that we said

earlier regarding that phrase.

MR. TSE: That's right.

MR. STRUBLER: And 5.6 I have it may not be possible to always check before 25 percent. It comes in with the same comments.

MR. TSE: Right. Right, we could say it the same way.

MR. GRAHAM: Be careful though. I just want to make a statement regarding some of the state regs however, that 25 percent is sometimes very liberal. Sometimes in state regs they want them done more frequently, even earlier than that.

MR. TSE: Right.

MR. KEARLY: I hesitate to bring it up but ACR says within two treatments.

MR. GRAHAM: And the state of New York says 20 percent, I believe, so that's --

MR. KEARLY: But gain if you put the weasel words in there, we'd be very happy. I think it's a good goal.

MR. BUKOVITZ: But there are certain situations where it's only three teletherapy treatments and if you catch it the next day you're a third of the way through.

MR. TSE: That's the comment made in the last workshop. You could use the same language that the JCAHO.

MR. KEARLY: Is that JCAHO? ACR.

MR. TSE: ACR recommendation.

MR. KEARLY: That's even more restrictive, 25 percent or --

MR. BUKOVITZ: 25 percent or two treatments?

MR. TSE: If the three treatments, three fractions treatments would be two fractions --

MR. BUKOVITZ: Well, you are 66 percent of the way through.

MR. TSE: Right.

MR. BUKOVITZ: But if you say 25 percent even if you catch it after the first treatment, you are 33 percent through so that one doesn't meet it either way.

MR. TSE: Well, what I am trying to say is that for those long, many treatment fractions, you might use 25 percent. For those with a number of fractions which is less than five or so, use two treatments.

But would that be --

MR. BUKOVITZ: No. I think that's too liberal then because if it's only three treatments we want to catch it after the first one because if you catch it after the second one, you're essentially all the way through and so I think we have to make provision for very short treatments, not necessarily in terms of days.

MR. TSE: In that case it would be like one out of three would be 33 percent of.

MR. BUKOVITZ: Yes, so if you exceed the 25 percent with one, then it had better be within 24 hours.

MR. TSE: How is that suggestion? Agreed?

MR. KEARLY: Personally I think that you ought to say the same things that the ACR is saying but put a "should" in there. I know that's tighter and I know I would be killed for telling you to --

MR. TELFORD: That's okay. We're going to talk to the ACR.

MR. KEARLY: I don't think we ought to have two different guidelines. That's why I'm saying it.

5.5, I think you ought to say that a weekly check will be performed to detect errors in treatment parameters because there is a lot more to what goes into the chart than just dose summations.

MR. TSE: Treatment parameters and any changes in prescription.

MR. KEARLY: That's fine -- in treatment parameters instead of daily cumulative dose summations.

The most frequent problem that happens with treatment charts is one digit of a monitor unit number or a time number gets altered. That is not covered by anything you said here.

MR. TSE: Is daily cumulative dose summation should be checked? I thought that said --

MR. KEARLY: I'd call that a treatment parameter.

MR. TSE: That's part of the treatment parameter.

MR. KEARLY: I think we all understand when we say "treatment parameters" that you look at the chart to make sure every number that's used somehow in the treatment of the patient gets checked and the daily summation is one of those things. It tells you when you're going to stop.

MR. STRUBLER: Summation would be perfectly all right, but they gave the wrong --

MR. BUKOVITZ: This is one of the cases that would be more restrictive than you are.

MR. TSE: Of course, we want to listen to your suggestions. We could say including -- because a summation, certain important considerations, some people did them.

MR. KEARLY: Following instructions, whether a wedge should be in or not; that's important.

MR. TSE: Right.

MR. KEARLY: All kinds of things that we look at -- field size changes. As you've said, the presc ption change.

MR. TSE: Right. Okay. Any others?

MR. BUKOVITZ: Okay. A question on 5.6.2: When you say the correct inputs for the patients were used in the calculations, the first thing it brings to mind is the patient's separation or the patient's thickness varies by a

centimeter or so. We may decide whether or not that's important, but you may not decide that that's important. Or the treatment distance, if it's 80 centimeters versus 80.5 or if it's 80.5 used on a treatment plan but we do a manual calculation at 80, things like this. I'm just picking small numbers.

Basically, where you say the correct inputs for the patient were used in the calculation, in many cases, the numbers that we use to check the computer output will be taken off the technician's instruction sheet. Those numbers may not necessarily exactly agree with the numbers to do with the computer isodose plan. But what we may end up doing is using the numbers that we took from the instruction sheet and that time or those monitor units will be close to what the computer plan generated, but we will not use the computer plan.

This is where the difference between the science and the art comes in.

MR. TSE: Let's talk about cobalt-60.

MR. BUKOVITZ: Okay. Well, then the treatment time.

MR. TSE: Yes.

MR. BUKOVITZ: All right. Let's say a plan is done. The technician generates or the dosimetry, somebody generates a computerized treatment plan. You look at the

numbers they put in for the distance from the source to the patient's skin for, say, a three-field arrangement.

Now, the numbers that were entered for that plan versus the numbers that are finally used for the patient's treatment may vary quite easily plus and minus a half to one centimeter. Now, that treatment plan looks good, but the numbers that we may use were the numbers that were actually used to set up the patient. What do we do in a situation like that?

MR. TSE: This is correct use -- correct use of patient data. So, a physicists, you determine which data is the correct data, and you use that.

MR. BUKOVITZ: Well, the thing is we have two sets of data. They're both close. I'm trying to bring out the point that you're going to see a natural variation in the numbers which are used, primarily for distances set up to the patient and for patient thicknesses.

Now, are you going to take umbrage with the fact that there is a variation on a day-to-day basis, or will you allow us to just accept that variation that we know is there?

MR. TSE: The practice is -- your current practice is you may use the slight variation. There obviously, I think, must be very small changes. It could not be a big change in terms of distance. It's a small difference

between the two numbers. And if you decide that the correct information, correct data should be used, that should satisfy this. But if you have a large difference between the two numbers, then you might -- as a physicist, you might say that looks not right, that it's a discrepancy, and you need to check it before you go ahead.

MR. TELFORD: Well, let's ask the question -- you're talking about direct transfer of data, correct use of pertinent data. What you're describing is -- you say it's the correct use, the correct transfer, but maybe the word don't imply that. What would you do to these words to allow you to do what you normally do in your practice?

MR. KEARLY: Could you use the word "proper" instead of the "correct"?

MR. TELFORD: Of course, what we're looking for right here is just a blatant mistake, and what he's describing is not a mistake at all. But he's bothered by the fact that one piece of paper says 80 and the other one is going to say 81, and we're going to -- looking at these words, it's going to say that's not a correct transfer of data. It's not proper either.

MR. KEARLY: Or "appropriate"? The patient looks different on the simulator than they do on the machine when they set up on a day-to-day basis. That's what Andy's saying. And you do the calculation for the best -- your

best estimate of what's happening on the treatment machine.

MR. TELFORD: We agree. I mean we want to allow this, but what are the words that we should be using here?

MR. STRUBLER: Just appropriate inputs.

MR. TELFORD: Appropriate input?

MR. STRUBLER: Because he's made the assessment that the input was appropriate, even though it's different.

MR. TELFORD: Okay, so that the person transferring it, if the -- if it's 81 instead of 80, then that person can somehow verify that it was the appropriate use, the appropriate transfer.

MR. STRUBLER: Yes.

MR. TELFORD: Okay. That's a good idea.

MR. TSE: Any other comments?

MR. STRUBLER: My final comment, if we want to jump ahead to comments on these others --

MR. TSE: Yes, you may just go ahead.

MR. STRUBLER: I thought that 5.8 to 5.11, some of that was, again, too specific and perhaps unnecessary.

MR. KEARLY: Don't you already say it in your reg?

MR. STRUBLER: And also somewhat confused.

MR. KEARLY: It's in the Maryland regs. I thought they're taken directly from you.

MR. TSE: No. Yes. Wait a minute. We did not say, you know, reg on these two items. To Ken's comments,

yes. You made the suggestion at the first workshop on 5.10.

MR. STRUBLER: I'm being consistent?

MR. TSE: We already did note this, and we will be trying to modify the lower portion of 5.10, not the upper portion, the lower portion. But if you have some language you want to suggest, you might say so.

MR. STRUBLER: Well, going, say, to 5.8, again, I think this whole area is very, very specific and too specific, because the annual full calibrations will include the determination of transmission factors for the beam modifying devices, and then you get examples, and if you're saying, well, you must make a transmission measurement of your low-melting lead alloy every year, and one could say, well, there's no primary set of change, is it necessary to do that? And I would say probably not. I mean we generally make decisions as to whether we need to measure transmission values on every single appliance that we may use that modifies the beam.

So, I think it's getting too detailed and specific as to what should be done.

MR. TSE: The suggestion of 5.8 is not in the current Part 35 regulations, and as you said, you measure these trays or wedges and your annual calibration. Right? How would you modify this such that it would be in the industry practice we can suggest on some other people today?

MR. STRUBLER: Again, to soften it and use a "should" evaluation, so that we can determine what we feel needs to be done on an annual basis.

MR. TSE: Okay. We have some discussions over "should" or "will." The guide is structured such that people could say I'm going to do this, meaning I, the licensee, will do this. That's how it's structured, instead of saying the licensee should do this.

Anyway, we're going to consider this.

MR. TELFORD: You're thinking of a case of the licensee adopts this statement, then the licensee should make a simple statement in their plan as to what they will do.

Your intent is to put in a "should" here and the let the licensee decide what they will do, and we agree with that. I mean we want to give alternative things that we think should be done and look for ways that ought to be sufficient.

Now, we don't really mean to imply that you would do all these things, but we've merely written this so that if the licensee just pulled up the statement that it would be easily used within their plan.

Really, what you're saying is that some of these may be appropriate for one licensee, but may not be appropriate for another licensee like the recastable block

material, for instance, depending upon what material you use.

MR. STRUBLER: I think it goes without saying that if they don't have it or they have a different kind, but my general count is just all these areas are far too specific, and even though we recognize the guidelines, there's still the aura of a regulatory aspect to it. Clearly, with 5.10, is also in the same vein.

MR. BUKOVITZ: In 5.8 I would, after trays and wedges are mentioned, I would not mentioned all these other items such as stock material, blocks and castable materials. The reason is -- I would include trays and wedges, because those are used on a routine basis.

Those can affect a lot of patients and that's just something that's run of the mill, but if you're going to make a compensator or if you're going to use bolus or if you're going to use recastable block material to make a half value layer block, normally what you do is once you make it for that patient, you're going to measure it anyway.

Then that's a patient-specific measurement.

MR. TSE: Therefore you do not need to measure annually.

MR. BUKOVITZ: Right, you don't need to measure it annually because your measuring it as you need it.

MR. TSE: Specifically for that patient. That's a

good comment. I think that it is a little specific, the recommendations. If we take the modifications suggested that perhaps the material and block material may not be necessary for --

MR. KEARLY: The paragraph at the top of the page; I have only one question I still have and I raised it before. I'm not sure that there is such a thing as an accredited TLD service.

MR. TSE: That's what? This was mentioned or suggested at the first workshop where Chapter 2 used perhaps a different word than this.

MR. KEARLY: There are some famous ones. I don't know if you want to use that word.

MR. TSE: You can make your suggestions.

MR. CAMPER: When you think of NAVLAB, for example, --

MR. KEARLY: No, they don't accredit TLDs for therapy measurement, no.

MR. CAMPER: Not at all?

MR. KEARLY: That's for the badges. When you think of accreditation for therapy purposes, you think of the AAPM monitoring the performance at some laboratory and doing that on an ongoing basis. The AAPM accredits with the help of NIST, but that's for therapy measurement chambers, not for TLD. As far as I know, they don't accredit any TLD

service.

MR. TSE: Any other questions or comments?

MR. BUKOVITZ: I have one quick question on 5.7 in general. It's basically -- after a source change, basically the unit is going to have to be calibrated twice? A full calibration and then a spot calibration?

MR. TSE: And an independent check.

MR. BUKOVITZ: So a hospital that does not have their own physicist is going to have to hire two physicists?

MR. TSE: No, that's why we put in the second alternative which is to have a TLD check.

MR. BUKOVITZ: But you don't have an accredited TLD service.

MR. TSE: We're going to change that word. Madison Wisconsin has a TLD service.

MR. BUKOVITZ: I have another question. An individual who did not perform the whole calibration using your dosimetry system, other than the one used during full calibration, but the TLD's are only good to plus or minus 5 percent. For therapy purposes, on a calibration, you want plus or minus 2 percent.

On an annual calibration, we're striving for plus or minus 2 percent.

MR. KLINE: That may be your inhouse protocol. The NRC is the five percent. Getting back to the TLD,

depending on the laboratory and the facility, reproduceability can vary and the accuracy -- there are facilities that do give you accuracy down to what they insist is less than 2 percent.

MR. KEARLY: That's when accrediting comes into account. I mean, if you can't connect it to NBS's rad -- and no one has tried to do it -- if you can't in an accredited fashion, connect it there.

MR. KLINE: Again, with that word, I believe it's speculative change for accredited, so that would alleviate that.

MR. TELFORD: But this is a check; it's not a calibration. You start out with this 5.7.2; the independent check will be performed by either -- so we've got two different ways to do that.

Are these two different ways sufficient? Should we have more ways here?

MR. BUKOVITZ: Well this thing about the TLD just bothers me. I've used TLDs long enough that, you know, people will say they'll give you plus or minus 5 percent, but a hiccup will change it to 10 percent. I just don't trust them.

They're great for a verification.

MR. TSE: But this is the verification.

MR. BUKOVITZ: Yes, but the verification is -- the

five percent just bothers me.

MR. TELFORD: How would you do the independent check then?

MR. BUKOVITZ: First of all, I'd ask; is it really needed? If you have somebody who is a quote, a qualified expert who does the annual calibration, who has equipment which is -- which meets your two year requirements for an ADCL calibration of his equipment -- and that's probably been checked against a constant output source, why are you -- why is this here?

MR. TSE: Because in our view, -- in my view, at least -- the calibration is very important. If for some reason errors have been made, then that error would be propagated until the next calibration.

MR. BUKOVITZ: Why would you not pick that up in the next month's spot check?

MR. TELFORD: We also have a spot check?

MR. TSE: Yes, we have a monthly spot check.

MR. TELFORD: Okay.

MR. BUKOVITZ: Part 35 says you have to have it.

MR. TELFORD: It's not in the guide; it's in Part 35.

MR. TSE: The spot checks are less. I think it's not as --

MR. TELFORD: Are spot checks plus or minus 5

percent?

MR. TSE: Yes, plus or minus 5 percent. It's in the regulation.

MR. BUKOVITZ: So if you use an instrument to do the spot checking and you say, well, I know what the response of this instrument is, now when you do a full calibration, you have an idea of what the spot check instrument should give you.

Now, if that's going to vary by more than a few percent, you're immediately going to suspect something is awry. Either the instrument you've been using for your spot check is no good, or the instrument you used for your full annual calibration is awry.

Right there, you've got two means to check your annual calibration.

MR. TSE: But this particular requirement originally started off as another person, another instrumentation.

So it is a truly check. But because of the problem, therefore it is different from the spot check. But the problem is that many facilities we heard that they may not have a second person.

And since M.D. Anderson has those services for TLD check, and TLD is like plus/minus 3 percent, so we thought that --

MR. BUKOVITZ: Maybe I'm taking umbrage with the fact that you have a qualified expert, and then basically, you are doubting the qualified expert.

MR. TSE: Not saying doubting, but just to make sure --

MR. TELFORD: We are just saying you can check a couple of different ways.

And number (2) is there because, within parentheses, because maybe the institution only has one expert. So the second individual is not possible. So you say well, just use a different method of measuring.

Maybe the instrument we've chosen here, the TLD, maybe you don't like that. Maybe you would prefer saying an instrument different from the one that you used to do calibration with, but let the same person do it.

And we're just looking for a signal to confirm the first signal.

MR. CAMPER: We're not doubting the ability of the qualified experts. But qualified experts are not infallible, either. Great surgeons do use patients.

MR. BUKOVITZ: Oh, yes. I grant that.

But if you have, see, the thing is, if you have one individual and he is using two different machines, or if you have two -- well, I don't like the idea of two different individual using the same instrument. That, you know, I

will agree with you with.

But one individual using two different instruments I think is just as good as two different individuals using two different instruments.

MR. TELFORD: Okay. Good point.

MR. TSE: Andy, with respect to checking, that's not really doubt.

For example, you do the checking on your calculations doesn't mean you doubt --

MR. BUKOVITZ: Oh, I'm not taking it personally.

[Laughter.]

MR. TSE: It is just the quality assurance procedures which are trying to prevent errors.

So your suggestion is that one person may use a separate set of instruments?

MR. BUKOVITZ: Right. Yes. Because I'm looking at the efficacy too of a smaller hospital having to go through all the extra cost, bother, and time.

MS. PICCONE: How often do you think it needs to be done? What is your understanding of when it needs to be done?

MR. BUKOVITZ: Oh, on an annual calibration.

MS. PICCONE: No, no. Only when you change a source.

MR. BUKOVITZ: That's right. It's a full

calibration or when the spot check shows --

MS. PICCONE: Right. If you have an error in a spot check or when you change the source.

So for most institutions, are we not talking once every five years?

MR. BUKOVITZ: I did not fully clarify that it was source change. I kept thinking of the annual calibration, for some reason.

MR. KLINE: Or the 5 percent change in output.

MR. BUKOVITZ: Or the 5 percent --

MR. KEARLY: That's how I interpreted this at the beginning.

MR. BUKOVITZ: My error. I still like the idea of one, even one -- well, never mind.

MR. TSE: You still made the suggestion, right?

MR. BUKOVITZ: Yes.

MR. TSE: Okay.

MR. KEARLY: Could I ask how 5.10 now reads? Because I know we've made a lot of comments about it before. And it is not clear to me what you are going to ask now in 5.10. What do you want 5.10 to do?

MR. TSE: I don't think I can read to you how it reads, because we need to go through the five workshops and then we discuss with the ACR, AAPM, so on.

But essentially, the suggestion is that we do not

need to have those detailed specifications of how to make the computation. Essentially, the last four or five or six or seven cases should be modified.

If you have a suggestion how you would like it to read, certainly we want to read that.

I think last workshop, the suggestion, the first few sentences, first few lines will be okay, but that the last few lines were the conditions. It's difficult.

MR. KEARLY: Could I ask now if this refers to both -- there are two situations for a dose, which we call dose calculations.

One is relative dose calculations, which do get factored into a dose calculation, isodose curves.

And the other is like central axis, percent depth dose, or if are you doing an isocentric, some kind of an isocentric depth dose calculation, a TMR or TAR value that you are looking for for your dose calculation.

My impression was from the first workshop that you are only covering that second issue. If a computer gives you the treatment time for a particular beam configuration, that's the number you want checked. That's the ability, the computer's ability that you are trying to check.

It's not the ability of the computer to match flatness, symmetry, over a wide range of field sizes for combined beams from different directions and compare that to

a physical measurement.

MR. TSE: In the parentheses, you read last sentence in the parentheses, if you do a relative calculation, you still need to check, you still need to check.

MR. KEARLY: What is being checked?

MR. TSE: Associated with the manual calculations, still check with output, against output. But before the first use of computer program, you need to at least make one calculation, make some calculations, and then check against the output under the same conditions, to make sure that they are similar.

MR. KEARLY: So you do intend to cover both types of uses of computers by this?

MR. TSE: That is what this parentheses stated.

Do you have any problems or concerns? Remember, this covers the first use, before first use of software.

MR. KEARLY: Right.

MR. TSE: So make a simple calculation, make a simple check to make sure the computer program calculates the numbers which you, actually matches the number you actually measure.

MR. KEARLY: It's acceptance testing of the computer and a computer used to generate any number that's used for treatment should go through acceptance testing,

because that's really what you are saying.

MR. TSE: Essentially, in a simpler manner.

MR. KEARLY: Because acceptance testing is a very --

MR. TSE: But we did not go through the very complex but very simple, minimum requirements -- not even requirements -- minimum suggestions of minimum should do.

Anybody else have a problem with this particular item?

MR. KEARLY: I just think you ought to -- if you are going to cover the cases where computers generate isodose curves you are getting into something which people have spent -- there's volumes written on what we ought to do to check such things.

I think it is a good requirement to require that. I think if anything in therapy departments that's not given enough time it's probably the checking of the output from the treatment planning computers. It is good to have a requirement that we have to do that, I think, but --

MR. TSE: Suggestion. This is a suggestion.

MR. KLINE: Let me comment on that. You bring up a good point here. The question is, are we looking at the profile sensitive curves? Are we looking at dose to a point?

Typically a dose to a point is a function of those

isodose curves and profiles. Therefore I think the thrust here is to confirm dose, not so much to critique the ability of the software program to generate the correct isodose curves based on physical measurements.

I don't believe that's the thrust of what the intent of this is.

MR. KEARLY: I am not arguing with it either way. What I would like to point out to you is that this is the first time anybody's said this about computers. There is nc Regulatory Guide about how we should be checking our computers.

There is a lot of Regulatory Guides about machine outputs but you guys have, in this paragraph I think unless I'm mistaken, it's the first time anybody is saying, any regulator is saying the computer has to be checked.

I hope that you say the best things that can be said. I am not sure how to tell you because it is a big issue. You may want to look into that with the AAPM I would think to say it the best way.

MR. TSE: We will discuss it with them.

Any questions either on this item or other items?

[No response.]

MR. TSE: If no questions --

MR. CAMPER: I have a comment, not so much a question -- actually a question and a comment if you are at

a point where you could entertain a generic comment.

We spent a great deal of time talking about a Regulatory Guide that by all accounts is designed to be comprehensive, to set up some guidelines by definition.

Let me be the devil's advocate for a moment and ask a question.

I have a concern that there might be institutions out there that look at this Regulatory Guide and say fine, if I commit to this Regulatory Guide then I have taken all the necessary steps that I should take to address this concern about quality assurance.

We all know that you can't put everything that you might want to into the Regulatory Guide. We also know that there are other organizations involved, College of Radiology, AAPM for example, Society of Nuclear Medicine, what have you, but also you have a number of publications that address this subject.

My question is, would it be advisable in your opinion to contain within this Guide a bibliographical listing of those other sources published by some of the organizations that I mentioned and draw the attention to the reader that these documents do in fact exist and that this Regulatory Guide is not designed to be all encompassing and/or the only word in quality assurance.

Is that worthwhile?

Should we do it? Should we consider it, or what have you?

MR. STRUBLER: I would say yes, in brief.

I thought that in some of your comments earlier you in general you make that general statement, to say that this is not an all-encompassing document and I don't recall where it may be but I would say it would be helpful because we realize that around the country there are many institutions that don't have access to qualified personnel on a regular basis and these are the institutions we might be more concerned with, who have a consulting physicist come in periodically and things have changed over the last 15 years I would say rather dramatically in regards to therapeutic applications.

I think it would be helpful. While we all say they should be aware of these documents, they may not be and if it is going to be reviewed by "Management," they may want to have guidance as to where these other documents may be found.

I would say yes to your questions.

MR. DORING: I agree with Ken.

MR. CAMPER: Thank you.

MR. TSE: Any other questions or comments with regard to the Regulatory Guide?

MR. STRUBLER: Yes. Could I backtrack a day here

and bring the nuclear medicine people into this for a moment. They might be getting bored with all these other things.

One of the questions you had raised, and I see here in my notes that I didn't bring up regarding any new objectives, and it's not perhaps so much an objective but guideline regarding the number of injections for nuclear medicine procedures that our technologists suggested that there should be a guideline that if you fail after two injections you should stop the procedure and seek guidance from the physician.

I don't know what routines are being done normally but it may be another guideline, so that someone who is constantly injecting then it may seem kind of foolish but you might want to make a recommendation regarding injections.

MR. NELSON: You mean failing to get the proper image?

MR. STRUBLER: No. If you are trying to inject for a radiopharmaceutical and the patient doesn't accept it you try and then you try again. You don't just keep on trying obviously, and some people may do that. I don't know.

MR. TSE: Let's ask the experts in nuclear medicine what do you feel?

MS. MOORE: In our case we naturally do that. If we try twice then we refer to someone else.

MR. STRUBLER: That's probably common but do you have any sense of whether that --

MS. MOORE: -- that should be regulated?

MR. STRUBLER: -- that be tried three or four times?

MS. MOORE: I don't know.

MR. TSE: Should the Guide contain a statement to say that if you inject more than two times or inject two times, don't continue?

What is your reaction?

MS. MOORE: I don't think it would be an imposition to say that, no. Are there always physicians available in that case? I don't know.

In our institution, yes, but maybe outpatient setting, no.

MS. FRANKLIN: I haven't had a problem with an outpatient setting and injections.

MR. TSE: Do you mean the injection is always done within the two?

MS. FRANKLIN: Yes, I really haven't had a problem with that.

The only times I have had a problem is maybe putting an IV for a thallium and then the doctor is always

available.

MR. TSE: What would you do if you cannot -- within two treatments?

MS. FRANKLIN: If I absolutely couldn't inject someone, I guess I would just couldn't do them if there wasn't a doctor available -- do it anyway?

MR. TSE: How many times you try it before you determine you cannot do it, generally?

MS. FRANKLIN: Maybe a couple times.

MR. TSE: Couple times.

MS. FRANKLIN: Three. Three might be more reasonable.

MR. TSE: Three times.

MS. FRANKLIN: And in the hospital -- I don't have a lot of hospital experience -- if I wasn't able to after once or twice I would get another technologist or if it was necessary, a doctor.

MR. TSE: So therefore --

MS. FRANKLIN: But I never would have considered just --

MR. TSE: -- just keep going.

MS. FRANKLIN: -- keep doing it.

MR. CAMPER: Let me make a comment about this level of detail.

Having once upon a time in my career been a

practicing nuclear medicine technologist myself and made thousands of injections or whatever I know that generally we turn to someone else if we can't make a particular stick and it's a good point, Ken, but the problem I think we have is if we start trying to address that level of detail in a Regulatory Guide I think the medical community will be in an uproar.

I mean they already say to us, you know, you are crossing the fine line of medical practice all the time anyway, and we start telling them how many times they should attempt to stick somebody I think we are going to be met with an awful lot of defiance, so I just don't know if we can really entertain that kind of level of detail or not.

MS. FRANKLIN: As far as that's concerned, I think most places have unit doses now. We have them. You can't just keep pulling out another dose, injecting so much and ruining it, and pulling another one out of a vial. Most places do it with unit doses.

MR. TSE: You're an expert. Would you think you would want to see such an item, or it is not necessary?

MS. FRANKLIN: I personally don't think we need to consider this right now.

MS. MOORE: I agree.

MR. DORING: I think you have a good idea, but I don't think you need a regulation. I think it's noble. I

can really see its noble effect.

MR. TSE: We heard the different views.

Any other suggestions?

[No response.]

MR. TSE: John. Thank you for your help.

MR. TELFORD: Let's look at the agenda for a moment here.

We have a couple of charts to see. We could take a short break and come back and go until about 12:00 O'clock or we could sort of take an early lunch and come back a little early.

The only consequence I can think of is that somebody may have plans to get out of here early, and they won't have time to get through reporting requirements. And I'm sure that is something you ought to do.

Let's talk about those things.

Does anybody have complications with leaving before, say, 5:00 O'clock today?

MR. GRAHAM: I do.

MR. TELFORD: You do? All right. Time.

MR. GRAHAM: 4:00.

MR. TELFORD: 4:00?

MR. BUKOVITZ: I have a 4:00 O'clock flight.

MR. TELFORD: 4:00 O'clock. All right.

All right. Let's take about a five minute break,

and we'll do a little bit right before lunch, and get in some how, then.

[Brief recess.]

MR. TELFORD: This is the item on the agenda that appears at 1:00 o'clock, the volunteers' suggestions for the part 35.33, the diagnostic reporting and recordkeeping requirements. Under that I have an item one -- I just have a keyword there as the theme. The theme of this is that we would like to structure reporting requirements that capture things you might think of as important occurrences, or cases in which the administered dose is substantially different than the directed dose, where something blatant went wrong, like you clearly have the wrong patient; you have a 100 percent difference in the dose you've given.

So, that's the theme I want to ask your help with. So we will go through each of the items in the reporting requirements and I will ask you if you would like to delete, modify or retain those items. So, in order to do that what you need is this handout that you have -- everybody has got to have this. And we need to turn to page -- 35.33 begins which is maybe 1447?

Okay, the first think that you see is that for diagnostic reporting requirements, we have divided it into events and misadministrations.

[Slide.]

MR. TELFORD: I've got these described cryptically in the viewgraph, so on the left here we have the -- let's just take the section (a) -- 35.33(a). These are the diagnostic events. Now the intent behind this originally, was to have a feedback loop that's internal to your hospital or clinic, such that you can detect something that goes wrong that's not really a big deal and you could correct it internally through your internal feedback loop. So these would be the (a) -- the little (a) would be reported to the licensee internally.

Now, would you like to delete, modify or retain little (a)? Is that a useful concept to you?

MR. STRUBLER: Well, again, the problem with both diagnostic and therapy is the licensee -- report to the licensee.

MR. TELFORD: The word, okay.

MR. STRUBLER: And -- and management. And management means the licensee. And I think the concern is that these things should be reported internally to the chair of the department or some other --

MR. TELFORD: Reported to the Radiation Safety Committee?

MR. STRUBLER: Probably not even that. I mean, as necessary, but certainly to the chairman of the department or some other division head.

MR. TELFORD: Reported to the responsible department chairman? Is that a useful concept to you?

[No response.]

MR. TELFORD: I think I'm hearing that you would -- you would retain little (a), but you would change the point to which it would -- you would report it, rather than it go to licensing management?

MR. STRUBLER: Yes.

MR. TELFORD: Any other suggestions?

MR. KEARLY: There's an interplay here between what you call a quality assurance program and records and reports. Number (1) under (a) is not something that's addressed in the QA program. Number (2) certainly is; and number (3) is not, I don't think. Is it? I can't -- if it's already covered -- if it's already covered in the program, why do we have to have an additional reporting requirement?

MR. TELFORD: Well, there's a fundamental difference between 35.35, which is the quality assurance program, and those items that you should include -- that's -- that's a performance-based regulation that you would have alternative ways to meet it -- this is prescriptive. This says you shall report to somebody if you make one of these mistakes.

MS. FRANKLIN: So, in the case of an outpatient

clinic --

MR. TELFORD: Yes.

MS. FRANKLIN: -- who do you report to? Your physicist who or the consulting physicist who comes --

MR. TELFORD: This is the case of a small clinic, an authorized user owns the clinic, so that -- well, when we think of it, we think of it as licensing management, now, that's the authorized use in this case, so -- is your point that -- that there's so few people here that they already know it? They already know those things, if they occur?

MS. FRANKLIN: Well, I'm actually the only person who, in my saying, or in the two outpatient settings I've worked in, or any technologist -- who would I report this to? The physician whose name is on the license?

MR. TELFORD: To the authorized user, yes. That's the answer. You'd report to the authorized user, which is the same thing as licensing management, in this case.

MS. FRANKLIN: So, if the patient came into my office without referral, which is a written request --

MR. TELFORD: Currently, it's a written referral, but in this case, think of it as some sort of referral. Whatever we finally decide -- or find to be a referral. If you have a diagnostic use without a referral, that says that you had treated a patient without a referral.

MS. FRANKLIN: That means I treated the wrong

patient, because I wouldn't treat one that didn't have a referral, right?

MR. TELFORD: I realize that you would not, but the reporting requirement says for anybody that did treat a patient without having a referral -- that the concept here is that that gets reported to somebody within the licensee organization. It could be it's the chairman of the department, it could be your authorized user.

Okay, you seem to be pretty passive on this. You don't feel too strongly one way or another, as long as we have it reported to the right person, such that you have an intelligent listener, somebody that can do something about it -- knows what to do, then it's all right?

Frank, did you have any remarks you wanted to make about 1, 2, and 3?

MR. KEARLY: No, not at the moment. This documentation and evaluation and that sort of thing --

MR. TELFORD: We'll get to records in a minute.

MR. KEARLY: Yes.

MR. TELFORD: Records is Part (e); we're on Part (a).

Okay. Let's move to Part (b), and Part (b) are things we call misadministrations. So, for instance, under (b)(1), this is a gross mistake, where you have the wrong patient or the wrong radiopharmaceutical or the wrong route,

patient, because I wouldn't t[illegible]t one that didn't have a referral, right?

MR. TELFORD: I realize that you would not, but the reporting requirement says for anybody that did treat a patient without having a referral -- that the concept here is that that gets reported to somebody within the licensee organization. It could be it's the chairman of the department, it could be your authorized user.

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MR. TELFORD: Records is Part (e); we're on Part (a).

Okay. Let's move to Part (b), and Part (b) are things we call misadministrations. So, for instance, under (b)(1), this is a gross mistake, where you have the wrong patient or the wrong radiopharmaceutical or the wrong route,

and (b)(2) is when the administered dose is 50 percent different from the prescribed dose.

MR. BUKOVITZ: Can we go back up to (b)(1) real quickly, please? Any diagnostic use other than that stated in the prescription and procedures manual.

MR. TELFORD: Yes.

MR. BUKOVITZ: There are certain diagnostic uses which are not wrong. My question is what happens if you do a procedure which you do not find in your procedure manual? It may be FDA approved, it may be totally innocuous, and absolutely nothing happened other than that you got some useful information.

Now, could that be a misadministration?

MR. TELFORD: Okay. Let me ask you to look at page 1447(b)(1) for the exact words. This is saying, in the exact words, that any diagnostic medical use, other than the one stated in the prescription or the referral and the manual.

So, that's sort of as if you're operating without any direction.

Let's take your example: How did the technologist know what to do?

MR. BUKOVITZ: Let's say the technologist was asked to perform a certain study, and the study is an approved study. The authorized user asked it.

user can make a diagnostic referral. His point is if the authorized user makes a diagnostic referral and they may not have it in the clinical procedures manual, and the way this is written here, it appears to tie those two things together.

MR. TELFORD: Well, that's something we should fix then.

MR. TSE: John?

MR. TELFORD: Yes.

MR. TSE: The authorized user could make a prescription. If he makes a prescription, then that would not be tied into a procedures manual.

So, like your example, he or she wants to do a certain study. He or she writes a prescription. That prescription is given to the technologist the he or she could perform that without having to worry about a diagnostic referral and the manual. Maybe you think it's not clear, but that's what the intent of this was.

MR. TELFORD: You're suggesting that we should allow the authorized user to direct a diagnostic study to be done, carried out by the technologist, and the study need not be described in the clinical procedures manual.

MR. BUKOVITZ: Right.

MR. TELFORD: Okay. We should fix those words; we agree.

MR. CAMPER: Let me ask Andy a question: If you read on in that same paragraph, Andy, where it goes on to say that incorrect medical use would include treatment of the wrong patient, administration of the wrong radiopharmaceutical, or radiation with the wrong sealed source, in your example, that would not have been the case, would it?

MR. BUKOVITZ: That's correct.

MR. TELFORD: Okay.

MR. BUKOVITZ: That brings up another question, though. A physician may request tech for a particular study, and this may be a referral; however, at the last minute, instead of looking at the kidneys, they wanted to look at the liver. At the same time, that study would give you adequate information on the liver. What happens in that case? We said I wanted to look at the kidneys, but then I really wanted to look at the liver after the fact. So, the study may have been requested for one organ, but you really did it for another organ, and you still got the appropriate information.

I'm trying to think of a specific example because I've done this more than once. Can you help me with it?

MR. TELFORD: Let me see if I understand this. You say that it's either a referral or a prescription, but you're supposed to look at one organ, Organ A, and the

proper injection was given for that study.

MR. BUKOVITZ: Right.

MR. TELFORD: But it turns out that you can also get an image from Organ B as part of the same study. Well, why isn't it all right if you followed the prescription or the referral and manual to do the image on Organ A?

If that was doing correctly, I mean you're following -- the technologist is following what they were supposed to do.

MS. FRANKLIN: Do you mean like a mammogram where you might inject MAA and then you get pictures of the lungs, too?

MR. BUKOVITZ: Yes.

MR. TELFORD: Do you see a problem there?

MR. BUKOVITZ: I know what I want to ask and I'll have to wait on that one.

MR. TELFORD: Okay. You're searching for something to put your finger on, okay.

MR. BUKOVITZ: I've seen occurrences several times whereby it may be considered a misadministration where in actuality, the information that was wanted was retrieved, even though it was not specifically asked for in the referral; where the referral asked for one study and the isotope which was injected, the amount which was injected, the route is fine, except that at the last minute, the study

which was wanted was changed or may have been changed after the fact.

MR. TELFORD: They didn't image Organ A?

MR. BUKOVITZ: Well, they didn't intend to image Organ A, but Organ A was imaged anyway and the study was then based upon the imaging of Organ A.

MR. TELFORD: Okay, they imaged both Organs A and B.

MR. BUKOVITZ: Right, but then B was originally requested, but then the study was really more interested -- the physician was more interested in Organ A.

MR. TELFORD: I don't see a problem.

MR. NELSON: What we'd get a written down then -- would Organ A get written down, the one that it was originally intended for, or would Organ B be the one that was finally used?

MR. BUKOVITZ: Organ B would be the one that was finally used, even though Organ A was the one that was originally requested.

MR. CAMPER: This seems to imply close physician interaction. I don't see it as being a -- other than the designated organ, it's not a route of administration problem and it's not really a pharmaceutical problem. This is almost a medical judgment call that at some point, the physician decides, I want to look at Organ B or I rather

initially intended Organ A.

It doesn't sound like a misadministration to me at all.

MR. BUKOVITZ: Oh, no, I'm not considering it as one, but I'm just wondering how you would look at it.

MS. PICCONE: Let me give you a renal study scenario and see if this fits into what you're thinking about. There's a diagnostic referral to do a renal study and in the clinical procedures manual, it lists what agents you should use for that.

Instead, this patient was injected with the bone imaging agent and on those images, you were able to see the kidneys and so they got what information they wanted because they saw the kidneys. Is this what --

MR. BUKOVITZ: It's close.

MS. PICCONE: That really would be a misadministration.

MR. KLINE: The prescription is made and a different pharmaceutical is injected?

MR. BUKOVITZ: Well, no. You can do certain studies whereby you're injecting the same pharmaceutical, same amount, by the same route, but looking at a different organ.

If the referral was made for Organ A, but then a final diagnosis and reading was done for Organ B --

MR. CAMPER: You're getting into clinical interpretation.

MR. KLINE: Unless you have differences in doses, let's say, Organ A required 5 millicuries and Organ B required 20 and you injected 20 when you meant to inject 5, that's a little different.

MR. BUKOVITZ: That, I agree. I'm really looking at the organ; the organ you wanted to look at and the one you finally looked at.

MR. CAMPER: Yes, but if the doctor ordered Organ A and the dose is administered properly for Organ A, and the interpreting physician, as part of his diagnosis, looks at Organ B, to my way of thinking, that's a clinical interpretation problem; it's not a misadministration problem.

MS. PICCONE: In addition to A, he looked at B -- in addition to A -- what was originally wanted?

MR. BUKOVITZ: Or he looked at B in lieu of A.

MS. PICCONE: Say a physician wanted a liver scan and they used the same -- just for argument's sake, the technologist imaged the lungs and they got an image of the lungs and so the study now interprets some study of the lungs when the diagnostic referral asked for something having to do with the liver.

MR. BUKOVITZ: The route -- there would be no

difference in the route, the dose for an organ.

MR. TELFORD: Seems strange.

MS. PICCONE: But there's a problem there.

MR. GRAHAM: Your documentation doesn't coincide with the written order, your written order plus the reports and obviously it would not come to you people as reviewing that.

MR. DORING: There's nothing wrong with doing what's asked and then some. But you can't do "and then some."

MR. CAMPER: That's not customary.

MR. BUKOVITZ: But see, I'm looking at the phraseology, because the administration of the radiopharmaceutical hasn't changed. It's not the wrong organ and it's not the wrong site.

MS. PICCONE: Is that you want to add that to this; that this should include if you imaged the wrong site?

MR. BUKOVITZ: If you imaged a -- well, it's not necessarily the wrong site. You imaged a different site, other than the one you originally intended. For whatever reason it happened, I don't know, but it's not -- it just happens that Organ B would have received this amount of radiation of the radiopharmaceutical, regardless of whether or not Organ B was requested to be imaged.

MR. KLINE: That would be visualizing an

additional site in addition to Organ A.

MS. PICCONE: He's saying, instead of.

MR. BUKOVITZ: Instead of.

MR. KLINE: Let's say, for example, like technetium DTPA which people at one time used for the brain and kidney, so you have two different organs and you're saying that the original order said, I'm going to a brain scan with DPTA. You inject and then the physician goes off -- I really wanted to look at the kidney?

MR. BUKOVITZ: Right, exactly.

MR. KLINE: It's a different organ.

MR. BUKOVITZ: Yes, and it's after the fact.

MR. TELFORD: Don't create a problem for yourself. Just have the physician say that I want to look at the kidney now and --

MR. BUKOVITZ: Well, they do.

MR. TELFORD: They direct. If you looked at both, then I don't see where there's a problem, but if you change in midstream, you need to change the directions so that everything corresponds.

MR. BUKOVITZ: But he changed in midstream after the fact.

MR. TELFORD: I don't think there's any way we can fix these words to --

MR. CAMPER: You're stepping a fine line between

misadministration and clinical interpretation; there's no question about that.

MR. BUKOVITZ: I'll leave it.

MR. TELFORD: Okay. It's noon. Let's break for lunch and see if we can come back sharply at 1:00.

[Whereupon, at 12:00 p.m., the workshop was recessed, to be reconvened this same date at 1:00 p.m.]

A F T E R N O O N S E S S I O N

[1:05 p.m.]

MR. TELFORD: Let's go back to business.

[Slide.]

MR. TELFORD: We left off with 35.33, I believe on Item (b)(2).

This would be a report for diagnostic use, such as the error resulted in a dosage that was 50 percent different than what was prescribed.

Would anybody like to make a suggested modification for that, or do you want to retain that?

MR. KEARLY: Is that the same as the old one? I can't recall.

MR. TELFORD: Yes. As current.

MR. NELSON: What would happen if you had a range in your clinical procedures manual? Would you go with the midpoint or would you go with the upper end, exceeding upper end, 50 percent of that range?

MR. TELFORD: Oh, you mean in case of a referral? You'd go with the upper.

MR. KEARLY: 50 percent of the upper and over, or 50 percent of the lower and below what was prescribed or what was prescribed with some place in the middle?

MS. PICCONE: Well, because there isn't an exact dose prescribed, the physician will accept anything in the

range.

MR. TELFORD: Okay. Let's move to (c). For the exact words, I'm going to refer you to what was in the Federal Register on Page 1448.

But basically it says that for any occurrence A or B, now that's any of these events here. A and B events are the misadministrations. This requires the RSO to investigate, make a record, and a report.

Now, how would you like to modify that?

[No response.]

MR. TELFORD: No modification?

[No response.]

MR. TELFORD: No?

MR. KEARLY: Can we at least add "or his designee"?

MR. TELFORD: We could accept that suggestion, sure.

MR. KEARLY: Because it is potentially a lot of work.

MR. TELFORD: Yes. That is potentially work.

MR. KEARLY: Especially since you are adding events to this.

MR. TELFORD: Now, how about, let me call your attention here, how about to the events here. This requires the RSO to investigate something here, make a record of it,

and a report.

MR. KEARLY: From my point of view, if I could have the chief tech. in nuclear medicine investigate any such event, I think that is perfectly adequate. Because he certainly knows what is going on there much more than I would.

MR. TELFORD: You would substitute, or put an alternative of your chief tech. instead of the RSO?

CAPTAIN HELLMAN: Well, the RSO or his designee.

MR. TELFORD: All right.

CAPTAIN HELLMAN: But the RSO is still responsible.

MR. DORING: These regulations don't preclude individual institutions deciding that they are going to delegate this responsibility, anyway. So is it absolutely essential that you have to even put "designee" down if the Radiation Safety Officer is going to assume responsibility and wants to delegate that?

MR. STRUBLER: I think we do, because it says Radiation Safety Officer. It does not say "or someone else." And I would include "or his designee" in there.

This also infers that there should be two reports. The first report is by the nuclear medicine, say, chief technologist. That's Part (a). Part (c) says someone else should also investigate.

So this report here from the nuclear med. tech. would not be appropriate for Part (c), which is a different statement.j

MR. KEARLY: I take Part (c) to be what it is that Part (a) generates. Those things require it and Part (c) says what it is supposed to be. It is a record of the event and it's an investigation of it.

MR. STRUBLER: Part (a) says a record and a report. Part (c) says also an investigation and a report.

MR. TELFORD: Well, look at Page 1447 under (a).

These three events here we say are diagnostic events for which a record and, under certain circumstances, a report is required. So the (a) (1), (2), (3) over here are the things for which the report might be required. This (c) over here says who will do it and basically what they will do, the broad steps, they will investigate, make a record, and file a report.

MR. STRUBLER: So it is acceptable if you put "or his designee", "or designee." (a) could be a record by the nuclear medicine tech. (c) could be a report by the same individual, which would differ from a record. It says "record or." So if it is a minor problem --

MR. TELFORD: No.

MR. STRUBLER: No?

MR. TELFORD: No. I apologize. My cryptic stuff

here is confusing you.

You have to look at Page 1447. This is really a list of things, occurrences that we are calling events, that will require something. Okay? This is what it requires.

I'm sorry. Please don't pay too much attention to my cryptic English up there.

Frank?

MR. KEARLY: That's how I interpreted it. But can I make -- this is a request: Following with the definition of events, I would like to see immediately the requirements for recordkeeping and reporting. Following the misadministrations, in that same section, requirements for records and reporting.

In the next half a page, you go into if this, then that, or that, then this, then this over here, then that. It's extremely confusing as to what kind of records are required when, what kind of reports are required when.

This is convolutional here.

MR. TELFORD: The order in which we give you the information -- you're saying that -- okay, records are at the end.

MR. KEARLY: And they go back and forth between events and administrations, depending on what the size is and so forth. Sometimes you do something for events and not for administrations and vice versa, and then sometimes you

do something for either or both.

MR. TELFORD: Okay.

MR. KEARLY: After events, what are the reporting requirements, the recordkeeping and reporting requirements?

MR. TELFORD: Okay. If I understand this correctly, you're suggesting you would like to see -- take events and treat them in total.

MR. KEARLY: Correct.

MR. TELFORD: Take events, do the report, do the record, and then go to misadministrations, do the reports, do the records --

MR. KEARLY: Yes.

MR. TELFORD: -- do the wherefores and all the other conditions. Okay. I understand.

MR. KEARLY: And make it clear that you want this documentation.

MR. TELFORD: Okay.

MR. KEARLY: I guess there's a difference between a record and a report. It's not quite clear to me what it is. And an investigation, also.

MR. TELFORD: That would be easy, because a record is something that you retain, and a report is something that has to go to somebody. I mean a record you just put in the file. But if it's a report to the NRC, for instance, you have to send it in. If it's a report to your authorized

user or licensee management or chairman of the department, whatever we say, it has to go to that person.

MR. BUKOVITZ: Is a copy of the record a report?

MR. TELFORD: Probably not. Probably not sufficient, unless you've structured all your records such that they can be turned into reports. I mean you could make it that way, but then you would have a file for essentially letters, letter reports. That would be too much trouble in my case.

CAPTAIN HELLMAN: E(4), or E(3), on 1448, says what a record must have.

MR. TELFORD: Yes. We were on (c) here for when this report must go in, either for (a), for events, or (b), for misadministrations. So, (c) really requires some work by somebody, and you could say RSO or designee.

Any other suggested modifications to (c)?

[No response.]

MR. TELFORD: Okay. Let's go to (d), and this says that you're going to report to the NRC within 15 days of either (a), which are events, or (b), misadministrations, if either the event or the misadministration involved unauthorized byproduct material, for some reason using byproduct material that's not covered in your license -- you know, maybe it's a new brachytherapy source and you just don't have it included on your license yet; that's an

example -- or there's a fivefold error in the dosage.

Now, let me apologize again. These are cryptic slides. So, for the exact words, you have to look on page 1448. But basically, you're talking about a fivefold error; the administered dose is fivefold different from the prescribed dose; or this one, the dose to any organ is greater than 2 rem or you get a half-rem whole body as a result of one of these events or one of these misadministrations.

Now, do you have some suggested modifications for (d)?

[No response.]

MR. TELFORD: The nuclear medicine folks should pay careful attention here.

MR. KEARLY: Could I step back just one second to the last sentence of Part (c)?

MR. TELFORD: Yes.

MR. KEARLY: We have "notify licensee management to take appropriate and corrective action" once again. And I think it is the same comment that was made before. Management is not the right place to go.

MR. TELFORD: Okay. Notify Department Chairman?

MR. KEARLY: Something to that effect.

MR. TELFORD: Something to that effect?

As you said before, whatever we work out from

before can go here, too. Okay?

MR. KEARLY: Okay.

CAPTAIN HELLMAN: Yes. I can see also, for (c), something that requires only a record, to not, let's say, have to go to the management. Something that in fact is a report, i.e., reportable through (d), which has been, as in today, these misadministrations, report them to the management, or to the Radiation Safety Committee, or whatever.

But I would separate reportable to the NRC events from nonreportable, as to how we handle them through our own management.

MR. TELFORD: You would like them to be separated?

CAPTAIN HELLMAN: Yes.

MR. TELFORD: Okay. I think we have.

CAPTAIN HELLMAN: Well, (c) does not require, (c) says any event or misadministration must have a record in Part (e). And Part (e) requires that anything that occurs, you are saying that anything that occurs whatsoever you need to report to your management.

And I'm saying let's have only those that are reportable to the NRC come to the attention of management.

MR. TELFORD: Oh. Have them the same. Okay.

Wait a minute. You're saying that under (d) if you report it to the NRC, it should also go to somewhere

within the licensee?

CAPTAIN HELLMAN: I think if you report it to the NRC, then only those cases should be brought to management, whereas the way (c) is, the last sentence requires that everything be brought to the attention of the management.

MR. TELFORD: Okay. That's all right. That's quite different.

You are suggesting that in effect we don't need (c) unless it is triggered, the trigger level here should be these trigger levels down here.

In other words, if it not worth reporting to the NRC, it is not worth reporting to the licensee management.

CAPTAIN HELLMAN: That's correct.

MR. BUKOVITZ: I don't know if I agree with that.

If you have a problem which may be a recurring problem, sometimes the only way you can take care of it is if management does know.

CAPTAIN HELLMAN: I'm not saying you can't, I'm just saying you don't have to. You know, the RSO can choose whatever he wants. If he wants to bring everything up to the committee, it is up to him. But I don't think every event or every possible thing should have to go to the management.

MR. BUKOVITZ: Not everything does have to. I'll agree with you there. But then I'm starting to wonder where

we are going to draw the line.

MR. KEARLY: Something got past us here in the whole process.

In (a) for instance, Number 2 says any diagnostic medical use without a prescription or a diagnostic referral. And we went around that circle a lot yesterday.

Diagnostic referral is something in writing, while sometimes we won't have such a thing. And that is allowed now by our current thinking. I mean, that is what we discussed yesterday.

So that means potentially we have a lot of, a lot of events. Who cares about that?

MR. TELFORD: I think we have to assume here that the -- just a point of clarification -- we have to assume here that when we are talking about a referral here, whatever we settle on is the referral, whether it is a written referral or if it is direct communication, oral referral.

MR. KEARLY: I still see that as potentially a lot of events. And how cares about them? Who should care about them? Management won't care about them.

MR. TELFORD: All right.

MR. KEARLY: Management shouldn't care about them.

Should the Department Chairman care about it? I mean, is there clinically something going wrong is really

our most important question to ask.

But when you ask who we refer to, this is part of the problem that I have with these two pages. Again, the requirements, you can state simply what you are trying to accomplish, but then there are requirements for recordkeeping and reporting that you have to go through four more paragraphs and pick out does it or doesn't it apply to what we are talking about.

So whatever you want to do with these things, say it right there.

MR. TELFORD: Okay. You are right. What this is after is that you have a diagnostic use without a referral. Yes. That means that you have patients coming into the nuclear medicine department that have been treated. They had neither a prescription nor a referral.

Do you want that to be --

MR. KEARLY: Whatever we decide on, I think if you make a reasonable definition for "referral," I think that that's okay.

MR. TELFORD: Okay. But I would assume you don't want patients coming into your department without one or the other.

MR. KEARLY: Right. Sometimes a referral can be a phone referral, I hope.

MR. TELFORD: Okay. Joe had a suggestion that he

was suggesting it is not necessarily a requirement to report things that would be under (c) but if it is going to be reported to NRC, that is, a sufficient level to be required to be reported to NRC, then those same kind of requirements ought to apply to the things that go internally.

CAPTAIN HELLMAN: Nothing precludes the RSO or his representative bringing other events up to the safety committee. It's simply that they need not have to go to the safety committee.

MR. TELFORD: Does anybody have any remarks about the trigger levels here? We have the five-fold error or the half rem whole body or two rem any organ.

CAPTAIN HELLMAN: Is that a relaxation from what we currently have?

MR. TELFORD: No. This is current. Two rem whole body; half rem -- two rem any organ; half rem whole body is current.

CAPTAIN HELLMAN: But, say, if someone prescribes protechnetate and they use pyrophosphate, that's not a reportable, that would not be reportable at this point? It's reportable now.

MR. TELFORD: You have the wrong radiopharmaceutical.

CAPTAIN HELLMAN: Yes. But reportable to the NRC, though, under (d), that does not look like a reportable

incident, any more.

MR. TELFORD: Well, let's take your example. You have the wrong radiopharmaceutical.

CAPTAIN HELLMAN: Yes.

MR. TELFORD: Did it result in a dosage that was five-fold or two rem any organ or half rem whole body as a result of it being the wrong radiopharmaceutical?

If it does, then it goes to the NRC.

CAPTAIN HELLMAN: I think it's a relaxation.

MR. TELFORD: It's a relaxation?

CAPTAIN HELLMAN: I think so. I think it can be.

MR. TELFORD: I didn't realize we were relaxing. I thought this was a lot more --

MR. CAMPER: Well, it's turned up the two rem triggering level with respect to almost all diagnostic procedures. If you administer the wrong radiopharmaceutical compound, you are going to go to an other-than-intended organ, and it's going to get a dose on that organ.

MR. TELFORD: Yes. See, if you get the wrong radiopharmaceutical, you can almost guarantee it, couldn't you assure that you are going to get two rem to some organ that wasn't intended?

CAPTAIN HELLMAN: I don't do nuclear medicine.

MR. TELFORD: Okay. Gene?

MR. GRAHAM: I don't do it.

MR. TELFORD: Linda?

MS. FRANKLIN: I don't do dose.

MR. TELFORD: Susan?

MS. MOORE: I'm not sure either.

MR. BUKOVITZ: Just administering the wrong radiopharmaceutical, now, really does not necessarily come anywhere an organ dose of two rem. Most organ doses are in typically-administered ranges of millicurie amounts of radiopharmaceuticals. It could be much less than a two-rem organ dose. But I don't think that's the issue.

MR. TELFORD: Okay. Is there an issue?

MR. STRUBLER: I think the issue was, as it stands now, my understanding was a misadministration is reportable to the NRC. Period. Now, we're qualifying what kind of misadministration is reportable. If it is a misadministration below two rems, it is not reportable. And that is the point that was being made.

MR. TELFORD: Anthony?

MR. TSE: Under the current regulation it stated the same way. Reportable to NRC if it is a five-fold diagnostic misadministration or greater than two rem. It is the same way.

MR. TELFORD: I think you'll find these in 35.33 currently. You find this in 35.2 currently.

Let's move to records then. We'll finally get to

records. Now, for the exact words, I believe that's on page 1448

MR. CAMPER: Point of clarification. It's the same as it is right now, but again, if you look at the 500 millirem, or the 2 rem organ dose, you're going to find that affects more nuclear medicine studies than you think. It affects the majority of clinical nuclear medicine studies.

MR. BUKOVITZ: It affects them yes, but the organ dose --

MR. CAMPER: It's a qualifier for misreporting. You've got to either hit 500 millirem whole body, or your going to hit the 2 rem organ dose for almost all nuclear medicine studies.

MR. TSE: I think, generally, they hit the 2 rem organ dose first.

MR. CAMPER: Yes. The 2 rem organ dose that's usually the trigger. It affects most of them.

MR. BUKOVITZ: My understanding is that most organ doses are going to be less than 1 rem for typically administered radioisotopes. Well, you know, I have no problem with that anyway.

MR. TELFORD: Okay. Records. Part (e) requests that you retain certain records. And this is for each prescription referral because this contemplates a written referral, and if we didn't have it written then we would

probably need some record of the referral. Now a record of the dose or dosage administered. And if you have a bunch of outpatients then you send a report back to the referring physician, so that covers you here for the record of the dose or doses that's given, and to keep these records for three years.

Two, is if you have a clinical procedures manual, and if you change a procedure in the manual, you keep the old one for three years -- three years after its last use.

And three is a record of each occurrence, either (a) the events or (b) the misadministrations for 10 years.

Yes?

MR. STRUBLER: I just have one question regarding the terminology. Because there are specific definitions for dose, which is accepted as the absorbed dose, it's also used to mean amount of activity administered. And here we have in this comment here, to keep a record of the radiation dose. And if you look at a strict definition, dose means probably absorbed dose; but we all know and understand the differences in dose and absorbed dose, verses amount of activity. And you might want to be a little bit more careful in the language.

MR. TELFORD: Okay. I'm looking at (e)(1), record of administered radiation dose. So we're contemplating what was administered.

MR. STRUBLER: Okay, but -- all I'm saying is that administered radiation dose -- some would say, well, radiation dose is -- I'd have to calculate it to be the two rems or something to -- to an organ, or something of that type. I realize that you've qualified it with an administered radiation dose; but -- radiation dose -- that phrase technically means delivered, absorbed dose and centigrays, and not activity administered, which is what people administer -- the amount.

MR. TELFORD: Okay. If we're talking about the radiopharmaceutical dosage?

MR. STRUBLER: I would say it would be administered activity.

MR. TELFORD: Okay.

MR. STRUBLER: Because activity has a very specific definition, in terms of quantities and units and we're talking about the quantity of activity, versus the quantity of absorbed dose, which are very specific and very precise definitions. And we use terms interchangeably to being one another, just as we use the term exposure to mean different things; but in a regulatory body, I think we should be very, very specific So I would use the term "activity."

MR. TELFORD: Okay.

MR. KEARLY: What's an actual radiopharmaceutical

dosage, if it's not activity?

MR. TSE: I think that's the catch -- is that radiation dose is the -- is the dose, instead of being rems or rad, and radiopharmaceutical dosage is the pharmaceutical -- millicuries/microcuries.

MR. STRUBLER: But people, in general, do not know the absorbed dose that's being delivered. That's not a value that you have available or that is calculated -- it is highly variable anyway. But what is not variable and what is measured, is the activity of the radiopharmaceutical. I think those terms should be used. And if you want to add in "or" that's probably not a very useful addition to say "or the absorbed dose," because people don't know that.

MR. TELFORD: Or we could say an EG or an IE.

MR. STRUBLER: Yes.

MR. TELFORD: You know, put it in some sort of clarification.

MR. STRUBLER: Yes, but the real quantity that you want to specify is the activity -- the radiopharmaceutical.

MR. TELFORD: Okay.

MR. STRUBLER: And then that's clearly defined.

MR. KEARLY: Record of administered radiopharmaceutical activity. And get rid of radiation dose out of there altogether.

MR. TELFORD: Okay. Any other? Yes, Tony?

MR. TSE: This particular item includes the teletherapy, brachytherapy and the radiopharmaceutical. The radiation doses refer to teletherapy and brachytherapy. Radiopharmaceutical dosages refer to radiopharmaceutical millicuries and microcuries.

CAPTAIN HELLMAN: These are diagnostic events in this?

MR. STRUBLER: Oh yes. And it doesn't matter whether it's diagnostic activity.

MR. TSE: Okay. But there are some diagnostic device which contains some sort of --

CAPTAIN HELLMAN: Sealed source?

MR. TSE: Right. This -- they have a radiation dose.

MR. STRUBLER: In general, the primary quantity is the quantity activity. In a sense that's clearly defined in the literature that should be used primarily, and then in addition, there are other examples. For absorbed dose is the quantity, then we should use that term "absorbed dose," because radiation dose, as I said, is not a scientific specific definition of any quantity.

MR. TELFORD: Okay. Any other final suggestions for diagnostics, before we go to therapy?

MR. KEARLY: Yes. Part (e)(3), if you read it, it says "every diagnostic event or misadministration regarded

as a report." So in (a), where you say a record or report, that's not true. It's a report. There is no such thing as just a record. You have to have a report of anything that occurs, either event-wise or misadministration wise, according to this.

MR. TELFORD: Let's look at the words here, (e)(3).

MR. KEARLY: "Each licensee shall retain the following records: (3) the report of each diagnostic event or misadministration, and it must contain this..."

MR. TELFORD: But provided you file -- provided you needed one?

MR. KEARLY: No. That doesn't say that at all. This says you need one.

MR. TELFORD: Well, the intention is to say, provided you needed one, because --

MR. KEARLY: When did it say you didn't need one?

MR. TELFORD: Because here in (d) is when you need one. Only in these cases do you need one; (e) is not to say you have to generate a report for all.

MR. KEARLY: So, you're saying a report is something that comes to the NRC; it's not an internal record?

MR. TELFORD: Well, the way this is structured, it's either to the licensee or to the NRC, so you could have

a report here, by this RSO, or you could have a report here to the NRC.

MR. KEARLY: This is extremely confusing.

CAPTAIN HELLMAN: Because (c) states that for any diagnostic use that resulted in an event or misadministration in (a) or (b) shall make a record and retain the record, as directed in paragraph (d); so, (c) requiring the full-fledged record. It says for any in (a) or (b) requires a record, as directed in (e).

MR. KEARLY: The record and the report contain the same information, but every once in a while you want a report sent to you, you want a record sent to you, and that's when you --

MR. TELFORD: In (c), it says shall promptly investigate its cause, make a record for NRC review, retain the record, as directed in paragraph (e). Okay. As directed in paragraph (e) says keep it 10 years. But we're not up to a report yet.

Go off the record for a minute.

[Discussion held off the record.]

MR. TELFORD: Pardon me?

MR. BUKOVITZ: Are you saying (e) happens only if (a) or (b) happens, or are you saying (e) happens if (c) or (d) happens?

MR. TELFORD: Ye -- (e) is you have a record, and

you have a record if you have one of these.

MR. BUKOVITZ: Okay. So, the report in (a) turned into a record for (e).

MR. TELFORD: No. There is no report in (a). Disregard this, because what this is meant to say, for these occurrences, you have an event. For these occurrences, you have a misadministration. Now, under certain circumstances, these events will require either a record or a report. Similarly, under certain circumstances, these will require a record or a report.

MR. BUKOVITZ: Okay.

MR. TELFORD: This is my cryptic shorthand up here.

MR. BUKOVITZ: So, (e) is a record of a record or a record of a report.

MR. TELFORD: No, no. We don't have records of records; we only have a record.

MR. BUKOVITZ: If (a) happens or if (b) happens, we have to keep documentation on it for the period specified.

MR. TELFORD: Yes. A single record of the event, yes.

MR. KAPLAN: If you added the words to (e), in the report is required, each licensee shall retain the following records, that would clarify it, wouldn't it?

MR. TELFORD: Yes.

MR. KEARLY: Isn't that already spelled out under (d), though, the records that you're supposed to keep?

We have an awful lot here to try to figure out if something happens. What category does it fall into, and what are we really going to -- I have another question.

Is (d) what you really mean by a misadministration, since you want a report? Are you just expanding your definition of misadministrations? Is that what the meaning of (d) is?

MR. TELFORD: No, like this one. If you're 50 percent different --

MR. KEARLY: If you have no misadministrations by (d), right? Isn't that what you mean by (d)? These are new definitions for misadministrations.

MR. TELFORD: These are the trigger levels for when you report to the NRC.

MR. KEARLY: You mean misadministrations?

MR. TELFORD: Both (a) and (b).

MR. KEARLY: When a diagnostic event takes place, if anything on the left page happens, if (d) is satisfied, it's a misadministration. I mean, effectively, that's what you're saying, because that's what you want to know about.

MR. TELFORD: Let's say you have a patient that got treated and didn't have a prescription or a referral,

then that's an event, not a misadministration. Okay? We have an investigation and a record and a report to the licensee under (c), and under (e), you keep that record that you made up here for 10 years. If this patient happened to get an organ dose that was not the intended organ for greater than 2 rem, then you may have to file a report to the NRC.

MR. CAMPER: Another point you made here, talking about -- triggering things, if you look at the fivefold error in the dosage, it is very easy to see a fivefold error in dosage to an organ that's over-prescribed. For example, you take technetium compounds, which are quite localized, obviously, and you administer only the proper compound, it's very easy to deliver -- in fact, you will deliver a dose in excess of five times that which was intended, because in many cases, it's zero or near zero.

MR. KEARLY: You don't mean that word to mean activity in that case?

MR. TSE: The fivefold is a millicurie. The dose is exact.

John, can I just try to address Frank's point?

Either (a) or (b) is a definition of event, this diagnostic event. If you have those occurrences, that's an event. Then, (e) is a definition of diagnostic misadministrations. If you have those occurrences, that

will be misadministrations?

What do you do once you have those is (c) says you've got to do internal -- you should take internal actions within the licensee; (d) says if you exceed certain threshold either in (a) or in (b) you need to report to NRC and whatever it says in (d). Then, (e) says if you have either (a) or (b), you need to keep some of those records. You do not have to report.

Then, the last one says that you -- (3) says that you need to keep the records if you need to file a report.

MR. KEARLY: Am I the only one who finds this very confusing?

MR. BUKOVITZ: No. There's a lot here.

MR. KEARLY: If a or b, then e.

MR. TELFORD: Yes, Joe?

CAPTAIN HELLMAN: I have a question about the three years for both e(1) and e(2).

What is the current licensing frequency?

We're at a point where we're getting annual where we are.

I do not know -- for myself I prefer keeping it for two years, some on an annual basis. However, agreement states are still -- may be on a three year cycle and then I can see keeping it that way.

MR. TELFORD: Some of the smaller licensees would

be on a three year inspection cycle.

CAPTAIN HELLMAN: I guess we're stuck then. I would just rather not keep that much, for that long. Okay.

MR. BUKOVITZ: Are we saying if a or b, then e?

MR. KEARLY: John, would it help if on the side, a, and then subtitle a so it would say diagnostic events requiring a record, full report and report refers immediately to d?

This is like a "if greater than" statement and what you have is a logical flow: if you exceed certain values in a and b, then you go to d, and if you exceed those values then go spit out a report that goes to the physician and NRC.

Is that not correct, so it's like a default mechanism once you exceed a certain trigger level. You go to the next trigger level that tells you to do that particular thing, so up here, these would be records but the report references only if you exceed that trigger level in d, which is unauthorized byproduct material, fivefold error, or organ dosage.

MR. TELFORD: Yes, if you have an event or a misadministration, you are going to have a record, so, Andy, you're right.

If a up here or b there, you're going to get e. You are going to get a record.

Now c says for certain events you can report internally. If you exceed these trigger levels the report goes to NRC.

Now when you look at the exact language on page 1448, d is rather long, a lot of words there but that is the basic tree you are talking about.

MR. KEARLY: You define a report or a record in two places but they are really the same thing, almost totally, okay?

MR. TELFORD: Where's that?

MR. KEARLY: Half-way through d you say the written report must include, and then there's a paragraph of stuff and e(3) says virtually the same thing.

MR. TELFORD: Ah, but they are going to different places, aren't they?

MR. KEARLY: That's not the point.

MR. TELFORD: Okay.

MR. KEARLY: You're requiring -- the thing in 3 is the record you are supposed to keep no matter what and almost all of it is contained in part d as well, so why don't you just say after a and b that the following records will be kept of these occurrences? Spell that out and then get into whether or not it requires a report someplace, internally or outside.

The record has within it the fact that you have

done an investigation also. I don't even think you have to -- I mean if one item of the record says a description of why it happened, then that to my mind is an investigation and how you can prevent it.

You don't even have to make an extra statement about an investigation and reports of investigations as though they were something different from the records that you are keeping anyway.

MR. TELFORD: Okay.

MR. KEARLY: The way we read it, it sounds like there are about five different things here that we have to go through but really you want one record and if d's trigger criteria are satisfied then we also want a report of that record sent to us.

MR. TELFORD: Okay.

MR. KEARLY: To my mind that would simplify this altogether, so a and b keep this record, forget c, d trigger level -- send us a report, and then you don't need anything else.

MR. TELFORD: Okay. Simplification.

Any other comments or suggested modifications on diagnostic reports and records before we go to therapy?

[No response.]

MR. TELFORD: Okay.

[Slide.]

MR. TELFORD: I can't put up all of the 35.34 at one time, because I have it on three view-graphs. So, let's step through the (a) and the (b) parts for therapy.

The same theme here is we're looking for things which are important to be reported to the NRC, and for example, dosage which are substantially different from what was prescribed.

Very similarly, we have Part (a), which are events. So, let's look at those.

In (1), we have the therapeutic use without a prescription or the prior review of the patient's case. And in (2), we have a therapeutic use without recording what was administered.

MR. BUKOVITZ: Pardon me.

MR. TELFORD: Yes.

MR. BUKOVITZ: There are occasions whereby, for the first treatment, the dosimetrist or tech may calculate the treatment time, they go right into treatment time, but will not enter the dose until the physicist or another person has checked it and actually recorded the correct dose for that particular treatment time.

MR. TELFORD: Is this (1)?

MR. BUKOVITZ: No, (b)(2).

It may be requested that 180 rads per day be delivered. The tech or a dosimetrist may calculate the

treatment time to deliver 180 rads, but they will write in the patient's name, the fields, the amount of time used, but not enter the dose for that day.

MR. TELFORD: Just the time.

MR. BUKOVITZ: They will just enter the time. And the reason they will not enter the dose is that the dose may not be correct, and they're waiting for a second check where the correct dose will then be entered.

So, instead of writing in 180 and then having that scratched out and 185 entered, they'll just leave it out.

MR. TELFORD: So, this is the very first fraction.

MR. BUKOVITZ: It may be the first two.

MR. TELFORD: The first two fractions.

MR. BUKOVITZ: Yes, maybe even three. It all depends, because if you have -- it will be less than a week, but what will happen is you may have site which does not have a physicist on location every day.

MR. TELFORD: Okay. What is your suggested modification for this, then?

MR. BUKOVITZ: Well, none right yet. I just wanted to bring that to your attention.

MR. STRUBLER: I'll give you my suggested modification.

MR. TELFORD: Okay.

MR. STRUBLER: That is I am a little bit disturbed

by all of these events and the inclusion of events for therapy, because there's many situations, as Andy and others have pointed out, that are complex or that would technically be "an event" and that, in general, when these things occur, the physician or the chairman are always made aware of it, unless it's trivial, and they occur with some frequency but are not considered to be disturbing or unusual, such that I would just keep the misadministrations and not get into these events, because when we get down to number 3, plus or minus 20 percent error in a fractional dose, what this is saying is that we have to develop a record or report, a notification process; again, the same things we talked about before apply particularly to the license management.

I would basically, I think, strike most of those items, events, because it's a part of the ongoing quality-assurance process, where if something irregular occurs that it's brought to the notification of the radiation oncologist, for example, and also, plus or minus 20 percent or greater than 20 percent error as an event is not uncommon, such that it's easy to correct, and it is corrected and without any consequences.

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

You're saying for these events listed here, we should delete all of (a), those four items.

MR. STRUBLER: In therapy events, some of the restrictive definitions here, I think, are not uncommon, such that you'd be into writing records, unless you define a record very broadly as saying yes, it's been noted and documented in patient chart that it wasn't 220 rads but 180, or vice versa, something like that, that goes over the 20 percent, or whatever it may have been. Without a prescription, as we've noted before, there may be some kind of an oral prescription given, or many, many scenarios in which these may be termed "events" under these new criteria.

MR. TELFORD: Okay. You said particularly for (a)(3) that this would not be something worthy of reporting to the licensee internally.

MR. STRUBLER: Yes. And again, let's use reporting to the responsible physician or the chairman of the department.

MR. TELFORD: Or the chairman of the department. Let's say it that way.

MR. STRUBLER: Yes.

MR. TELFORD: Then this is nothing to bother that person about.

MR. STRUBLER: I'm saying that usually they are notified. The responsible physician to that patient is notified that this error has been made, a recording error, some very simple thing, and it's corrected, and then you

move on, or you make some correction for the next day to keep the recordkeeping clean.

MR. TELFORD: You're here in (a)(2)?

MR. STRUBLER: In all of those.

MR. TELFORD: They didn't write the record down that day.

MR. STRUBLER: I mean there could be something similar to what Andy is saying.

MR. TELFORD: They wrote it down the next day.

MR. STRUBLER: Yes.

MR. TELFORD: But let's say you're 20 percent different for that fraction.

MR. STRUBLER: Yes.

MR. TELFORD: Then did I understand you correctly that we shouldn't call that an event, because that occurrence is not worth alerting the department chairman about?

MR. STRUBLER: Yes.

MR. TELFORD: Okay. How about (a)(1), a therapeutic use without a prescription?

CAPTAIN HELLMAN: Actually, you could say without both a prescription and a prior review.

MR. TELFORD: Yes. What do you think of that?

MR. STRUBLER: The same thing. There are many exceptions, and they're not uncommon, but they're not

necessarily common either, in the sense that a deviation from standard practice may occur. There may be a verbal order of some kind. There may be change. The physician's at another hospital. And you're doing a weekend emergent case.

MR. KEARLY: I think at the heart of this is that therapy is a process as opposed to a single occasion. We don't treat people, except in exceptional cases, once. Somebody is going to be there for 2, 3, 4, 5, 6, 7 weeks. And so, some parts of the procedure may not be completed at the moment that you're asking for this sort of thing to be finalized.

MR. STRUBLER: And I can also interject, reading this again, (a)(1), the last section: "and a prior review of the patient's case by the authorized user." In radiation therapy, that just does not happen.

MR. TELFORD: Okay.

MR. STRUBLER: Period. The physician must review the patient's case to make a determination of acceptance for therapy and suitability for medical application --

MR. TELFORD: So we would almost never have an (a)(1)?

MR. STRUBLER: You could have an (a)(1) without a written prescription, because it's been given orally, or he has changed, he or she has changed their minds and calls the

technologist and says I'm decreasing Mrs. Jones's dose from 400 to 300. And there's not another physician to initial.

MR. KEARLY: Right. And it may get initialled a day later, but, technically speaking, a use has occurred before that, while in the more general term, the use, referring to therapy for the patient, hasn't totally occurred.

MR. TELFORD: Okay. So we're saying that --

MR. KEARLY: You just have to acknowledge that therapy takes place over a long period of time --

MR. TELFORD: Right.

MR. KEARLY: -- with changes taking place during that time and the completion of it. I mean, you don't have everything done all at once sometimes.

MR. TELFORD: It's not like radiopharmaceutical therapy.

MR. KEARLY: It is significantly different.

MR. TELFORD: Patients come back again and again.

MR. KEARLY: That's right.

MR. TELFORD: And Ken's point was that these are not important enough to alert the Department Chairman about, in general.

Yes, Joe.

CAPTAIN HELLMAN: I have a differing opinion on these.

To me they are acceptable and reasonable. If I have a 20 percent use, 20 percent error, I sure want to know about it. I think it's something that would certainly alarm me.

MR. TELFORD: As an RSO or department chairman?

CAPTAIN HELLMAN: As a physicist I'm concerned, and I think my chairman would certainly be upset with a 20 percent use. That's our own internal problem. I hear Ken's comments.

I'm not concerned with what I see up here, other than number 2. And I'm worried about the case where my tech. forgets to write it in that day, and I catch it on chart rounds. And I refer to my chart review and I find that oh, he forgot to write in Tuesday, you know. And I do not want to have to call that an event and trigger it, when I catch it later that week.

MR. TELFORD: Okay.

MR. KEARLY: I agree with Joe.

I think the big problem here is what you are asking us to do with this. Anybody who sees a problem, if the dose was different by 20 percent or more, you are certainly going to do something about it. You are going to tell the physician who is responsible for that patient, or you may have a policy at your facility as to how to handle such things.

It may be possible for the physicist and dosimetrist to make changes that would bring it back into the intended treatment within a certain period of time. You make agreements like that beforehand. In each case, maybe you want to tell the physician, maybe you don't. You have trigger levels that you talk about for certain types of things.

20 percent may not be a big deal. But the biggest problem with 20 percent is, your machine breaks down in the middle of treatment. Now, is that something that is an event that requires a record and a report? You are getting kind absurd, then.

MR. TELFORD: It is, because that would be 20 percent less, because of a machine breakdown.

MR. KEARLY: That is correct. It is, unless we put an exemption in.

MR. TELFORD: Oh, do you mean this to be a positive, do you mean that to be greater than plus 20 percent only; is that what you mean?

MR. KEARLY: No, no. No, no. We have to look at the exact words on 1448.

MR. STRUBLER: I think it's both ways.

MR. TELFORD: This is Item 3, (a)(3). It is administered fractional dose differing from the prescribed fractional dose by more than 20 percent of the prescribed

fractional dose. So that can go either way.

But if you want to suggest that we put in an exer tion for this item, when the machine breaks down, and you happen to give a less-than dose, less than what was prescribed because of the machine failure, then you don't have to do what it says in Part (c) or the Radiation Safety Officer or designee to -- and I threw in the "as designee" because that's what we talked about in diagnostics, right?

So to take appropriate action here is to investigate and report back to the Department Chairman.

CAPTAIN HELLMAN: Are you modifying (a), by the way, to be Department Chairman as opposed to licensee management?

Because again, I don't mind keeping track of these events, but I do not see that these warrant necessarily having to go up to my Radiation Safety Committee. I think most of these are internal departmental things, and not something that needs to go to the licensee.

MR. TELFORD: That's what we discussed for diagnostics, was to say that the reports on the events could well be better served if they went to the Department Chairman rather than to licensee management.

CAPTAIN HELLMAN: 35.33 doesn't state to the management, whereas this one does.

MR. TELFORD: Okay.

MR. KEARLY: For both sections, I would like to see (a) here, and I guess it was (a) and (b) in the other one, to just be definitions. Just get out any reference to records or who they are sent to and just put that in the lower parts. Then you define the record, then you define who things are sent to.

MR. TELFORD: Oh, you are talking about the order in which we presented you this stuff. Okay.

MR. KEARLY: Yes. It's too confusing.

MR. TELFORD: Okay.

MR. KEARLY: Because you have multiple orders in different parts of the regs, otherwise.

MR. TELFORD: Yes. I would assume that if we changed the order in which we talk in 35.33 we would give you a very similar order in 35.32.

MR. KEARLY: Right.

MR. TELFORD: Order of presenting the information.

MR. KEARLY: Right. And in the, at the beginning of it you just take out any reference to either records or where they go. Records and reports or where they go.

So (a) and (b) in 33, for instance, would just be definition of diagnostic event and diagnostic misadministrations.

MR. TELFORD: Okay. You want us to say in 35.34 that a therapy event is one of the following.

MR. KEARLY: Yes. Just leave it at that. Don't confuse it with the requirements that you might have later.

Then, I also agree with Ken. I would rather not have events that we would have to keep records of.

If somebody changed a monitor unit and you catch it later -- no, that's not wouldn't be -- that's not quite under this.

MR. TELFORD: Let's say here they didn't make a record that day.

MR. KEARLY: If they didn't make a record that day, you'd tell them, and the record is put in the next day. Nobody makes a record of such an occurrence in a report.

MR. STRUBLER: I'm going to reiterate one more time. I feel rather more strongly, the more I'm thinking and listening, than perhaps the others do, regarding the dismissal of this, simply because there is occasion upon occasion when these things will occur.

And if we are going got insist that a record, meaning something written, describing what happened, not necessarily being a report, but describing what happened to whom and where and how, creates quite a burden.

It is important, and I agree with Joe saying that yes, I would want to know. And virtually everything in our department in any of these sequences, I'm the one that knows about it or the first to know about it.

And the physician then would also be consulted, except for trivial things. If it is a matter of leaving out a dose, you put it in and you carry on.

And I'm just not sure what the impetus of these requirements, and this new definition of an event, where the necessity comes in. Because the ongoing process of this as described over a long term is such that these things occur frequently, they are very minimal and minor, the internal structure and organization is such that the appropriate people are always notified.

It does not require a record to be generated on that basis. You handle it on an individual basis. And if you see trends occurring, you take steps to prevent that.

But when you are doing however many tens of thousands of treatments, ten thousand treatments a year, you are going to have a lot of cases where the technologist fills everything in except the dose, or there is a monitor unit transposition and change, an incorrect 20 percent error in one day, wedges left out. All of these things are not uncommon.

And to precipitate a report creates quite a burden, I believe. That emphases my point.

MR. KEARLY: I agree completely, Ken, but there's a real distinction. In nuclear medicine you only do it once and you have done something to the patient. In therapy you

don't know that you have done something to the patient until the end of treatment, which is your misadministration rulings and that is appropriate to ask for, but in the middle of treatment you are engaged in the treating process and you make adjustments and corrections for things that aren't what you want to see and it has no clinical consequence to the patient whatsoever, so I don't think it is a relevant thing to require reporting for.

It is certainly relevant to include in the quality assurance program, that you check for such things.

MR. TELFORD: Okay. Any other comments on (a), 35.34(a)? Tom?

MR. DORING: No.

MR. TELFORD: Okay. Would anybody object to taking about a ten minute break right here? We're about half-way through our afternoon for time availab[illegible], I believe.

MR. STRUBLER: I wouldn't mind just plowing through.

MR. TELFORD: You want to keep plowing?

MR. STRUBLER: Yes.

MR. TELFORD: All right. Let's keep plowing then. Let's go to --

[Slide.]

MR. TELFORD: These are 35.34(b). Let me say

again, what you see on the viewgraph, these words are just rather cryptic and for the exact words you need to refer to the handout which is page 1448.

MR. STRUBLER: Can you remind us? Is this a significant change? I understand it is not.

MR. TELFORD: Let me point out the changes to you. now in (b) we are talking about misadministrations and if you have a misadministration it is one of the following.

If one of the following occurs, you have a misadministration. It will result in a record. It will result in a report to the NRC.

MR. STRUBLER: But is it a change from what's existing right now, or where are the changes?

MR. TELFORD: This is the same.

Number one is the same where you have the patient or wrong source, wrong route.

Basically this is a difference in what was prescribed.

The ten percent error in total dose, this is --

MR. BUKOVITZ: Is that millicuries administered?

MR. TELFORD: This is radiopharmaceutical.

CAPTAIN HELLMAN: You want activity, I think, not dosage.

MR. TELFORD: Okay, this is radiopharmaceutical therapy and a 10 percent difference is the same as current.

Teletherapy, the 10 percent in total is the same, (ii) the factor of two difference for a fractional dose, that is an additional definition. It is not currently in 35.2.

MR. KEARLY: Is it a fraction?

MR. TELFORD: Yes. This is a single fraction, a daily fraction. You are a factor of two off. In (iii) this is something you haven't seen before. It's not in 35.2. This is you keep a running total after each daily fraction and you are to stay within 10 percent of the prescribed total.

The brachytherapy leaking, lost or unrecoverable source, I believe that is an addition, okay? I'll get a confirmation it is.

The brachytherapy administration is 20 percent different. What is different about that is the 20 percent. Currently it is 10 percent. That is a recognition that brachytherapy is a bit of art as well as science.

MR. BUKOVITZ: I have a question on b(3)(ii).

MR. TELFORD: Okay.

MR. BUKOVITZ: Okay, the definition of error, if for any reason the technologist must turn off the treatment unit early and the patient was only delivered 5 rads out of 180, is that a -- I would take it that is not an error.

MR. TELFORD: Let's look at the exact words, page

1448, third column. We have "For any treatment fraction the administered fractional dose being greater than twice or less than one-half of the prescribed fractional dose."

Now your case, I think yes it is, unless we build in an exception that says due to machine failure or due to the fact that the patient couldn't stay on the treatment table.

Yes?

MR. BUKOVITZ: There are a lot of situations where you just stop treatment. You have to.

MR. KEARLY: What if the machine breaks down and the patient doesn't get treated?

Is that a misadministration?

MR. STRUBLER: According to this, it is, and I think you are getting the idea that we don't like that.

We also --

MR. KEARLY: Generally speaking, things that happen on one day are not what you want to regulate.

MR. TELFORD: So you would delete this one?

MR. KEARLY: Yes.

MR. BUKOVITZ: Yes.

CAPTAIN HELLMAN: I understand your intent, why you mean it, i.e., if someone does screw up and give twice the daily fractional dose.

MR. TELFORD: How about the case where it is not

due to machine failure and it is not due to the patient can't stay on the table but rather it's an error that the technologist made?

MR. KEARLY: It certainly deserves investigation.

MR. STRUBLER: Everybody knows about it. It's going to be investigated. It does deserve investigation.

MR. TELFORD: Does it deserve a report to the NRC?

MR. STRUBLER: No, no, I don't think so.

MR. TELFORD: Are you saying that that is something you might call an event and have to report it to your department chairman?

Are we up to a level --

MR. KEARLY: Well, we voted to do something else with events.

MR. TELFORD: That's true, but that was principally because you didn't like the 20 percent, perhaps, but what if this is now a factor of two? Is that something -- in other words if I could give you your choice, would you rather have a factor of two reported to the NRC or reported to the department chairman?

MR. STRUBLER: I'll tell you again the concern I have is generating lots of records and reports for things that are not uncommon occurrence, not because of neglect or sloppy work but these things happen when you are dealing in therapeutic areas.

MR. BUKOVITZ: Because just to elaborate a little bit, there are a lot of the cases whereby you have to stop treatment early and what is normally documented in the chart then is the patient may have gotten 20 rads instead of 200. The patient was sick. The patient had whatever, and that is written right into the treatment record, the treatment chart at that time and then that's all that is ever done with it.

MR. TELFORD: What if this were only an overdose, not an underdose? This were -- was a factor of two greater than what was prescribed?

MR. KEARLY: Does that have any significance whatsoever?

MR. STRUBLER: It could have, but I think that my response would be the same thing.

MR. TELFORD: Okay.

MR. STRUBLER: If it's really a gross error --

MR. TELFORD: Okay.

MR. STRUBLER: -- and the technologist really messes up, then we all know about it, and a report -- verbal report is made. And if it's just a matter of something happened, and there's nothing you can do to control it and you don't foresee it happening again, then you make your appropriate response to the technologist to try and say, why did this happen and don't let it happen again.

You know, if it was just a matter that -- had a

bad day, or if it was symptomatic of something, then you take some action and you report and you record that.

MR. TELFORD: But, if you had a fraction of -- a daily fraction of 400 rads and that was greater than a factor two -- it was 850, what if that 850 resulted in a dose to an organ not in the treatment volume?

CAPTAIN HELLMAN: If, in the opinion of the physician, it results in adverse -- you know -- in an adverse effect, then I can see your reporting it to the NRC. I mean, I'd be certainly concerned about it if somebody gets twice what they're supposed to get. But again, if it doesn't affect the total output, you know, if the total dose is not exceeded, nor if it is results in any adverse effect to the patient we wouldn't necessarily be concerned.

MR. TELFORD: Okay.

MR. STRUBLER: These are serious episodes and we all take them very seriously and we would all take action; but we all have been involved in these episodes and it's just a matter, again, of trying to avoid even the minor ones, but his is a much more serious situation, but doesn't always require a report being generated. There's documentation of the event and internal discussion regarding it, but --

MR. TELFORD: You're sort of downplaying this, I take it, because this is a daily fraction. What if it's in

the total dose?

MR. KEARLY: There's no problem there. 10 percent is -- no problem here.

MR. STRUBLER: In keeping the existing criteria, I don't have a problem with it. It's the added features that I might quarrel with.

MR. TELFORD: But if we don't do anything with fractional doses, then we don t need the summation.

MR. BUKOVITZ: Especially not that one, because I would have to read it six times just to see what it said.

MR. TELFORD: Okay? How about brachytherapy?

MR. KEARLY: Before we leave those items, well -- there's one very important issue, as well, in this. What do you mean by prescription? For instance, one physician may feel that a proper -- an appropriate prescription for a particular site being treated is perhaps 5,000 rads; while another physician might choose to give 6,000 rads for a completely acceptable treatment.

Now, suppose that, through an error, 5,600 was given rather than 5,000 -- it's greater than 10 percent; but the physician looks at it and says, well that was an option I had right from the beginning, there's absolutely no clinical consequence associated with that. Can he change his prescription at that point?

MR. TELFORD: No.

MR. KEARLY: He could before.

MR. STRUBLER: I can tell you now, it's going to happen.

MR. TELFORD: You don't mean that. I mean, come on. You've got an authorized use, he says, give the patient 5,000 rads and 20 fractions. You get to the end of the 20 fractions and you find out you gave 5,600 rads.

MR. KEARLY: Oh, we'll certainly consider that as an important thing to have been done wrong. But is it a misadministration, in terms of having a clinical effect on the patient? Why do you want to know about misadministrations? Why are we sending you reports of misadministrations, if it's not for clinical effect?

MR. TELFORD: Okay. That's two questions in one. But, is a misadministration? Yes. Does it have a clinical effect on the patient? That's what I'm asking recommendations on. I mean, we started out with -- I'm asking my theme -- we only want things reported to the NRC that are important, that are substantially different. So, the volunteers should be the ones --

MR. KEARLY: We ought to allow leeway for the physician to make a clinical judgment.

MR. STRUBLER: Yes. Frank's scenario is not an unusual one. They may say treatment plan that we talked about yesterday, is I intend to do this and this is the

range. It could, in fact, be as much as 5-6,000, although that may be unusual, but it could well be that. And physician A would be completely different from physician B.

And it may be that he intends to take to 6,000, if the patient can tolerate, and finds out that the patient has a rocky road and has other medical problems intervening that are unanticipated. So he decides to stop at 5, but because of some error occurring, they go to 56 -- and from our point of view, we're saying well, that would not be a misadministration. And the physician may say all right -- and cross out the 5,000 and put 56.

MR. TELFORD: It seems to me that the authorized use could have first prescribed 6,000. And if the patient could tolerate only 5,000, they would -- you would amend the prescription at that point and say --

MR. STRUBLER: No. You don't start high and go low. You start low and go up higher. So you put the 5,000 question mark --

MR. TELFORD: Okay. Then when you go to 5,000, the authorized use could say, I'm going to amend the prescription and add an extra thousand and keep going an extra 5 treatments at 200 rads per fraction.

But, you see what I mean? How can you have it both ways. Because if you're going to say, the prescription says 5,000 and we're going to have something like -- you're

going to have a misadministration at 10 percent, then I don't see how you can have it both ways. You've got to declare that that's it. If you don't like 10 percent, tell me a better number -- tell me why.

MR. STRUBLER: Well, we're saying there are gray areas and that's why, when the art of medicine come into there, there's many, many gray areas.

MR. TELFORD: Okay.

MR. STRUBLER: And we've been all in the field long enough to know that there many variations, even among physicians who have 20 years' experience. And the consensus best management is something that is sometimes a very rocky road agreement.

MR. TELFORD: Okay.

MR. STRUBLER: And these are not exceptional circumstances where there's a lot of gray and uncertainty involved, and there may be an error thrown in that as well, which precipitates this unusual case. And we're just saying there has to be perhaps some mechanism to -- to resolve --

MR. TELFORD: Okay. Yes. How can we fix that? What's the mechanism? Could we -- could we say, all right, it's 10 percent error in total. The administered dose was 10 percent -- yes?

MR. KEARLY: In the final prescription?

MR. TELFORD: Well let's not complicate too much.

Let's just say there is a prescription -- let's make it a fairly simple example. We've got a prescription, it says 5,000. We truly intended to give the patient 5,000, in increments of 200 rad per day. But, make it simple -- the technologists didn't stop in time, they gave the -- they gave the patient three extra treatments.

Okay. So what you're saying is, I think, that the extra three treatments are really possibly no big deal?

MR. KEARLY: Right.

MR. TELFORD: All right. So how can we define "no big deal?"

MR. KEARLY: By allowing the clinician the ability to do his job, which is to say, he judges, in his judgment, the clinical impact is not negative.

CAPTAIN HELLMAN: And thus, he's willing to increase the prescription to cover it.

MR. KEARLY: He's willing to put his signature on the line for that prescription for that patient.

MR. TELFORD: Okay. All right, so we would say, reporting requirement something like: It exceeds 10 percent in total -- in total --

MR. KEARLY: The total final prescribed dose.

MR. TELFORD: All right. And you're --

MR. KEARLY: It will do two things. It will make it sensible and it will avoid asking the question, did this

guy really write this two weeks before he dated it?

MR. TELFORD: So you would like the authorized use -- if -- if this is not going to be reported, you would like the authorized use to certify two things: One is that the extra dose had no consequence, no clinical impact and they would sign a revised prescription that the, whatever the extra was, 600 rads, in this case, was just as good as the 5 -- as --

MR. KEARLY: If the clinician is willing to put his reputation on the line for what was done to the patient, then that should be okay with you. That's his judgment.

MR. STRUBLER: I can give you one other quick example, without belaboring this. Is that with breast therapy, where we're moving away to more conservative surgery, followed by radiation; and this country's been much slower than the European countries, but nevertheless, with excisional biopsy, followed by radiation.

In the past, 10 years ago, surgery was much more radical and the radiotherapy was much more radical. Breast therapy was often given pushing 7,000 frequently, with very aggressive therapists. Now, we've backed off of that considerably, so we only give 5,000 plus the boost. And so there, again, the clinical impact is such that even if an error were made, it would not be a significant one.

Even though we don't take these lightly, by any

means, that there is a greater than 10 percent error, but it probably would have not clinical consequence.

MR. TELFORD: Let me ask you kind of a hard question. Do you think we would get any misadministrations reported if we did that -- put in these extras? I mean, wouldn't almost all authorized users be able then to say --

MR. STRUBLER: We're talking about exceptions here, and the rule is for -- in general, if you prescribe 5,000 and gave 5, that would be administration --

MR. TELFORD: Right, current.

MR. STRUBLER: -- with these exceptions we're bringing about. And that's why we're saying the exceptions may only be 10 percent, but 10 percent is -- is a fairly sizable fraction that may occur -- or 5 percent. And they will occur. And that's not the norm, it's just that that may occur and we can get some avenue for it.

MR. TELFORD: Could there be -- say it's above 10 percent, but it's below 25 percent, or below 20 percent, or some other number. Then if we allowed the authorized user to make this certification, and so attest by their signature within that range, perhaps we could that. But wouldn't there be some level, you know, above which you would just say, gee guys you blew it?

What if you were -- what if that were 50 percent?

MR. BUKOVITZ: You'll have to talk to the NCR on

this one, because you're talking clinical judgment.

MR. KEARLY: You're talking to the wrong people to ask that question fully.

But, for instance, the 2,000 rad dose for palliation of bone pain that results -- you do a treatment and suppose that the resulting treatment was 4,000 instead of 2,000. It's probably all right. You'd get a lot more relief quicker probably and --

MR. TELFORD: You're doubling the dose. Okay, but that's for palliative cases.

MR. KEARLY: For that particular one, yes.

MR. TELFORD: What if it's a treatment, and you're trying to get rid of a tumor?

MR. KEARLY: You can't that that fine in your distinctions, I don't think. You can just start asking questions about whether they're palliative or curative in your regulations, you're way out of bounds.

MR. TELFORD: All right.

MR. KLINE: John. I've got a question and a comment for the physicist here. In your experience in the clinic or the hospitals you've worked at, have you seen the prescribed dose expressed in a range?

MR. BUKOVITZ: Yes.

MR. KLINE: Okay. To say what -- 3 to 4,000 total? Five thousand, 6000?

MR. BUKOVITZ: I've seen the whole gamut, 5,000 plus or minus.

MR. KLINE: We're kind of talking about a margin here or a range so to speak. Do you have any comments on that from your experiences dealing with -- with departments which specify a range in the prescription?

MR. BUKOVITZ: One thing I've tried to do successfully in most cases, is to have them specify a concrete dose and number of fractions. Then if they want to increase it, you know, just say increase in dose to such and such an amount, or if they want to decrease it, have them write it.

But there are many of the older physicians who really prefer to write a large range, and the range -- they specify like either say 4,500 to 5,500; or maybe specify it as 5,000 then they'll put the numbers plus -- or the letters -- symbols plus and minus after it with no numbers.

MR. KLINE: Or a question mark?

MR. KEARLY: Or a question mark?

MR. STRUBLER: We don't approve of that.

MR. KLINE: No, no. Well, the question, if we're looking at what, I guess, the practice of medicine is, what is a common practice, the question is is this a common practice with your facilities, or is this common practice with a majority of facilities?

MR. BUKOVITZ: Well, there was a larger facility that I was associated with previously that had six radiotherapists, and prescriptions were written four different ways. I had gotten together with the chairman of the department. We tried to get things on a uniform basis. It was almost like taking away their pension plans.

MR. STRUBLER: I've had similar experiences in the university environment, particularly in a community hospital, and we can be a little bit more dogmatic about things and not allow that to happen, even though some of them like to go their own ways. But in this regard, we would never permit that. But in terms of th[illegible]reatment plan, there was a range, just I've indicated, of many medical factors that enter into the circumstance, not only the tumor site location and histology but the age of the patient and how well they're tolerating it and so forth.

So, while the intent is -- to control the disease, they know they'd like to give 6,000 or 6,600, but they don't think they can get that in. But if all goes well, they'll push on and take some risks involved in order to control the disease to optimize cure.

So, we don't -- at our institution, now, we always specify a number, and then at that dose, you modify or reassess or whatever it may be. I think that's probably a common practice, but it's not uncon[illegible]on what Andy was just

saying either.

MR. TELFORD: Okay. You made some suggestions for teletherapy here, and we will talk to ASTRO. How about brachytherapy, either a leaking source or the 20 percent error -- 20 percent difference from prescribed dose?

MR. STRUBLER: I guess I would reiterate the same comment. Twenty percent is still a very fine line, even though you increase from 10 to 20.

As I mentioned before, a 1-millimeter change for a linear source of 2 centimeters cesium sealed source, 1 millimeter is 10 percent.

MR. TELFORD: Okay.

MR. STRUBLER: And so, 20 percent is not far behind that.

MR. TELFORD: Okay.

MR. STRUBLER: And these are really very clinical judgments on the part of the physicist and physician, primarily, so that that's still a very narrow range when you look at target line or treatment line.

MR. TELFORD: Okay. What should it be then?

CAPTAIN HELLMAN: Hard to answer.

MR. KEARLY: There isn't always a prescribed dose for brachytherapy. Sometimes it's a time.

MR. TELFORD: Same thing. That translates. We're talking about the final prescription here. You already had

a pre-plan, you've got an implant, and now you're going to watch the clock.

So, if you -- if it's a high dose rate after loader, then you may have input the wrong distance into your planning. If you didn't catch that, then you might exceed that very quickly. But really, I'm here to hear modifications.

MR. STRUBLER: This is difficult territory that we're getting into. That's all I'm trying to show.

MR. TELFORD: All right.

MR. STRUBLER: And I don't know any quick answers.

MR. TELFORD: I hope you can see that we're showing a lot of acknowledgement in the beginning there, because currently, in 35.2, that's 10 percent, and based on our earlier discussions, we published 20 percent in the proposed rule. So, could be we haven't gone far enough.

MR. BUKOVITZ: Really, the physicians are the ones who are really going to have to deal with this one. Okay?

CAPTAIN HELLMAN: I think 4 is acceptable.

MR. TELFORD: Okay, 4 is okay.

Now, is all of it okay, the leaking and the lost or the un-recoverable? What if this is a sealed source that's un-recoverable in the patient? What if the physician just decides not recover it?

MR. STRUBLER: I'll give you an example of that,

and that would be an oral cavity with permanent seeds, and you insert 10, knowing it's for 10, and 1 becomes dislodged, and the patient swallows it, and at the time of radiography, you see that it's in his or her stomach. I've seen that happen before, and on that basis, there is nothing you can do nor should you do, and it's going to pass through, and you don't ask for it to be collected.

MR. TELFORD: Now, is that a misadministration? You wouldn't call that un-recoverable, would you? I mean you would just wait 36 hours, and you would have it.

MR. STRUBLER: If you want to get it. That would not be a circumstance that I would say is a misadministration that needs to be reported.

MR. TELFORD: Okay.

MR. KEARLY: What about the O-rings that fell off? Would they search within those, or is it just the O-ring?

MR. STRUBLER: The source is in there.

MR. BUKOVITZ: Those are events. Those are definitely events I would report.

MR. KEARLY: But it's not a misadministration.

MR. BUKOVITZ: No, but it's a reportable event. It doesn't meet this definition.

MR. KEARLY: What's it reportable under?

MR. BUKOVITZ: I don't know.

MR. TELFORD: Okay. We've gone through all of the

items in (b). You don't like (3) very much, and you think there is some limit here in total dose that we ought to have, that we should talk to ASTRO, and the same thing in (5), talk to ASTRO about the 20 percent.

Item (1) for the wrong patient, wrong source, that's a current -- currently reportable, and the radiopharmaceutical therapy of 10 percent difference in what's prescribed, that's current.

So, let's move to the part (c), which is the same as before. We're calling for if you have, let's say, a misadministration, that would be one of the (b) items; then you have an investigation and a report internally, as well as to the NRC.

MR. KEARLY: This is not a radiation safety issue. I know you guys are radiation safety people, but these are medical and sort of medical physics issues.

MR. TELFORD: Well, isn't this a mishandling of byproduct material?

MR. KEARLY: The RSO may not know anything, really, about therapy, though.

MR. TELFORD: Okay. RSO or designee. Okay? Do you like that?

All right -- (d) would say the report goes to the NRC, I think. This (d) is you call the regional office, contact them by telephone; (e) is the written report within

15 days. I believe that's a current requirement.

MR. TSE: Yes.

MR. TELFORD: Okay. Then (f) -- part (f) here are the records that you would keep. So, you keep a record of each prescription, a record of what was administered for 3 years, and if you have a misadministration, you keep the record for 10 years. That's very similar to 35.33.

CAPTAIN HELLMAN: What about a patient who dies? Sometimes we transfer the entire files, based on my system.

MR. TELFORD: Dies within the 10-year period?

CAPTAIN HELLMAN: Yes. Well, actually, number (1) I'm talking about, even the 3 year.

MR. TELFORD: Dies within 3 years.

CAPTAIN HELLMAN: Sometimes those files go with the patient, and often -- file system in St. Louis.

MR. TELFORD Okay. Well, if we really wanted to see them, could we get copies?

CAPTAIN HELLMAN: Hopefully.

MR. TELFORD: There was a story about, you know, a record storage area there in St. Louis burned, and bunch of Air Force records were destroyed, including my own. But ordinarily, we could get the copies. So, that's probably not a problem. They have to be available for inspection, but they have to be in an auditable form. So, if we really needed those for that patient for a case, we could certainly

get them.

Any modifications that you would make to these parts, (c) through (f)?

MR. KEARLY: Well, if you include events into this recordkeeping, we're going to -- it's absurd. A report of an event that includes the patient's Social Security number, any possible effect on the patient, improvements needed to prevent recurrence -- I hope we no longer have events after these workshops. And keep them for 10 years?

MR. TELFORD: Okay. You advise strongly against having events --

CAPTAIN HELLMAN: And even misadministrations.

MR. KEARLY: You're not talking about anything that's going to lead to clinical -- any clinical improvements, in my view.

MR. TELFORD: Well, we're after adequate protection.

MR. KEARLY: That translates to clinical significance.

MR. TELFORD: Clinical significance?

MR. KEARLY: The recordkeeping process here is of no benefit whatsoever, since through quality assurance you do these things.

MR. TELFORD: Okay. We could make two assumptions here. One is we don't have any events. Therefore, this is

no problem. They go away.

MR. KEARLY: You're not making that assumption. Oh, you mean in the regs.

MR. TELFORD: In the regs.

MR. KEARLY: Yes. In the regs, we could assume -- yes, I could.

MR. TELFORD: Okay. The other assumption is we have something here. Let's say that one of these are we put something back. We have something there that's an event.

Now, what would be your suggested modification to (f), assuming that something survives for an event?

CAPTAIN HELLMAN: The question is why 10 years?

MR. TELFORD: Why 10 years?

CAPTAIN HELLMAN: Yes.

MR. TELFORD: Well, if you have a 3-year inspection cycle, then let's say you find something that looks as if it ought to be fixed, and you say to the licensee, what are you going to do about this? It's either a very low-level violation or just below that, you know, not quite a violation. But you say to the licensee, what are you going to do about it? And they tell you. It sounds reasonable. So, you've got a record here today that's probably 3 years old, could be, because it could have occurred the first year, and you've come in the third year as an inspector. So, the record's 3 years old.

So you are going to come back three years from now and find out if they really did what they agreed to do. So now the record is six years old.

And let's say that gee, they look like they tried. And they almost got there. And this is not something that we have to, you know, really give a high level violation to, but it's something we want to track.

So you say to the guy, you almost made it. What are you going to do this time?

And they say, they tell you.

So you are going to come back three years later. And now the record is nine years old. And they made it, let's say. Or otherwise, my records go away. So that's why they're ten years old. I mean, that's why I need them for ten years.

CAPTAIN HELLMAN: If there's a problem that you haven't identified by year six, then I think it is not a very serious problem. Even for therapy, I think a shorter time period would be appropriate.

MR. TELFORD: Six years?

CAPTAIN HELLMAN: Six to seven years.

MR. TELFORD: Six or seven? Okay.

CAPTAIN HELLMAN: Five years, whatever. I mean, if you're on a three-year cycle, give it six years. Ten seems too long.

MR. TELFORD: All right. Tony?

MR. TSE: I think the Government has the standard record retaining period, and it is something like five and ten.

MR. CAMPER: Three, five, and ten.

MR. TSE: Right. So we're trying to make a determination to this standard period.

MR. KEARLY: Can I add one more thought to this?

MR. TELFORD: Sure.

MR. KEARLY: Especially in this event business, you are heaping onto us a lot of recordkeeping. In our QA process, we are already required to go through a lot of recordkeeping of things that go wrong in the QA that are caught by our QA program.

MR. TELFORD: Yes.

MR. KEARLY: This kind of stuff would be part of that. Now, you are requiring an additional record for no additional purpose. I mean, only for you to be able to look at it in a different format, in a different place, for different people to look at it, for no additional gain.

MR. TELFORD: Let's say in your review, what we call an audit, you discover one of these events. Okay. You are going to make a record of it, as part of the audit.

MR. KEARLY: Sometimes yes, sometimes no. I mean, that's up to us as to whether or not there is something

going on that is --

MR. TELFORD: Well, if this requirement survives, you would make a record. But you would only need a single record of that. Not multiple records of that.

I mean, if you --

MR. KEARLY: My records are a different format, if I'm reporting for QA committee purposes, and this is something that eventually might go up to the hospital's QA committee as part of a JCAHO process. Different format. They want to know different things.

MR. CAMPER: Are we asking you, thought, to document things that you are not currently having to document in your QA procedures?

MR. KEARLY: Well, we would never write down a Social Security number, for one thing.

MR. CAMPER: Can we just take your -- I mean, I envision this as a little bit more paperwork, not a vast amount. Because if you are already documenting in your QA process, you can really take that whole thing, throw a cover letter on there, and --

MR. KEARLY: Oh, no. For teletherapy administration with more than 20 percent in the fractional dose, that might show up as a check on a monthly review sheet of things that happened generally throughout the department.

It won't be spelled out as so and so patient with such and such action with such and such consequence. It won't even come close to that.

It will just be a tally of things that happened that you don't want to continue. There is no way that you would keep any more record than a checkmark for many of the things you are talking about here. And that is adequate for a QA program, and it is adequate for clinical efficacy.

So you are really asking for us to do a lot more work, because it is the kind of thing that does show up all the time. Problems. I mean, if something shows up, we do note it in different ways.

MR. TELFORD: So this is a good reason to get rid of events?

MR. KEARLY: I'll say.

MR. TELFORD: Okay. That's your bottom line. Okay.

Any other suggested modifications or additions or deletions to therapy reporting requirements or recordkeeping requirements?

[No response.]

MR. TELFORD: Okay.

Why don't we take about a ten-minute break, and then come back at about 3:00 or no later than five after, and we can have concluding remarks and concluding questions,

and then we are done.

Okay? Let's break.

[Brief recess.]

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

We've come to the point on the Agenda that is the final item today and for this workshop.

We have individual air time now for the volunteers or any other participants but I see the other participants have left so we're down to the volunteers.

You can each have approximately five minutes or whatever you like and you can give us your summary remarks or your final questions or comments.

Let's start here with Ken.

MR. STRUBLER: All right. I'd just like to comment that we appreciate the opportunity for the development of this program and for you to listen to our input and for us to discuss the items cited in the regulations and guidelines.

I think it has been very valuable for us as well, these last couple of days and last two-month period and I think it also serves perhaps as a benchmark for other programs that you or other aspects of the Government may propose and develop so that we can work closely with people who are going to be involved and coordinate the programs to optimize both what we are all after.

This is not an adversarial relationship that sometimes is construed that way, I think, in that we are all in this to achieve the highest quality of care to our patients across the country and I think it serves as again a benchmark perhaps for other programs that are going to be developed in the future and even in other areas, as we discussed over dinner, lunch yesterday for some of the other Government agencies that you may want to relay your observations and comments to some of your colleagues in other departments not associated with the radiologic sciences.

Again, I appreciate the opportunity to make comment on these proposals.

MR. GRAHAM: Well, just to reiterate what Kevin stated and also express appreciation that we were given the opportunity to come in and listen and to participate in these regulations, authoring these regulations.

Certainly that gives us a lot of insight I think in some of the trials and tribulations that other -- we are not all alone, I guess. Everyone has the same basic problems in trying to maintain and continue on with some of these programs.

MR. TELFORD: Kevin?

MR. NELSON: I would like to just thank you all again for coming and as a representative of the contractor I

would also like to thank you for submitting your proposals and your roadmaps and your questionnaires to us.

I think your participation in this is sort of a unique event in that I believe the NRC is really looking for your opinions and your suggestions to make the best rule possible.

Thank you again for your suggestions and your input.

MR. TELFORD: Josie?

MS. PICCONE: I think I'd just like to support what Ken said because -- and I'll speak for the teams, the rest of the teams not here, the QA team that we feel the same way. This is not an adversarial, not should it be, rulemaking. We are in this together. The goal is the same.

Also, we do wish to thank especially those volunteers which were visited and interfaced with the team members because that involved a good deal of additional time, not only in scheduling but in making people available for the site visits, and we do appreciate that time and effort.

Thank you.

MR. TELFORD: Tony?

MR. TSE: I would say the same as Josie, as a QA team member. I also would like to ask you if you have any subsequent faults or suggestions. The communication should

not stop at this meeting. You can always call me. My phone number and so on is in the Federal Register notice. And thanks for your help.

MR. TELFORD: Ed?

MR. KAPLAN: To reiterate what I said before, this has been a wonderful display of professionalism. It is a unique experiment. And I've been very happy to participate. And I am very happy to have worked with you.

Thank you.

MR. TELFORD: Frank?

MR. KEARLY: I also want to thank you for the opportunity to participate in this development. I will reserve total praise until we see the final effort.

I just want to say that I, over the past two or three years, we have been trying to develop our quality assurance program. And it is that kind of "back to the drawing board" effort that I hope we avoid through this process.

I hope that it is coordinated very well with what other agencies and professional groups have spent years in developing already.

And please, keep our recordkeeping to a minimum.

MR. TELFORD: Okay. Joe?

CAPTAIN HELLMAN: Well, like all the others, you know, I have enjoyed the interactions, and look forward to

some very positive rules coming out of this. And I think you for the opportunity to participate.

MR. TELFORD: Susan?

MS. MOORE: As with everyone else, I thank you for being here, and for your efforts in hearing us out.

And that's it.

MR. TELFORD: Tom?

MR. DORING: It's tough being the last one.

[Laughter.]

MR. DORING: I'm going to say it anyway. Thanks, thanks for allowing us to participate. This has been a very, very interesting experience, since the official meeting.

Just a personal note, and also one that we, at least in our institution believe. And that is, I think anything to do with a quality assurance program is going to prove to be beneficial, for the reason why we are all, or we all should be in this business, and that is to take care of our patients. And from that aspect, it is going to bear some fruit in the end. And thank you.

MR. TELFORD: Mike, do you want to say anything?

MR. WEBER: Nothing.

MR. TELFORD: Well, thank you all for coming. And I appreciate it. I will certainly keep your thoughts in mind, and carry through to the end.

Meeting adjourned.

[Whereupon, at 3:20 p.m., the meeting was adjourned.]

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