OFFICIAL TRANSCRIPT OF PROCEEDINGS

Agency: Nuclear Regulatory Commission
Medical Quality Assurance Program

Title: Roundtable Discussion with
Agreement States

Docket No.

LOCATION: Rockville, Maryland

DATE: Wednesday, March 14, 1990 PAGES: 1 - 190

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

UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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MEDICAL QUALITY ASSURANCE PROGRAM

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ROUNDTABLE DISCUSSION WITH AGREEMENT STATES

Nuclear Regulatory Commission
One White Flint North
11555 Rockville Pike
Conference Room 6-B-11
Rockville, Maryland

Wednesday, March 14, 1990

The above-entitled conference convened at 9:40 o'clock a.m., when were present:

PARTICIPANTS:

John Telford, Chairman, RES/NRC
Lloyd Bolling, GPA/NRC
Kathleen Black, AEOD/NRC
Anthony Tse, RES/NRC
Dorothy Michaels, OGC
Harry Tovmassian, RES/NRC
Kirk Whatley, State of Alabama
Terry Frazee, State of Washington

Rita Aldrich, State of New York

Roland Fletcher, State of Maryland

Janet P. Kofra, OCM/JC/NRC

Susan Bilhorn, OCM/KR/NRC

Marjorie Rothschild, OGC/NRC

Michael Weber, OCM/KC

PROCEEDINGS

[9:40 a.m.]

MR. BOLLING: I would like to welcome the state people from out of town, Kirk Whatley from Alabama, Terry Frazee, from Washington state, and Roland Fletcher, from the state of Maryland. We'll have Rita Aldrich coming down from New York as soon as she gets proper plane connections.

The purpose of this meeting is to have a frank and constructive discursion on medical matters, but most especially the recent proposed QA Rule. I think, correct me if I'm not wrong that -- not right -- that we will be prepared to discuss anything in the Part 35 area.

As John said we probably will be going out to a number of states or perhaps to locations to meet with groups of states to discuss their concerns or questions and this will be recorded and be part of the record so that we meet the requirements that the commissioners put on us for getting involvements of the states in this rule making process.

That's about all I have.

MR. TELFORD: Okay, well, let's let everybody in the room introduce themselves. My name is John Telford, I'm the Section Chief of the Rule Making Section in the Regulation Development Branch in the Office of Research.

MR. TSE: Anthony Tse from the Office of Research.

MR. WHATLEY: I'm Kirk Whatley, Radiological Health Program, Alabama.

MR. BOLLING: Lloyd Bolling, State Agreement Program, NRC.

MR. FLETCHER: Roland Fletcher, Radiological Health Program, the state of Maryland.

MR. FRAZEE: I'm Terry Frazee, of the Department of Health, the state of Washington.

MR. TOVMASSIAN: Harry Tovmassian, from the Office of Research, also.

MS. BLACK: Kathleen Black from NEOD.

MS. BILHORN: Susan Bilhorn, Office of the Commissioner.

MS. KOFRA: Janet Kofra, Office of the Commissioner.

MR. TELFORD: Okay. I'd like to move to where it says agenda and protocol on the agenda. Let me propose that this is our agenda for the day, if anybody would like to modify that speak up. What I have in mind is to step right through the proposed rule starting with 35.35 and going through the reporting requirements in the guide.

I would like to make sure that you understand the intent of what we've tried to say and then I'd like to hear from each of you on -- whether you would do it that way or whether you'd do it differently. Seriously, we're here to

learn from all of the agreement states and we tried to write this rule, this is our attempt.

I take it you've heard this story about the first crier never has a chance, so somebody has to start, we did, so I take it everybody understands how we got to where we are. Back in '87 we had two rules that we proposed, one was on basic quality assurance and one was called comprehensive quality assurance, and that led to a prescriptive rule on basic quality assurance that we took to the commission in March of 1988.

The medical community came in and said that they objected to this rule because it was prescriptive. They didn't really want to be told how to do things. Therefore in July of 1988 we took some rulemaking options to the commission and it was in July that the commission requested a performance based rule and the staff has met with various medical associations and we even had a workshop with licensees in January of 1989 on the way to developing this proposed rule.

The proposed rule was given to the commission back in August of 1989. There was a lot of debate and discussion among the commissioners and the staff received what we a call a staff concurrence memorandum for how to modify the proposed rule before it's published. That was done and the proposed rule was published January 16th and that is what

you have, this package which you were sent, which is the rule and the guide.

So, now, all the facts are on the table. We can freely talk about our intent and how we would -- how you would like to do this. So, I propose to start with page 1449 of the this publication on the federal register notice. This is the paragraph that proposed 35.35.

Yes, Terry.

MR. FRAZEE: Before we go on, could you summarize some specifics of how the prescriptive rule would have infringed upon the flexibility of practicing medicine?

MR. TELFORD: Well, that would be speculation on my part.

MR. FRAZEE: They did not specify?

MR. TELFORD: Well, that's, you know, they said -- they're telling us to do the following twelve things. What if we don't want to do it that way? What if it would be more effective or efficient for my hospital to do it differently? You're telling me exactly how to do it and they wanted more flexibility, so I don't know that in and of itself would require infringement on the practice of medicine at each and every possible. It may, it may not, so my opinion is they basically just said we would rather be told what to do, not how to do it.

MR. FRAZEE: A philosophical objective.

MR. TELFORD: In part, yes, but also in part they said we have tight budgets. We would rather say -- we would rather hear what the objectives are and then figure out how to do it that best suits our hospital or our clinic. The commission has a long history of trying to go with performance based rules in many areas. It's more difficult, of course. It's more difficult for both the regulator and the regulatee.

I mean, we had a meeting of 18 licensees in January of 1989, I think it was in this very room, and if you look at the transcript of that meeting several of them said would you guys please just tell us what to do then I'd know whether I've done a good job. So, it cuts both ways.

MR. FRAZEE: In telling them what to do in the draft reg guide for this, can you characterize the draft reg guide as it stands now and the 1987 prescriptive rule, how close are they?

MR. TELFORD: Well, I think you're very observant. We took a lot of the requirements in the prescriptive rule and we tried to incorporate them into the guide, but the guide is optional, it's not a requirement. The licensees can use that if it's helpful.

One of the things we did was to go to the American College of Radiology, Dr. Gerald Hanks is the chairman of a quality assurance subcommittee for national standards for

the ACR. They, as it turned out, in early 1989 were trying to develop a national standard for oncology.

We have talked with them and admittedly borrowed procedures that they would have in their model QA program that's optional. They've put into the guide a lot of this stuff on the teletherapy, like when you change a source. We didn't invent that. They went to a national authority. So, you're very observant.

MR. FRAZEE: Are there other areas where non-NRC standards, ANSI, for example, are used as a basis for fulfulling a basic requirement. I guess, in a word, sort of not inventing the wheel, or re-inventing the wheel, but as we go forward with this how significant is it for us to have our own set of criteria? Or, well, regulatory guidance as opposed to sort of the performance based concept which is you've got to have a basic quality assurance program, and an acceptable one would be ACRs or whatever -- JCAHU --

MR. TELFORD: For therapies.

MR. FRAZEE: Right.

MR. TELFORD: Teletherapys, excuse me.

MR. FRAZEE: Are those kinds of other or non-NRC agency rules or requirements, are those permissible?

MR. TELFORD: Yes, I think there is the -- I think there's ample precedent that we -- the NRC has adopted national standards like ANSI, ASTM and others to be -- the

way we endorse a national standard is with a regulatory guide.

For instance, in this situation if the American College of Radiology said here's our standard, it's all developed now, we think it's great for teletherapy, and maybe brachytherapy. The NRC has the option of endorsing that guide with a reg guide which would say to the licensees this is acceptable, these are acceptable procedures to use.

MR. TSE: May I amplify a couple of points with regard to your questions. First is an example, certain public comments and also the community medical community gives us examples, for example, in the proposed prescriptive rule published in 1987 it says that you must look at the patient charts before you go ahead and administer whatever the dose you want to give. The example is that if a patient -- in some communities a patient comes from far away, and for some reason they forgot to bring their charts. Now, do you want them to go back to get the charts? Or do you want to wait until somebody sends the chart? A telephone call to the physician at that particular location, tell me what kind of chart, or what kind of condition. Is that sufficient? That's a specific example. There are others.

Second, in terms of prescriptive rule versus regulatory guide, I think that the regulatory guide because it's voluntary and because of this we do it after. It's

much closer now than previously. So, it's more items in the regulatory guide, in the prescriptive rule. For example, the computer that somebody -- in Maryland somebody forgot to change the computer code because they changed a source and that's how they're trying to kill that problem, in the regulatory guide, but not in the prescriptive rule. So, it's more proposed, since it's not mandatory. So, there is difference between the two items.

The third one is applicable non-NRC standards. They are quite a few non-NRC standards published by the professional societies and so on, except those standards really do not go into details of trying to prevent what we are talking about. They give one sentence or two sentences to take care of this problem and therefore may not be -- may not be applicable in this particular case.

Now, of course, there are many many other QAs, just this is just one particular small area of the QA which we're dealing with and the standards to do really specifically address those areas.

MR. TELFORD: Let me propose that the way we go through this is I'll focus on something, a part of this, and I'll clarify the intent, and then I'll allow each of you to respond. Let's give it a try here. On 35.35(a) this is the opening paragraph of the proposed rule. The key to this, or the intent here is to have a quality assurance program that

provides high confidence that errors in medical use will be prevented and it just tells the licensees to establish it, to implement it, and it's got to be written.

So, what I would like to hear from each of you is your response to this, or would you do this in your state, or is this all wrong. Tell me how to do it better.

MR. WHATLEY: Let me respond, I guess, first by saying I don't really know where they are, one or two in here, one is for the Nuclear Medicine Committee, and also from the state of Alabama, and I can assure you that my comments, I want it understood that my comments today don't represent the views of the agreement states because I've got some comments, and I'll leave you copies. There's a great diversity of opinion among states that I have received so far regarding their approach to this. There are differences of opinion within my own office. So, my comments will be mine and mine alone this morning.

MR. TELFORD: That's fair.

MR. WHATLEY: I had some notes here on these. One of the things that has concerned me for a long time, nuclear medicine relates to a standard condition that's put on NRC license regarding -- may be used by or under the supervision of an authorized user, authorized physician, that's practicing nuclear medicine, and this condition allows physicians basically to gain training experience.

I think if we're looking at quality assurance, ways to reduce unnecessary exposure or reduce the likelihood of a therapeutic event where a diagnostic event was planned, that one of the areas that needs to be looked at is this supervision.

MR. TELFORD: You're implying that it's a little too weak?

MR. WHATLEY: Well, let me explain. Physicians before they're put on license to use radioactive material as an authorized user. Their training experience is reviewed by some regulatory agency, NRC or agreement states, and they have to meet certain criteria before they can prescribe, select patients, prescribe radio pharmaceuticals and interpret results. There are certain training requirements. But in a teaching institution a physician under the supervision of an authorized user can perform all those duties without anyone ever having looked at his training experience prior to that. I guess my question is what does supervision mean? I think that perhaps --

MR. TELFORD: Are you implying that we should have a definition of supervision?

MR. WHATLEY: I think it would help the medical community, I think it would -- I think this has been a grey area to many of us over the years, it certainly has been to me.

MR. TELFORD: Okay.

MR. WHATLEY: I know what the definition of supervision says in Part 35, but that's not the physician relationship, that's referring to technicians, generators, and preparing kits and such. In my opinion there is no guidance given. I do not recall seeing any regarding the supervision between an authorized user and a physician receiving training.

MR. TELFORD: Okay.

MR. WHATLEY: Now, this allows someone who is in training to basically do anything that that licensee is authorized to do, supposedly under the supervision of an authorized user, and I'm not sure that sufficient guidance is given there.

MR. TELFORD: All right, good point. How about --

MR. WHATLEY: This refers specifically to 35(a)(4)

MR. TELFORD: Okay, what I was going to do is go through A and then go through the eight objectives.

MR. WHATLEY: All right, that's fine.

MR. TELFORD: Your comment is well put. I understand that you're saying that we say an authorized user or a position under the supervision of an authorized user, and position is not -- I mean supervision is not defined, so it could be fairly loose or fairly tight,

depending upon the hospital, or however they want to do it. That's a good point.

MR. WHATLEY: I pulled some old NRC letters and looked at them before I left home and it is interesting to go back and look at concepts that have changed over the years where NRC used to enforce a user condition by saying that a physician selects patients, prescribes a dose, and then checks his results. That was the written procedure of NRC for many years and interpretive letters have been written to that effect. But as I understand now that's not the way it is and as Dr. Tse was talking about the flexibility of our problem awhile ago mentioning, reviewing patients' charts, the criteria for selecting the patient wa always understood by me to mean that the decision could do that three ways, select a patient, receive radio pharmaceuticals, or any other drug and that is by examining the patient himself or consulting with a referring physicians, those are the three ways.

So, I think as long as that flexibility remains I personally don't see where something like this necessarily infringes on practicing medicine if this is doing the way it's always been. That's my personal comments.

MR. TELFORD: Okay. Roland.

MR. FLETCHER: Well, the only thing I wanted was to get back to the incident that occurred in Maryland, and I

understand completely the fact that the term supervision may have many meanings to many different medical staffs, but position in this particular case supposedly was under supervision, but the practice, you know, the therapeutic practice that was engaged, turned out to be under no one's particular supervision just because of the way that hospital viewed its role and I don't know how -- I don't if we can ever specifically designate exactly what that relationship should be between the, you know, the physician who is actually administering and the supervision. We do have a quality assurance plan that we've gotten from that particular hospital which is satisfactory, and that involved oversight by a committee, a radiation safety committee, of all administrations, and that might be an alternative to having just a single designated individual.

MR. TELFORD: This first paragraph (a), is that a way to start a performance based rule?

MR. FLETCHER: Well, as I said, we have received such a plan, we haven't -- it hasn't been that long so we haven't seen, we haven't done followup to see how it's working. This is a start as long the program, the nuclear medicine program is abiding by, not only the -- I guess you get involved in a letter and intent, you know, the spirit of a rule because you can never put enough words down to cover every circumstance, and you've got to make sure that those

things that are not specifically said are still being followed. I can't tell you right now. We have assurance in our early followups that sufficient supervision would be exercised, but it's only been in place for a three to six month period, so, I can't go beyond that to say whether or not this is, you know, their supervision is sufficient to preclude the number of misadministrations that occurred before it will occur again.

MR. TELFORD: Well, in our proposed 35.35 we're saying in the first paragraph you must have a program. It's supposed to provide high confidence that errors in medical use will be prevented.

MR. FLETCHER: Right.

MR. TELFORD: Then we have these eight objectives.

MR. FLETCHER: Right.

MR. TELFORD: We don't say you have to do anything in particular about those, but you have to address those, those have to be incorporated in your program if applicable.

MR. FLETCHER: The first step --

MR. TELFORD: The first step.

MR. FLETCHER: I have a question, if this is first step, I would say yes across the board. As a first step, yes.

MR. FRAZEE: I agree with Kirk's statement. There is a wide diversity in opinion, including on my own staff as

well. To me it seems that there is a basic dichotomy, and this is a simplistic approach. There are those of us who believe that the physician is next to God, and then there are those of us who believe that secretly he buries his mistakes, and neither extreme is justified, and so there needs to be a middle ground strike some sort of a balance, and I think we need to look back at a couple of things.

One, let's take ALARA to begin with, the key point is reasonable. We can go out and design and build the best, safest, most reliable car and it will cost us a million bucks a piece, mass produced, but none of us can afford it, and ALARA does address the economic considerations versus the risk to the patient. In this case the patient.

The risk to the patient looking at the data that NRC has collected I was struck by the fact that there doesn't seem to be a lot of misadministrations reported, particularly in the -- or, especially in the therapeutic realm, and that if you look at the break out between teletherapy and brachytherapy and liquid therapy, the rate seems to be pretty uniform, essentially the same, and it struck that, gee, does this mean something? Have we reached a minimum reasonably achievable point already? If there were a difference between them, then I'd say, hey, clearly the one that has the higher error rate there must be something that we can do to reduce it.

So, kind of a basic question is are we dealing with an error rate that's sort of the minimum? I mean, this is human nature. Errors are going to be made. Is it reasonable for us to think that we can actually reduce -- we can prevent, which implies zero errors, can we prevent every misadministration? And, if we are indeed at a low, perhaps a reasonably acceptable error rate, what is the cost of achieving the next, in the order of magnitude, improvement. I mean, is this going to break the bank, so to speak.

Another point, sort of in background to the overall rule, the NRC's 1979 policy statement indicates that if there is voluntary compliance the NRC would not interfere.

MR. TELFORD: Yes.

MR. FRAZEE: And I guess a basic question is how has the voluntary standards -- or, have the voluntary standards, how have they failed? Have they failed? Basically it's saying where is the problem? Is there is a real problem here? Certainly if there's a problem then definitely we need to do something about it, but if we have reached the point where our requirements upon the licensee are going to be onerous, and not really effectively achieve our purpose, then, you know, we have not helped we have hurt the industry. Certainly the industry is coming out and saying that, you know, we are in fact approaching the point

of hurting the industry.

This brings me back to the beginning point which I'm neither totally pro-industry or pro the opposite. And I really want to find, to help get us to a place where we can accomplish basically both ends, not hamper the industry, but enforce the regulation requirement that they have, the statement, the requirement that they have, a basic written quality assurance program, I think is reasonable, and it's in the details that we make, have some input.

MR. TELFORD: Okay, let me reflect on your question, or, actually reflect it back, because I notice the statement that the quality assurance program is to provide high confidence of medical use and we didn't quantify high confidence. So, what you're alluding is that there is a basic rate of misadministration currently, you're really asking me is that low enough, so what I would like to ask to each medical society that I talk to, which agreement state is, what's low enough in your state? What's low enough for your society? I would like to appeal to the authorities, people with the medical societies with the credibility to tell me what's low enough. So, if the current rate is low enough in your state, that's an acceptable answer. But maybe my basic question is should we define how confidence, should we quantify it?

MR. FRAZEE: It seems that your basic standard --

MR. TELFORD: For instance, in the area of reactors, the commission has a policy statement on the safety call, this is a simplistic statement I'll make, but it may help. The probability of death from all causes -- no, the probability of death due to this reactor will be one-tenth of a percent of all other causes. Okay, the probability of cancer, say, in what? Okay, high confidence. What if we could hear a proposal that we could quantify high confidence, that the frequency of occurrence of misadministration will be at a certain low rate and that's good enough. The beauty of the safety call is that it says how safe, safe enough is. You don't have to be infinitely safe. Just like hear, you're asking the question, do these guys have to be infinitely good? Do they have to make zero mistakes? I think the obvious answer is no, but how many is too many? I mean, how many overdoses of I-131 will be allow as regulators. How many Cumberland events do we allow as regulators?

There was an event recently, last winter in Phoenix, I believe, in which a patient got a massive overdose of I-131. How many of those do we allow? Your gut reaction is not many, and in the case of ALARA, in some cases we have gone one step further from something like a concept like the safety call, we have said, what is it, a thousand dollars per manrem, just to be a little guideline

that we used, that was if you can reduce the exposure by one manrem and spend a thousand dollars, do it. So, does that concept make any sense to you?

MR. FRAZEE: One tenth of one percent is what, ten to the minus third risk?

MR. TSE: Ten to the minus third.

REPORTER: I can't hear you. Could you speak up?

MR. TSE: Yes, he's asking one-tenth of one percent is ten to the minus three, and I said yes.

MR. FRAZEE: Right, and the general risk associated with radiation exposure is ten to the minus fourth, and we're dealing with the possibility of misadministrations that's on the order of ten to the minus fourth, and therefore the risk to patients is going to be multiplicative so it's -- what is it now? Ten to the minus -- at least ten to the minus seventh, ten to the minus eighth, that's the risk to the patient presently.

MR. TELFORD: You mean of getting cancer?

MR. FRAZEE: Basically.

MR. TELFORD: Oh, yes, per.

MR. FRAZEE: Getting a significant -- yes --

MR. TELFORD: You're alluding to the Beir V numbers of, what is it, ten to the minus five per rem of getting, the probability of getting cancer?

MR. FRAZEE: But the point I'm making is the risk.

MR. TELFORD: It is four times ten to the minus four?

MR. FRAZEE: Okay, nice big number, comparable to the risk of receiving a misadministration, and therefore we're talking ten to the minus eighth in terms of an overall patient --

MR. TELFORD: Well, that's per rem, but we don't know how many --

MR. FRAZEE: Okay.

MR. TELFORD: We don't know how many rems that person would get in a particular misadministration, and that's also sort of a lump average over the whole industry and we would note that there are probably a broad range of rates among hospitals or among clinics. I mean, you could view this real one way as saying all the poor performance have to measure up. It's really no bother to the good guys. Like, if you don't have any misadministrations in your hospital, you can say --

MR. FRAZEE: You're doing fine.

MR. TELFORD: I'm doing fine, that's right. Well, the question I have for you is, is that a useful concept in your state to quantify the high confidence? Would you consider that fair? Let's go back around.

Kirk.

MR. WHATLEY: I have to think about it.

MR. TELFORD: Okay.

MR. TELFORD: Roland.

MR. FLETCHER: It sounds plausible, but, you know, we've only dealt with therapeutics, so we -- even our regulations only view it on a therapeutically. I'd have to say it sounds reasonable, but once again my office is not totally in agreement. Based on what we're talking about now it sounds plausible. ALARA is still be argued as far as that is concerned.

From my perspective I bring it up as a point of discussion and it probably would have the same result as the rule itself, it will be argued, and as you say, there's a target and somebody will always have some concerns about it, and we'll get back in the same controversy. It's not tightened up, or it's too tight, it's going to be rationed both ways.

I'm not convinced that establishing a quantity, certainly not in the regulations, or maybe not even in reg guide, although that may be the better place to put it, that setting a quantity is necessarily a good idea because those of us who don't trust them will let it slide. If they're good, hey, if we can let it slide we don't have to worry about it.

MR. FLETCHER: Either that or they can do better, but they don't because they've reached the goal.

MR. TELFORD: That's a good thought.

MR. FRAZEE: So, I guess I'm not proposing that you put in a numerical number. Basically I'm bringing it up to say let's keep that in mind, that concept in mind, as we go forward, because it's when we get to the detail where people are going to start chipping away at us and if there really isn't a problem then we're going to be on very tenuous grounds, but if as we develop or continue improving upon the basic rule, we continue to reflect back on the risk, you know, why are we doing this, and does this make sense, then we'll be a lot firmer when we actually go to finalize it.

MR. TELFORD: Okay, well, let's move to the details. Let's look at the eight objectives now. I'm not sure how to take these. We can take them as a group of eight, or whether we should take them individually. Does anybody have a sense of that?

MR. WHATLEY: Why don't we just go through them one at a time?

MR. TELFORD: We'll go through them one at a time, okay. Okay, we list these as objectives. They are not must do things, but rather these are objectives, goals, targets that ought to be in your program. You tell us -- we'd say to the licensee, you tell us how you're going to handle each one. So, let's take number one.

MR. WHATLEY: I will comment on number one. It says ensure that any medical as indicated by the patient's medical condition -- I guess my question, I understand that for therapeutic uses, the authorized user must do it, but it goes back to my earlier question regarding diagnostic referrals. Who is going to make that determination? Who will make this determination?

It says someone must ensure that any medical use is indicated for the patient's medical condition where a patient comes to an institution on a diagnostic referral, who makes the determination.

MR. TELFORD: Let me give you the answer now.

MR. WHATLEY: Okay.

MR. TELFORD: You'll see it when we get to the definitions, but the authorized user is in control.

MR. WHATLEY: Well, they just go on a diagnostic referral. Now, it's my understanding that any physician for a diagnostic -- I understand for a prescription, but for a diagnostic referral it says it can be under either a prescription or a diagnostic referral, and a diagnostic referral can be any physician.

MR. TELFORD: Yes, okay, let me explain my statement.

MR. WHATLEY: Okay.

MR. TELFORD: In the definitions we have attempted

to define prescription, diagnostic referral, and clinical procedures manual. So, if any physician, a non-nuclear physician, sends a patient in with a diagnostic referral, the procedure requested must match the procedure in the clinical procedures manual. The authorized user approves the clinical procedures manual. So, what gets done to the patient by the technologist in the clinic or hospital is controlled by the authorized user, which is the nuclear physician. So, if the referral says I want a liver scan, but use one millicurie of I-131, even if the technologist doesn't tilt when he sees that, he looks in the clinical procedures manual, it says liver scan, and it's a different procedure, he doesn't do it, so there's various way of ensuring under (a)(1).

MR. WHATLEY: I guess I interpreted one to mean the patient's need for the particular study as opposed to matching a chart. Does a patient need that study?

MR. TELFORD: Oh, well, the intent of one is to say there should be a cognitive process that goes on, that the physician has -- as you said earlier, either looked at the patient, looked at the patient's chart, or talked to the referring physician, and said, well, let me use those three in this case because we would like the physician to have done some subset of those three before the physician decides that something should be done to the patient even if it's

diagnostic.

MR. WHATLEY: That is by a physician who, in all likelihood, has never had any experience in nuclear medicine.

MR. TELFORD: In referrals, that's true, but it's the function, then, of the nuclear physician to overrule those.

MR. WHATLEY: Not the way this is read.

MR. TELFORD: Okay. You're saying, all right, you're saying it's not really clear as to --

MR. WHATLEY: As I read this, let me just, hear me out --

MR. TELFORD: All right.

MR. WHATLEY: As I read this, for a diagnostic referral a physician who, let's just assume, has no training or experience in nuclear medicine whatever, has a patient come to his office --

MR. TELFORD: Right.

MR. WHATLEY: The physician suspects a liver problem for the patient. He calls the hospital and sets up a liver scan for the patient. The patient arrives at the hospital. The technician takes a look at the order and goes ahead and does the exam, and that's it. Now, nowhere has a physician who has been trained in nuclear medicine made a determination that is needed. It's been determined solely

by someone who has no experience in nuclear medicine. That's my concern.

MR. TELFORD: If I am hearing your concern correctly, you would rather see it say the authorized user has ensured that --

MR. WHATLEY: My point is I don't understand why doctors have 200 hours of training in basic radioisotope-handling techniques and so on, plus 500 hours clinical supervision at an institution and so on, and then allow a doctor who has no experience whatsoever to prescribe radiopharmaceuticals.

If I was one of these doctors that spent 6 months in a training program, I'd be asking questions.

MR. TELFORD: Yes. Okay. I understand.

You're saying why go through all this training and then not use these people.

MR. WHATLEY: In my opinion, the technicians are practicing nuclear medicine.

MR. TELFORD: Okay.

MR. WHATLEY: NRC used to interpret -- and again, I pulled this letter and looked at it -- that it's the responsibility of an authorized user to make the determination that this prescriptive drug, which all radiopharmaceuticals are, should be administered to a patient and that only certain physicians are authorized to

prescribe radiopharmaceuticals to patients, and those are the physicians who are named on a radioactive material license.

Now, here is a physician -- under this diagnostic referral, any physician not named on a radioactive material license is prescribing that radiopharmaceutical to the patient, or he sends his patient to the hospital, and the technician is the one who goes ahead and administers it.

I question whether or not technicians are not practicing medicine, in this case.

MR. TELFORD: Okay.

Roland.

MR. FLETCHER: Well, as I listen to Kirk and your interpretation of his explanation, I agree with him. This doesn't say what you intended to say. And I haven't looked at it specifically, as he just outlined it, but I can see some of the loopholes in it, whereby someone trained to use radioactive materials and appearing on the license may never see -- and I don't know what quantity of patients we may be talking about that get through the system without being seen by someone who has gone through all this training. I have to agree with him.

MR. WHATLEY: All they do is interpret results. That was my point.

MR. FRAZEE: And now for the real world -- I mean

that's exactly what's done, and if you were to propose that, you'd really have the meds -- the doctors screaming, because that's not real world.

MR. WHATLEY: I just raised a question.

MR. FRAZEE: You're right. I mean you're absolutely right, but now let's get back into just the basic risk thing, and I guess I tend to fall a little bit closer to the medical side because of background.

I come across sometimes thinking, well, you know, a diagnostic study, hey, no big deal. The exposure is not trivial. There is an exposure from a diagnostic study. So, we don't want to tend to go too far in that direction.

But by and large, the practice of nuclear medicine now, as Kirk stated -- the authorized physician is really interpreting scans. That's what he's getting the big bucks for. And he has set up a program, the clinical procedures manual, for the technician to use in performing studies referred by the referring physician, and I think, by and large, that's reasonable, because the exposure to that patient, even if it's not truly necessary, is not that -- is worth the benefit of having the physician's being able to come back and say, hey, at least, we know that's not what's wrong with you.

And so I think that, in terms of cost benefit, it's reasonable to allow them to do -- continue practicing

medicine as they have and that the simple instruction to ensure that the medical use is indicated is reasonable, without restricting it specifically to the authorized user and certainly not beforehand. You know, that is for diagnostic. When you get to therapeutic, then, yes. Now, we're talking orders of magnitude greater risk to the patients.

MR. TELFORD: Okay.

Let's move on to number (2).

MR. WHATLEY: Some of my comments are -- come from being an inspector, also. In the field, for an inspection, we'll be faced with making an interpretation on this. The institution may have one idea and the inspector have another, and I just don't think it's -- I guess the gist of my comment was I'm not sure it's clear, and I'll let it go with that.

MR. TSE: May I make a point first?

When I listened to the discussion, I was wondering, in your view, Kirk, is the NRC agreeing that they should be responsible for the radiation safety aspects of the use of byproduct material, or we also would be responsible for the practice medicine?

The point is -- you were using the word "supervision", because in NRC's regulation, we do have supervision in terms of radiation safety.

In terms of how to -- what kind of radiopharmaceutical to prescribe, that's something, probably, is under the practice of medicine, and we really did not address anything says you should only prescribe this for certain things, and therefore, the supervision of a physician who is not an authorized user, seems to me, it's related to radiation safety and the use of material, byproduct material and so on, and not in terms of supervision how you should prescribe. That's medical science.

Second, as I listened to the discussion of the first item, "medical use is indicated", I believe that, in my thinking, the licensee always has the responsibility -- "licensee" meaning the hospital and, therefore, the authorized user within the hospital.

In terms of therapy, there is no question about he should have a prescription. In terms of diagnostic, there was a suggestion that the dose is so low it's not trivial but much smaller than therapy and, therefore, the authorized user may or may not necessary to go through each prescription for each diagnostic referral if he feels that the referring physician -- he can't trust the referring physician. But if he cannot trust the referring physician, if it's the first time the referring physician comes in, he might want to check it to make sure this physician did

something that, you know, in his view is correct.

The actual -- who is determining the patient needs a liver scan? My thinking is that -- is that where the referring physician has the responsibility or the nuclear physician? Seems to me it's the referring physician, because he knows the condition of the patient, and he's supposed to know what he wanted, so that he can make a determination of the treatment.

That's just my view.

MR. WHATLEY: I think someone should make a determination other than the technician that a radiopharmaceutical should be administered to the patient.

My personal opinion is that a physician that does not have the adequate training and experience in nuclear medicine does not have that knowledge, does not have that experience. If he does, then my question is why do nuc physicians have that training? Why not just letting them learn how to interpret films? What's the purpose of the rest of it?

I think that the responsibility is with the authorized user, and what I am saying is I do not think it's being done, in most cases, and I don't think, the way this is written, that it will be done. And again, my question was was that intended?

MR. FLETCHER: A follow-on to that is that this

referring physician has no experience with radiopharmaceuticals, and he asks for this particular test over and over again for various patients, and there is no check to see, you know, what is his basis for referring to this specific treatment.

Maybe some kind of a check system can be put in place, because if you say this is what's going on, and I'm sure you're right -- this is what's going on, but what we seem to -- we seem to be recognizing a route around our own requirements, and that bothers me as a regulator, because you know, physicians are like anyone else. After a while, if they -- you know, some of their patterns of recommendations of treatment are redundant. They see the same symptom, they refer the same thing, and they may be, in a worst-case scenario, referring more and more patients to this specific treatment that don't even need it, and they don't know that these patients don't need it, because no on has apprised them of it.

MR. TSE: You said "treatment".

MR. FLETCHER: I mean diagnostics. I mean testing.

MR. WHATLEY: The purpose of this is "to prevent, detect, and correct the cause of errors in medical use". I guess my point is here that the two people involved in these diagnostic studies, which is the diagnostic referring

physician and the technician, in my opinion, in many cases, neither one of these have the knowledge to do that.

MR. TELFORD: To do number (1).

MR. WHATLEY: To do number (1).

MR. TELFORD: Yes, I think you're right. That's kind of a loophole. You can tell from the objectives that we're focused more on therapy that we are on diagnostics, and they way that we were attempting to let the authorized take control of the diagnostic procedures was through the approval of the clinical procedures manual and any oversight that they wanted to do on the acceptance of the referrals. You would think that they would have a working relationship with the physicians. They send them patients, but --

MR. BOLLING: Not necessarily.

MR. TELFORD: Not necessarily true. And what Roland says is also probably true, that one doctor may be prescribing more diagnostic tests than the patients need, and there is no built-in mechanism here. We have to leave that as the practice of medicine. But I accept your comment.

MR. WHATLEY: From a practical standpoint, in large institutions, teaching institutions and so on, where they have a nuclear-medicine department, technician, technologist or whatever, in all likelihood, it's not going to be a problem. Apparently, it hasn't been a significant

problem.

MR. FLETCHER: Or at least we haven't recognized it yet.

MR. WHATLEY: This applies to the lady that works in the floral shop who comes down and does nuclear medicine on the side. Those are out there. And a doctor calls up and sends my wife to the hospital -- she's pregnant -- to have some kind of study done. I would like somebody that knows something about the different isotopes that are available to be used, which may not cross the placenta barrier and so on, to be, at least, considered.

I think someone that's knowledgeable in the use of radioactive material should make the determination that radioactive material is to be administered to all patients before it's done.

MR. TELFORD: Let me pick this point up again when we get to the audit paragraph. That may be a place where we can -- let me just sort of throw this out, and you can think about it as we're going through the other objectives.

Rather than getting Terry all excited here --

MR. WHATLEY: Can I add just one other thing? And then I'll give off that.

MR. TELFORD: Yes.

MR. WHATLEY: Our Advisory Committee in the State of Alabama reviewed this, and they support that. That's

reviewed by our Medical Committee in the State of Alabama.

MR. TELFORD: The idea is that part of the audit function, we could have the Licensee's management audit the cases, these diagnostic cases, and see if the authorized user physician, the nuclear physician, was doing any approvals. You know, let them use this feedback loop to determine if that's --

MR. FRAZEE: If it's in accordance with their own state's requirements.

MR. TELFORD: Yes.

MR. FRAZEE: Alabama may choose to do it one way and Washington another way as far as the medical community is concerned.

MR. TELFORD: Right. Yes.

MR. FRAZEE: My comeback here is that there are indications and contraindications to using a particular drug. The indications and contraindications both are something that the authorized physician, who had all the training, et cetera, is aware of and should impose it being part of the clinical procedures management. And, once that is done, then, it is the practice of medicine for the referring physician to look at his patient and say, aha, you have such and such a condition and that is an indication for this particular study and, therefore, I want a liver scan, a brain scan, whatever. That is the practice of medicine. He

calls up the hospital, gets the study scheduled and the technician has the -- well, really, the technician's responsibility is, probably, to say, well, are you pregnant, is there, again, from the list of contraindications in the procedures manual, are any of these things applicable? If not, he has the authorized user's blessing to proceed with the diagnostic study.

MR. TELFORD: Yes.

MR. FRAZEE: And, again, I don't think that's unreasonable.

MR. TELFORD: Gee, I thought you guys were going to tell me, we don't need number one.

MR. WHATLEY: Do you what FDA's policy is on -- all these package inserts say, you know, the standard wording, administer to the patient only under prescription, whatever that wording is on that. I have, probably, a hundred package inserts here. Who do they say can prescribe these? Can any doctor prescribe a pharmaceutical to a patient?

MR. TELFORD: The package inserts say that you have to follow the manufacturer's instructions and you should use it for the indications. Currently, we have a regulation that says, for therapy, you have to use it for the indications and methods of administration on the package insert.

MR. TSE: FDA has a specific regulation that says that a physician can use any drug for any indication in the practice of medicine. They do not have to follow the package insert in terms of indications.

MR. WHATLEY: Can any physician use any drug? Can any physician use narcotics?

MR. TSE: Okay. That is controlled substances. Under the regulations, FDA's regulations, if they want to use something different from the approved drug, they must go to the -- I am talking about approved drugs, meaning that it is marketable in the U.S. Those physicians can prescribe for patients, for those indications which are not listed in the packages, that's what the particular regulation says. Now, the interpretation of that, meaning that if it is a legal drug --

MR. TELFORD: The state medical boards would have something to say about which physicians in each state would be able to prescribe regular pharmaceuticals. Just like some states differentiate between pharmacists and nuclear pharmacists. But, I think the FDA probably would not tell them they could not prescribe radiopharmaceuticals.

MR. FLETCHER: I don't know how feasible this is, probably not, and probably it would get the medical community up in arms, but it would appear to me that some type of tracking system for, say, the number of times a

referring physician prescribes the use of a radiopharmaceutical. You know, there is a whole lot of difference if one has made the referral ten times a month rather than ten times a year. At some point, there's, I don't know, some type of review or question as to what -- is there a reason this is occurring and, if so, perhaps that's the time to, at least, give that physician some indication or some type of training on the use of -- I'm not saying 200 or 500 hours, I don't think that's required. But I think there needs to be, at least, some understanding of the fact that, you know, is this the only recommendation you can make? Is that why you are doing it? Is this the only drug you are familiar with to do this kind of thing? Is that why you are doing it? Do you really have the knowledge and belief that this is the only one that will work? Like I say, I don't know how feasible that is.

MR. TELFORD: Shall we move on to number two?

The intent of this one was to say that for every procedure you should have a prescription and, for any diagnostic procedure involving more than 30 microcuries of I-125 or I-131. Now, what we are trying to prevent here is any use of iodine in any quantity -- it is a written directive that people can follow. We are particularly trying to prevent the micro to milli switch. That is our first attempt here, you will see more, okay?

Kirk?

MR. WHATLEY: Just a comment. I sent this out to all the members of my committee, which are Terry, Stuart Rosenberg in California, Ray Dielman in Florida and Cheryl Rogers in Nebraska. I got comments back from them and I just relay Ray Dielman's comments that a prescription fee should be written for all radiopharmaceuticals. That was his comment and I will just pass that on.

MR. TELFORD: How do you feel about that?

MR. WHATLEY: Well, it sort of goes along with what I just got through saying. In my viewpoint, a prescription is not just necessarily a piece of paper.

MR. TELFORD: What else can it be? An oral directive?

MR. WHATLEY: It can be an oral directive like in most doctors' offices where it is entered in the patient's chart and signed by the physician.

MR. TELFORD: Isn't that a written directive?

MR. WHATLEY: After the fact.

MR. TELFORD: Oh, after the fact.

MR. WHATLEY: My viewpoint of a prescription is -- well, I normally think of a prescription is me going to my doctor and him handing me a piece of paper. Prior approval by the authorized user is what he is saying.

MR. TELFORD: Well, when we get to the

definitions, when we talk about the definition of prescription, I'll try to lay out the intent but it is basically that we want a written directive. Perhaps prescription carries the wrong connotation, but what we are saying is tell us what you are going to do, write it down, then do it, and tell us you did it.

MR. WHATLEY: I think your definition of prescription is adequate. That was just --

MR. TELFORD: Yes. But you are saying that a written directive before the fact may not necessarily be a good thing all the time.

MR. WHATLEY: I would support a written directive for therapy. I have no problem with that at all.

MR. TELFORD: All right.

How about diagnostics of 30 microcuries or more?

MR. WHATLEY: Well, I go to my doctor and he gives me a shot of penicillin. You know, he doesn't write out a prescription, he just does it. But it is entered in my chart and he signs.

MR. TELFORD: But that is in the case of the authorized user, in this case, is actually administering the drug. In this case we don't really know that. I don't think I would differ with you, you know, debate with you about if the authorized user physician, the nuclear physician, if they said, if they had their own clinic and

they said we are going to use 50 microcuries of I-131. He is going to use it. He doesn't have to write it down for himself as a directive. What we are after, of course, is if he tells the technologist, give Mr. Jones 50 microcuries of I-131 and the technologist hears 50 millicuries.

MR. WHATLEY: I have no problem with that.

MR. TELFORD: All right. Let me ask you this: written versus oral, for that situation, would you suggest that oral is all right or is written required?

MR. BOLLING: Let me jump in for a second. Where I used to work, Mount Sinai Hospital in New York City, we handled about 55 patients a day and that's about the upper limit of any hospital in the country that might be three or four that did more.

MR. TELFORD: How many people? How many technologists and how many physicians?

MR. BOLLING: Around fifteen, perhaps three physicians, the authorized user and his two assistants and maybe a resident or two.

MR. TELFORD: And fifteen technologists?

MR. BOLLING: Yes. And none of us were ever allowed to touch a patient unless there was a requisition form which we treated as a consultation form. A physician, either an in-house physician or a physician who was attending from outside, would say, gee, I think my patient

needs an examination of the liver and it could be that that patient needed an ultrasound study so they would check off liver examination, we would get the form, schedule the patient the night before and one of the physicians would examine all the forms to see that, yes, this patient has been requested to have a liver study, they have a suspected tumor of the liver or perhaps it is a tumor which could go to the liver and they seem to match or, maybe it's a screening study of some kind. But, at least, it was related to what was being requested. We treated it as a request or a consult.

Then, the following morning the technicians would line up all the doses, give them to the patients but only after they had checked the requisition forms and saw the physician's little initial at the top that he had seen it and that it was okay to go ahead.

MR. TELFORD: That is the authorized user physician.

MR. BOLLING: Right. Yes. Other than that, we were not allowed to touch the patient.

MR. FLETCHER: I am in favor of written prescriptions. First of all, it gives you -- you write down exactly what you mean, so that there is no -- even though the handwriting of some physicians is kind of up to question, there is no doubt about what you mean when you put

it down.

Verbally, to me, there is the potential for mistakes. A physician may write down something he doesn't mean, but he's got a record of what he did. Verbally, he's got no record. If the nurse wrote it down wrong or the technician wrote it down wrong, there is no record of what the doctor actually said.

So, I would favor written instructions, written prescriptions, even while you're administering to a patient. That should be written down and, I believe, checked by the doctor, to make sure what was written is what he intended.

MR. FRAZEE: Written is reasonable.

MR. WHATLEY: I think we hear over and over again, in our business, where people compare x-ray to nuclear medicine, and they say if x-ray was handled the same way that nuclear medicine is done, exposure to patients would be reduced dramatically, and I think what we're talking about here is directly related to that.

I hesitated before in answering that, in a little hospital that does one patient every 3 days -- that was the reason I did that.

MR. FRAZEE: Where did the "30" come from?

MR. FLETCHER: I'm glad you asked that.

MR. TELFORD: There is one train of thought there that if you make the micro to milli switch, what's the

consequences? Some would say 30 is too high, and some would say 30 is too low.

MR. FRAZEE: If you put up the number, you've got a target.

In the practice of medicine, particularly with thyroid patients, are they still 100-microcurie capsules?

MR. BOLLING: I think it really depends on the patient. Fortunately, they're using a lot more I-123, which has accelerated-produced and has a lot short half-life. They use more of it, but a shorter half-life.

It really is kind of 19th century technology to use more than, say, 30 microcuries of I-131, except of a patient has got a very enlarged gland that diffuse. So, they may want to image that gland using a rectilinear scanner instead of a camera.

But that requires intervention on the part of the physician anyway. He or she has got to determine, well, gee, you know, what we have in our procedures manual is not going to cover this particular patient, and you must examine the patient in a thyroid case. You just cannot, you know, decide that, gee, this patient needs a scan. Let's just scan them.

You've got to palpate the gland. You've got to determine how much it weighs and where it is. Is it below the sternum, in the chest, or is it where it's supposed to

be, in the neck?

MR. FRAZEE: Is there any reason to distinguish between capsules and liquid?

MR. BOLLING: Not anymore. It's my understanding that the capsules are embedded -- the iodine is embedded in the inner surface of the capsules, and they, of course, are not hermetically sealed or anything. Then they leak and give off iodine, just like liquid would, especially the upper amounts.

MR. FRAZEE: In terms of a manufactured product, you ask for the I-131 caps and you've got them in stock, and they come in 100 and 50 and whatever, right on down the line.

If that's what's available to physician, or the technologist for dosing the patient, then you're not going to make a mistake unless you're going to double up and triple up and give them the whole vial. If you've got a liquid solution, then there's the potential for making the kind of error that you're talkir about.

Isn't it true or isn't it commonplace for most of the diagnostic studies with I-131 to be done using capsules?

MR. BOLLING: Yes.

MR. FLETCHER: Do they come in 30 microcuries?

MR. FRAZEE: I believe they're lower than that point -- 150 to 25 or whatever is how they decay out.

MR. TELFORD: Do you have a good number for us?

MR. WHATLEY: They're available in packages containing 1 to 50 millicuries at a time calibration.

MR. FRAZEE: Usually, you only order those special orders.

MR. FLETCHER: The way of getting around the 30 microcuries is to not have any number designation.

MR. FRAZEE: Or specify it for liquid. If you're going to dispense liquid I-131 or I-125, then there you have the potential for drawing up an assay and making a mistake.

MR. TELFORD: Well, what if they pick up the wrong capsule?

MS. BLACK: What if they order the wrong capsule?

MR. TELFORD: There is a case in Texas where a microcurie amount was given by an oral directive to the technologist, and the technologist heard "microcuries" and ordered it from the pharmacist, and the pharmacist said why do you want this much? And they said that's what I want. The millicurie amounts were delivered and given to the patient, and the doctor says oh my gosh.

MS. BLACK: I think that happened three times. I mean it was caught on the third error over a short space of time.

MR. TELFORD: So, just because you're dealing with capsules is not the panacea for fixing this problem. I

think we have to be careful.

What I keep in mind is if the hospital is really good anyway, these requirements are not going to bother them at all. They can easily meet them. But my responsibility is that hospital out there someplace that either isn't very good or doesn't care and repeats mistakes like that. Like Kathleen said, it happened three times.

MR. FLETCHER: All three oral instructions?

MS. BLACK: Well, I think it was the technologist didn't know the difference between micro and milli.

MR. FLETCHER: That's why you write it down.

MR. FRAZEE: You write it down, but that speaks to training.

MS. BLACK: Well, yes, it does. These happened in short order, over the space of a week or so, and it was only the last time, when she said why did I have to wait -- or he said why did I have to wait 2 days for it? You know, I ordered it before. The guy said, well, you ordered milli and not micro. This time you ordered micro. And then it all came out.

MR. WHATLEY: There is a July-September 1989 report to Congress on abnormal occurrences. There is one in there on medical diagnostic misadministration.

When the referring telephoned the order, a scheduling secretary incorrectly wrote I-131 caps, rather

than a thyroid scan. They intended to give 300 microcuries of I-123 and gave 3 millicuries of I-131.

And this article contains a lot of concerns that I have already raised, and sometime today, I'd like to -- I'd just like to have an opportunity to maybe say a few words about that, because it raises some real concerns.

MR. TELFORD: Yes. At the end of the day, I have individual summary remarks. I neglected to tell you that at the beginning. You will have a block of time that you can say, in summary, anything you want to say, including remarks like that.

Shall we go on to number (3)?

Excuse me. Dr. Tse has a point.

MR. TSE: If this particular item (2) becomes required, would that be catching those kind of cases?

MR. WHATLEY: Yes. This was directly -- in my opinion, directly -- I wrote NRC, and this thing said the licensee did not have adequate procedures to ensure that prescriptions were in writing and the doses were verified before they were administered.

I agree with that, but I submit that the real cause was -- and this may be what's intended here. The real cause was that a physician that's had training and experience in nuclear medicine was never involved in this procedure.

MR. TSE: And in this particular proposed requirement, anything greater than 30 microcuries, the technician cannot do it. He has to get the authorized user to write a prescription and, therefore, would prevent --

MR. WHATLEY: It should help prevent. I agree with you.

MR. TELFORD: Number (3) then.

Here we're talking about -- you can either have a prescription or a diagnostic referral for a diagnostic procedure involving less than 30 microcuries.

This one says that -- ensure that you have a diagnostic referral for your diagnostic procedures. It gives them the option, of course, of having prescriptions for the same, and anything under 30 microcuries, we're saying diagnostic referrals are okay.

MR. WHATLEY: Real quick, my personal comment is that I do not agree with the diagnostic-referral concept.

MR. TELFORD: You made that point earlier. We understand it.

Okay. Thank you.

No debate.

Roland?

MR. FLETCHER: I'm just looking at the footnote again.

MR. TELFORD: That footnote occurs in both (2) and

(3), and it says if you have an emergency, please go ahead, do the procedure, and write it up later.

MR. FLETCHER: I'm just trying to think of --

MR. TELFORD: An emergency case for a diagnostic --

MR. FLETCHER: Yes.

MR. TELFORD: Maybe a car wreck and you need a lung scan.

MR. FLETCHER: As long as there's some mechanism to ensure that what was done is recorded and reviewed by a physician.

MR. TELFORD: An authorized user?

MR. FLETCHER: Right.

MR. TELFORD: Okay.

MR. FLETCHER: I'm a bureaucrat. I'm in favor of writing things down. Word of mouth just -- especially if you're talking about an emergency in this case, where everybody is kind of in a high state of activity, things can be done improperly, through no mis-intent or mal-intent, just done improperly, because they are having to be done so quickly, and I think those things need to be recorded.

MR. FRAZEE: As it says.

MR. FLETCHER: As it says.

MR. FRAZEE: It doesn't say beforehand, but --

MR. FLETCHER: Well, if it's an emergency, I don't

want that to take precedent over the health and treating of the patient, but as soon as possible thereafter, yes, before everybody forgets what was done.

MR. BOLLING: You know, I'm wondering if we shouldn't consider changing or deleting "prescription" and put in there "requisition" or something that has that connotation, because "prescription", I think, in the medical community means I am the doctor, I'm going to write it on this little piece of paper, and the first person that I give this to is going to make sure it gets done. It doesn't mean that the first person I give it to is going to question it, whereas a requisition does have that connotation, a request for a referral.

MR. TELFORD: That's a good point. You need to bring it out in a later section.

MR. BOLLING: In the medical community, among the technologists and the physicists that one is a directive for action and one is a request for consideration.

MR. TELFORD: All right. Let's discuss that when we get to definitions.

I think it's Terry's turn on number three.

MR. FRAZEE: I think a written prescription, a written record, again, is reasonable -- at least there is an escape clause for emergency scans and the 30 microcurie quantity -- I mean, apparently, it is a standard amount for

most of the thyroid studies.

MR. TELFORD: You said record. This is --

MR. FRAZEE: Well, it is something that is written --

MR. TELFORD: It's beforehand.

MR. FRAZEE: -- beforehand so that it is not misinterpreted.

MR. TELFORD: Okay.

Let's move on to number four, then.

This says ensure that you are doing what the prescription or the referral -- you have to use the referral and the procedures manual together. So, this says that either one or the other is understood by the responsible individuals. This sort of speaks to your internal procedures at the hospital that, somehow, you assure yourself that the individuals know what they are supposed to do.

MR. WHATLEY: I assume that a responsible individual might be defined in the manual that they wrote, is that correct?

MR. TELFORD: That was my first question.

MR. WHATLEY: Well, responsible individual means anybody involved, especially the technologist.

MR. TELFORD: Or, in the point that you brought up, the physician. Perhaps you are right. Maybe we need to

ensure that those people are defined in the critical procedures manual because that is sort of a list of authorized individuals. Okay. If we assume that, then you are stating agreement with it that it is necessary? Good for something?

MR. WHATLEY: I will agree very much.

MR. FLETCHER: I guess my only question or hesitation is ensure that the procedures manual is understood by the responsible individuals. Now, what mechanism, and by whom, is the assurance that it is understood, how i that going to be?

MR. TELFORD: Well, we are placing that responsibility on the licenses. So this comes to the nuclear physician, the department chairman for diagnostic studies. That authorized user physician has to approve of the clinical procedures manual.

MR. FLETCHER: I guess I am going back to the situation in Texas where the technician didn't understand the difference between this and that in a -- Like you said, the medical community doesn't like to have things written step-by-step, but some comment about this evaluation or, at least --

MR. TELFORD: Oh, maybe in the guide what you are searching for is something in the guide that explains what would be what we intend the licensees to do before they

should be willing to say this person knows what they are supposed to do.

MR. FLETCHER: You ask almost any trainee almost anything, after they have been through say a few weeks, say, do you understand, they say sure. Then you put it into practice and it's not quite what you thought they meant. That's my concern, that's all.

MR. TELFORD: I think that's a good suggestion. We could do that on the guide. When we get to the audit paragraph, that's a built-in feedback so then the licensee management is responsible for saying their QA program is sufficient from before.

MR. FRAZEE: I agree that the reg guide is the place to expand upon and define, give examples of what you mean by ensured, what types of things are in the QA manual, what is meant by responsible individual under the supervision of, that's the place to include those kinds of detail which, depending upon the state, can modify it for their own practice.

MR. WHATLEY: I think what Terry means is if a state wanted to modify and add on requirements, they could. The final rule, upon approval by the Commission, will be a matter of compatibility.

MR. TELFORD: That's the rule though. Where does the reg guide fit into that? Is the reg guide also a matter

of compatibility?

MR. WHATLEY: No. Interpretation of the misadministration rule is a matter of compatibility, I assume, isn't it?

MR. FRAZEE: Yes.

MR. WHATLEY: And that's what a reg guide is, isn't it, interpretation?

MR. FRAZEE: Misadministration? No, that's a rule.

MR. TELFORD: Currently, we have a reporting requirement in 35.2. It defines six events and says these are misadministrations. If you have one of these, report it.

MR. FRAZEE: That's is what is a matter of compatibility.

MR. TELFORD: It's how --

MR. WHATLEY: How you interpret that is a matter of compatibility. You must interpret it the same way NRC does.

MR. FRAZEE: Give me an example. I am not sure what you mean.

MR. WHATLEY: Radiation exposure limit of 1250 milligrams.

MR. FRAZEE: Oh.

MR. FLETCHER: You could go one step further as

the agreement states.

MR. TELFORD: The definitions, the QA rule and the final reporting requirements will all be a matter of compatibility.

MR. FRAZEL: I guess I agree with Kirk. It does become a matter of interpretation when you look at the rule. What does ensure mean, what does responsible individual mean? And NRC will have a reg guide that would say this is what our interpretation is. But, the point I was making is, in any given state, the authorized user physician under supervision means something peculiar to that state then that is how the state would interpret that particular detail. We would still be compatible because we are adhering to the basic requirements that are included in the rule which says to ensure, and we will come close to 100 percent of the reg guide which, although they are not mandatory, everyone knows that they are the next thing to, because the licensee is going to take a look at, well, all right, what's it costing me to implement this thing lock, stock and barrel versus what's it going to cost me to try to come up with something different and convince the regulator.

MR. TELFORD: Except, in this case, in the preamble to the rulemaking, we say this is a performance based rule. We are giving these eight things as objectives to the lead-in paragraph and to ensure, here, means that the

licensee has to have a sufficient program, sufficient to have high confidence to prevent errors, and we have a feedback loop which we will get to in the audit paragraph.

Did that complete number four? Let's go to number five. This just says that make sure that any medical use is in accordance with the prescription or referral in the manual. Basically, this says that the technologists do what you told them to do. In other words, they have to have some internal procedures or some internal mechanism to make this happen.

Kirk?

MR. WHATLEY: I have no comments.

MR. TELFORD: You agree?

MR. WHATLEY: Yes.

MR. TELFORD: Roland?

MR. FLETCHER: Yes, I think the other comments above apply here also. It seems to me that almost any medical use needs to be reviewed by someone. For a prescription, you have got a written note. A referral, hopefully, is in writing. The clinical procedures manual is in writing. As I read that, I almost wanted to say, and is reviewed by, you know. Maybe that's too much, but that's what I felt like adding at the end.

MR. TELFORD: Maybe when we get to number seven, something like that will come up.

Terry, number five?

MR. FRAZEE: Again, reasonable, to ensure.

MR. TELFORD: Okay. Number six. They say identify the patient. The reason, of course that we had that objective in there, it could be considered that it's redundant, but we wanted to err on the part of redundancy here because we see so many mistakes, as Kirk has pointed out, the misadministrations that get reported to Congress. We find a lot of wrong patient events in there.

MR. WHATLEY: A couple of months ago, we had an exact -- there were two men in a doctor's office on an outpatient basis, no arm bands, nothing, who had the same name. One of the men got up and went to the bathroom and the nurse came in and said, Mr. Jones or whatever his name was, come on back. So the guy got up and walked back there. They did the wrong study on the wrong man. I don't know how you prevent that.

MR. FLETCHER: That is one of the worst case scenarios we've seen.

MR. TSE: Possibly it requires two identifications. One is like the name, address, Social Security number.

MR. WHATLEY: Some have them, some don't.

MR. TELFORD: Roland, do you have any comment on number six?

MR. FLETCHER: No. The same comment as always, as long as you designate who is doing this. The onus is put on the licensee and just having the verb there that, to me, just kind of leaves it open, "ensure that."

MR. TELFORD: You want to put in the sentence.

MR. FLETCHER: Well, we have got ensure in every paragraph. You had said earlier on the previous ones that this was based on the licensee and those responsible for handling it. As long as that is clear. You know, make it clear someplace.

MR. TELFORD: All right.

Terry?

MR. FRAZEE: The same comment as usual. This is, obviously, a reasonable requirement. Again, you know, we have to define what "ensure" means.

MR. TSE: Roland, who do it would be depending on the institution. They may assign somebody to do it. Would that be -- should that be in the program? They have a program. That program would say who is supposed to do it.

MR. FLETCHER: It should specify.

MR. TSE: Right, but should not be in the regulations, should it?

MR. FLETCHER: We probably don't need to be that specific, but I think in your (a) maybe, someplace in there, you describe the overall basic assurance program by

indicating that they designate by name and position who is responsible for carrying out all the rest of these things, and that leaves each hospital -- whatever their QA program, whatever their written program is, they can designate by name and position those individuals, and there is no doubt, then, who is responsible for that.

MR. TELFORD: Okay.

Now, in case of an inspection, then, you could tell the inspector to check up on who actually did those things, and see if their QA programs were followed.

Okay. Good idea.

MR. FRAZEE: Is that more in line with a reg guide, as opposed to a prescriptive requirement?

MR. FLETCHER: In that particular case, I would like that to be a requirement of the basic program in here as a rule rather than as a guide. I don't think there should be a guide that you may or you should appoint an individual by name and position. I think that should be a rule. You must appoint an individual by name and position. I don't think that should be an option.

MR. FRAZEE: If someone leaves or they go on vacation or there is a change in personnel --

MR. FLETCHER: The licensing process virtually requires that anyway. I don't think I'm saying too much different from what's required now, except that for these

things that we're specifying, I don't there is any harm in repeating that responsible individuals need to be designated.

MR. TELFORD: Do you see any problem with that, Terry?

MR. FRAZEE: I guess I don't have a "well, this is wrong because". I don't have that kind of a feeling about it. It's just that it's like, oh, crud, this is going to be another thing that the medical community is going say you are infringing upon the practice of medicine, because we want the latitude to change or alter who the person may be from time to time, and if it says that in the rule and if it's allowed to be changed on an ad lib basis --

MR. FLETCHER: Well, I don't think we would preclude changes.

MR. FRAZEE: This plan -- this QA program is submitted as part of the license application, and therefore, all of the sudden, that name and position is locked into a license. Does that mean, therefore, that when they have to change, they've got to scramble and come back in for a license amendment to change that name?

MR. TELFORD: No, no.

MR. BOLLING: I wouldn't put it that way.

MR. TELFORD: You wouldn't put it that way. But I think what Roland is suggesting is that their QA program

name the people and the positions that are responsible for doing these jobs. They could name multiple people for each job, and they certainly have the authority to change their QA program, by substituting names, when somebody goes on vacation or gets sick. It wouldn't require a licensing amendment.

MR. FLETCHER: You wouldn't expect there to be, once again, a great deal of difference between those designated on the license as, you know, those permitted to use the radioactive materials operating under the supervision. If these people change, you do an amendment. I don't see that as being an unnecessary or such a heavy requirement that the medical community will say, hey, we can't do that.

MR. FRAZEE: Under the supervision of a physician named -- "under the supervision of" is not named. It's just one line that says radioactive materials shall be used.

MR. TELFORD: Yes, but that's for any kind of jobs -- any administration of any radiopharmaceutical material. That's sort of carte blanche. What I think Roland was saying here is that we're giving out certain jobs, certain responsibilities in our objectives here.

While the licensee would have a written program that says what is going to be done in order to meet this objective, Roland suggests they give the person's title

that's going to be responsible for that, so that you as an inspector would know who to ask.

MR. FLETCHER: I guess that's what I'm looking at it from, from an inspector's perspective. You know, we've got all these things the program is to ensure. We go in and the licensee says we have ensured these things. I'd just like to see some verification of who did the ensuring and how.

MR. FRAZEE: I think you need to know what are the areas that they are ensuring and that they have designated an individual for those areas. All you need to know is what areas are they ensuring, and so, when you walk in the door as an inspector, you say okay, show me your QA program. Then you look at, okay, who is the individual that's designated to do this, and that's when you verify it.

That, to me, is reg guide material, not a directive here that says thou shalt name an individual.

MR. TELFORD: In typical licensee plans, you would see a physician title. You wouldn't see a person's name. That gives them the latitude of hiring and firing, without having a person's name being changed. It's just easier for them.

MR. FLETCHER: I would go along with position title. Programs don't ensure anything. People ensure. I guess that's the bottom line I'm getting to.

MR. TELFORD: Okay.

Let's see. Let's go to number (7).

Number (7) says that, first of all, identify unintended deviations from either prescription or the referral in the manual, and you evaluate it in some sense.

So, we're setting this up for the audit. We visited Johns Hopkins, and for all of their therapy procedures, they have a -- say, in -- for teletherapy, they give multi-day exposures. The whole plan is laid out, and each day, the physician comes by and puts their initials down as to their keeping track of the plan and so, they're keeping track daily.

So, this would be what we would mean by a deviation that's been identified. The physician could say I see it; it's no big deal. In the case of teletherapy, they could increase or decrease the next day's dose within a margin that we give them. But in particular, the intent here is to say their records would identify these deviations, so that, come audit time at the end of the year, you could see if it's important or not, if you have a bunch of little ones or you have a few big ones or just what the case is.

Kirk?

MR. WHATLEY: I support it.

MR. FLETCHER: I concur.

MR. FRAZEE: Same.

MR. TELFORD: Are you guys getting easy on me here? We're just getting started.

Okay. Number (8). For brachytherapy and teletherapy, just follow the prescription. That's what this says.

Kirk says yes?

MR. WHATLEY: I say yes.

MR. TELFORD: And Roland?

MR. FLETCHER: Yes.

MR. FRAZEE: Yes.

MR. TELFORD: Okay.

MR. WEBER: John, I have a question.

MR. TELFORD: Yes.

MR. WEBER: How is (8) different than the collective views of (2), (3), and (4)?

MR. TELFORD: Number (8) says "treatment planning". See, for brachytherapy and teletherapy, there are usually fairly elaborate treatment plans that have to be defined, which has to be done before the patient can be treated. So, it's an elaborate calculational procedure that has to be done and has to be done correctly that's on and beyond the prescription, over and above the prescription.

MR. WEBER: I didn't mean (3) and (4). I guess I meant (2) and (5). Number (2) is be sure there is a

prescription; (5) is be sure that the use is in accordance with the prescription.

MR. TELFORD: Okay. That could be radiopharmaceutical therapy. However, if we had stopped at (5), it would not necessarily say anything with respect to the treatment planning. It doesn't specifically call it out. So, the intent for number (8) is to specifically call out treatment planning, because like in the Cumberland event, that's where the mistake was made, was in the treatment planning, in a computer program.

So, if we didn't have a number (8), we wouldn't be requiring the licensee to specifically address treatment planning in the QA program, and in my opinion, it would be big hole.

MR. WEBER: Thank you.

MR. TELFORD: Let's come back at 11:35.

[Recess.]

MR. TELFORD: Is everybody ready to roll?

Okay. We're up to the audit paragraph which is (b)(1). Our intention here is to have the licensee conduct an annual audit to verify compliance with all aspects of the rule or their program. Licensee's management shall evaluate and determine the effectiveness of the basic quality assurance program and promptly make changes that will prevent reoccurrence of errors.

In other words, if they have a problem that's occurring in their hospital, they need to fix it to prevent reoccurrence, they should do so immediately. They don't need our permission and there's a record of the audit and of the management evaluation, particularly finding that their program is effective and sufficient.

This is intended to be a feedback loop to let them comply with paragraph (a) and to iterate until they have achieved high confidence.

Kurt?

MR. WHATLEY: I basically support it. My question is, how do you envision a small one-physician clinic meeting this criteria -- performing his own audit himself? Would that be sufficient?

MR. TELFORD: Well, the guide will talk to that. To the extent that the guide would say that it's preferred that somebody who didn't really do the work to audit it. I mean if you had an -- you do not have to bring in an independent outside auditor but if you -- there was one doctor that's on the QA committee for the American College of Radiology and he said that in his practice, he has a number of technologists and every month or every quarter, he will designate one of the technologists to do an audit.

He says it's basically an audit of himself, of the boss, he says, and to make sure that things are being done

correctly, that he's not short-circuiting the system, that he's not taking short steps which he should not be doing and it's also to check on everybody else. So one technologist in this case could do all the audits.

Or, if you have two hospitals that are nearby, maybe they could exchange RSOs and they could do audits that way. It's meant to be fairly flexible but in the case of the one-person show, that's a little more difficult because that person has to make sure there's an audit, make sure there's a management finding which is that person and make sure there's a record that all that happened. It's kind of like a meeting of the board of directors.

They may have to seek assistance. They may have to get somebody else's RSO or technician, technologist, to come in and help them do the audit. We haven't definitely said that you can't do your own audits. We have not said you have to bring in an outside auditor but it does look real suspicious if the same guy's doing everything. That might not be acceptable.

Roland?

MR. FLETCHER: As overall guide, I think -- I have no problem with it. Perhaps because Cumberland is so fresh in my mind, the 12 months as an agreements date, we might even shorten that. My problem would be if something is wrong and if you don't audit once every 12 months, you may

go 12 months not knowing that thing is wrong. That's my only problem with that. Otherwise --

MR. TELFORD: Would you recommend to us that we have shorter intervals?

MR. FLETCHER: Well, I was thinking about it but I'm looking at it from my perspective and our recent experience and I wouldn't way to say impose that apprehension on everyone who may not have had that kind of experience or may not even have counted it and as the agreements state, I can go further than this individually.

MR. FRAZEE: I agree with the concept, again because of the variety of institutions, I don't feel that any more frequent than 12 months would be justified. We have the latitude to shorten it ourselves. You're very careful in choosing your words and there are two in here that I'd like you to embellish upon. One is "comprehensive audit" and the other is "auditable form" or part of the record.

What are you trying to prevent by specifying those?

MR. TELFORD: Our intent of saying comprehensive audit is that the audit cover all aspects of the program. It's exhaustive. You don't just say oh, I'm going to audit this half. You audit all parts. That's what I intended to say.

MR. FRAZEE: You're talking about breadth, covering all the aspects as opposed to comprehensive being in depth.

The audit of all elements of the basic QA program at intervals not greater than 12 months. Comprehensive to me implies a good job and I think the licensees would react to it, the task that you are --

MR. TELFORD: Well, maybe we should say in the reg guide like under (a)(7), you've identified all of these unintended deviations in the audit, look at all of those, review all parts of your program to make sure that your program is still effective. That's -- by saying "all parts" that's the intention here of comprehensive.

MR. FRAZEE: An audit implies that the basic program is alive and well and functioning and they are finding mistakes as they go along and they are correcting them. An audit is merely to come in and make sure, double check, that in fact the program is working well.

MR. TELFORD: Well, it's an annual assessment. It's once every 12 months you stop and you say let's review the last 12 months, how well is our program working and is it working up to our expectations? Is it working as well as last year or the year before? Are we at least -- are we staying where we are or getting a little better? Are we going downhill?

That's the responsibility of management in their review to have a finding that the program is sufficient.

MR. FRAZEE: All right. Back to the word "comprehensive." I think I have a slight problem with that. Conduct an audit of each aspect of the basic program, what do you call these, aspects?

MR. TELFORD: These are objectives.

MR. FRAZEE: Each objective.

MR. TELFORD: The licensee is to have a program which addresses all of these. So maybe we should say something like "audit all aspects of the program," a particular address all of the unintended deviations, causes thereof.

MR. FRAZEE: What is an auditable form?

MR. TELFORD: That means you -- I think that's a legal term. It basically means it's a record that's available and I can read it as an inspector.

MR. FLETCHER: Not a PC disk or something.

MR. TELFORD: If you give me a printout. The disk is okay but give me something I can read. If it's a fiche, a microfiche, either have a viewer for me or give me a printout. Don't tell me the dog ate it. Don't tell me that the --

MR. FRAZEE: You want hard copy.

MR. TELFORD: Yes. Don't tell me that it decayed

such that it's no longer readable.

MR. FRAZEE: Right.

MR. TELFORD: Actually, I believe there are some OMB requirements. Didn't our office of administration have a rule on the content and the format and the degree or quality of all the records? It seems like I remember that about two years ago. What they're basically saying is you have to have a readable record. You can't allow it to decay in any sense so that it's no longer usable.

MR. FRAZEE: All right.

MR. TELFORD: Okay, that's all the comments on (b). I would suggest that we go to the definitions now.

MR. WHATLEY: You're going to skip over (b)(2)?

MR. TELFORD: Unless you'd like to say something about it. Go ahead.

This says licensee may make modifications with NRC approval if there's any doubt that it may decrease the effectiveness of the program. If you're sure it's going to be an improvement --

MR. FRAZEE: We would receive the information either in advance or after the fact in 15 days. Therefore, we would presumably look at it, evaluate it as to whether or not it does make a significant decrease or potentially decrease the effectiveness of the basic program and if indeed they follow through within 15 days, we still have

ample time to come back and say hey, wait a minute. You can't do that. Change it back. Or, come in with a better idea.

MR. TELFORD: So there's two people. One would be the licensee and the other is the regulator.

Anybody else want to say anything on (b)(2)?

MR. FLETCHER: I guess I have just a basic concern about being notified 15 days after and maybe having to say change it back when, if I'd been notified 15 days prior or 30 days prior, you wouldn't have to institute it and then go through a change and those individuals who might have been affected by that change would not have occurred. Our procedures normally have let us know ahead of time what you're going to do. We'll talk about it. You can argue your point and then we'll make a decision. Then, it makes it a lot easier. I don't have a strong concern but that is my concern.

MR. FRAZEE: A licensee is not going to do something that is so radical that it would impinge upon any of these basic objectives. So I don't think this is out of line.

MR. TELFORD: Jack, I think I'll ask you to put this in perspective because they have to have the program. They have to meet the objectives. They have to do the audit.

MR. FRAZEE: It wasn't strong.

MR. TELFORD: Maybe the answer is that in each state you could tighten that up but if you want to recommend to us that 15 days is too long, maybe it ought to be 5 or maybe it ought to be before the fact, we'd listen to that too.

MR. FLETCHER: I don't have that strong an objection.

MR. TELFORD: Okay. Like I said, if within our state we feel that we need to do something, I'll go back to that.

Is there anything else in 35.35 that anybody wants to speak to?

[No response.]

MR. TELFORD: Okay. Go to "Definitions" then. That's at page 1442. Page 1447 -- excuse me.

Okay. Shall we take "basic quality assurance" first? This is sort of standard definition that's got a few key words in it. So, you apply it to medical use.

MR. FRAZEE: Prevent the occurrence of any error?

MR. TELFORD: Well, let's take this in turn.

Kirk?

MR. WHATLEY: I don't have any comment.

MR. TELFORD: Okay. It's okay to you? I mean you understand it?

MR. WHATLEY: Sure.

MR. TELFORD: Roland?

MR. FLETCHER: I had a thought when he said "any", but in the context of these regulations, I don't think there would be too much doubt as to what kind of error we're talking about.

MR. FRAZEE: We set high goals for ourselves, zero errors.

MR. TELFORD: This is the definition of "basic quality assurance", and the rule says provide high confidence that errors are prevented.

MR. FRAZEE: Zero.

MR. TELFORD: Does "high confidence" mean zero to you?

MR. FRAZEE: The rule says --

MR. TELFORD: Paragraph (a)?

MR. WHATLEY: The design is to prevent.

MR. TELFORD: The second sentence of paragraph (a).

MR. FRAZEE: High confidence that errors will be prevented.

MR. TELFORD: Yes.

MR. FRAZEE: "Prevented" is zero.

MR. TELFORD: The intention of paragraph (a) says provide high confidence that errors will be prevented. It

does not imply zero for an error rate.

MS. BLACK: Is it simply something that if said any -- the occurrence of errors, as opposed to any error? I think the "any" was to include all errors.

MR. TELFORD: Right. The emphasis is different. The connotation of "any", to you, is that it's zero errors. We're trying to say that any kind of error, so maybe just "errors", plural, would make you feel better.

MR. FLETCHER: Or is the word that you're concerned about "prevent"?

MR. FRAZEE: Right. That clearly is the problem. "Prevent any errors" is -- boy, that sounds zero to me. That's absolute. High confidence means absolutely that we're going to zero it out, nothing. That's the way I read it. I think that most who see it will read it that way, and say my gosh, they're really putting a burden on us.

MR. TELFORD: Okay.

MR. FRAZEE: Especially when you get to the enforcement section.

MR. TELFORD: Okay. I hear you. We'll look at that.

MR. FRAZEE: Say we're going for as low as reasonable achievable. I mean let's be reasonable about it. There may be some baseline error rate that we just can't avoid.

MR. TELFORD: Any other comments on that definition, Terry?

MR. FRAZEE: No.

MR. TELFORD: Okay. Shall we go to "Clinical Procedures Manual"?

Does this meet your --

MR. WHATLEY: I support that definition.

MR. TELFORD: We're saying it's a collection of procedures. It's in a single binder. It describes the method and other instructions, precautions, by which the licensee -- meaning any employee that's authorized to do so -- performs clinical procedures, and the manual is approved by the authorized user.

MR. FRAZEE: Okay. Contraindications?

MR. TELFORD: That would be under caution or under precautions. We could have use the word "contraindications". Would you prefer to see "contraindications" in there?

MR. FRAZEE: The reg guide can handle it.

MR. TELFORD: Okay.

MR. FRAZEE: If the reg guide has it, that's fine.

MR. TELFORD: Roland? Does this sound like what you know the clinical procedures manual to be?

MR. FLETCHER: Yes, it does. I guess I get back to my basic "prepared by whom"?

MR. TELFORD: Well, if the authorized user approves it, is that enough?

MR. FLETCHER: Okay.

MR. TELFORD: Because we say "approved by the authorized user".

MR. FLETCHER: Okay. That's good.

MR. TELFORD: Anymore comments on that, Terry?

MR. FRAZEE: No.

MR. TELFORD: Okay.

All right. "Diagnostic event." This comes from the use of the word "misadministration". We were attempting to offer another term, rather than "misadministration", and the word was "event".

So, all this says is that if you have an occurrence, as described in 35.33(a), you have a diagnostic event.

MR. FRAZEE: As far as the current misadministration requirement is concerned, that group of misadministrations means the same. "Diagnostic events" are a new category?

MR. TELFORD: This assumes that you take the six events that's currently in 35.2, take those away, remove those. This is a replacement for those.

So, you will see in the reporting requirements a dichotomy of things we call "even s" and things we call

"misadministrations", and it's more like to the degree of error then we call it a "misadministration" in this proposed rule.

Does anybody have any comments on that?

[No response.]

MR. TELFORD: Okay. That's what I thought.

Let's go to the "diagnostic referral". Now, here is where we say any physician can send their referral, and Kirk has pointed out that this may be a weak point.

MR. WHATLEY: I just personally do not like that definition even being in there. It's just my personal opinion.

MR. TELFORD: Well, let me see if I understand. If we're going to have a diagnostic referral at all, then we probably need to define it.

MR. WHATLEY: No question.

MR. TELFORD: But you would prefer us not to use "referral" at all.

MR. WHATLEY: That's correct.

MR. TELFORD: Okay.

Roland, any comments on this definition?

MR. FLETCHER: Basically the same ones as earlier. I can see Kirk's point on what could happen.

Maybe the definition is just not complete enough, or maybe there's not enough requirements put on the

referral. I don't know. I have some uneasiness about the way it kind of leaves open the fact that there is no check-balance system in here.

MR. TELFORD: Well, this is just the definition of "referral" now.

MR. FLETCHER: I understand.

MR. TELFORD: And Kirk says, of course, the weakness is it's written by a non-nuclear physician, which is true. What we're saying is you have to write the referral ahead of time, it has to be dated and signed, and it has to include the patient's name, the diagnostic clinical procedure, and the --

MR. FLETCHER: Well, as a definition, the way it's use in the other part of the manual, I mean, that covers what it is. I guess I just have some uneasiness about its existence, too.

MR. TELFORD: Well, I think you're saying you have some uneasiness about the whole system of using the referral without some sort of an over-check on the non-nuclear physicians requesting these procedures.

Okay. I got it. Thanks.

Terry?

MR. FRAZEE: Lloyd raised the concept of the term "requisition".

Lloyd, can you tell me how a requisition would

differ from a diagnostic referral?

MR. BOLLING: "Referral", to me, indicates a prescription. Let's see.

MR. TELFORD: Did you mean a requisition in place of the term "prescription"?

MR. BOLLING: Yes.

MR. TELFORD: Okay. We'll take that up next, then.

MR. BOLLING: Okay.

MR. FRAZEE: But a requisition, to me -- I mean I don't know how you define it, but I read this, and this sure looks like a requisition.

The key point is that it needs to be something that's written, and therefore, it cannot be confused, if it's legible.

MR. WHATLEY: It is written.

MR. FLETCHER: Well, would this whole -- the definition, if we pulled it, and in its place -- of course, this is probably going to put the community, again -- alarm the community, but if we indicated that it must be a consult, whereas -- you're not recommending a diagnosis. You're also recommending a second opinion by a trained -- someone trained in nuclear medicine. Make a consult rather that a diagnostic referral.

I think that would address Kirk's concern and

mine, too. But I'm not sure what that would do as far as the ratio of trained people versus the number of physicians who might be making them.

MR. FRAZEE: Doctor in Clinic A tells his nurse or receptionist, phone up the nuclear-medicine department and order this scan. The technician or nurse does that, talks to the technician on the other end, and the patient is scheduled, and off it goes.

How often, how frequently does that sort of a scenario occur? And is that such a -- I mean are there significant problems with that? There is no written instruction that goes from Point A to Point B. They're strictly, hey, the patient needs a liver scan, schedule him, and it's done.

MR. FLETCHER: A consult would handle that problem.

MR. FRAZEE: Now, there's the phone call that occurs from Dr. A to the authorized physician who, then, double-checks the meaning. Do you really mean a liver scan? Okay. Here are the indications. I will ask you about the contraindications. I agree with it. He fills it out, it's done. There is certainly a written prescript. because that is the authorized user.

I just wonder how often we are going to run into a situation where you get Dr. A just phoning in and saying

just do it. The patient just left the office. I sent him over there and I want you to schedule him for an XYZ scan. There isn't even a diagnostic referral. Nothing there.

MR. TELFORD: We are telling those people we want a written referral. Which, you are saying, is tougher than the way the industry works now but it's not tough enough.

MR. FRAZEE: Not tough enough for other colleagues, I guess.

MR. FLETCHER: Well, let's look at it different way. As I said, as far as the diagnostic end of the thing, we really haven't really been doing much in that area. Have you seen specific problems with diagnostic referrals?

MR. WHATLEY: We have always interpreted the concept that an authorized user must prescribe the isotope and interpret the results. That has always been the case of every license that I have ever written. It is in our regulations that prior to the administration of any radiopharmaceutical to a patient that a physician named on the radioactive material license must select a patient -- and he can do that three ways: he can examine the patient himself, he can consult a referring physician or look at the patient's chart. The second thing he must do is prescribe the isotope and the dose to be administered. That can be done through charts, standard procedures set up in the office, and so on. And the third thing is he must interpret

the results. That's always been the way we have interpreted that.

MR. FLETCHER: That, to me, is what a consult does. You know, when one physician, say, does an examination and wants further tests, they usually fill out a consultation form to send you to radiology, to send you to neurology, with instructions to that physician, I suspect so and so, can you verify, et cetera, this. And that second physician who has training in the other area be it radiology, neurology, takes a second look before that patient is given a radiopharmaceutical, et cetera. That's what I interpret a consult to mean. And, to that incorporates what a diagnostic referral would do and it meets your license requirement would be.

MR. FRAZEE: Being from Washington, this may be a strange state, maybe.

MR. WHATLEY: I have always assumed that was NRC's interpretation, when we got into the business. Several years ago when they said in the Food and Drug Administration said it was their responsibility, we continued to do it because we worked hard on that for a long time to get that done.

I think we have got a problem if we go this way and, in my own mind, I have a real problem with -- the big concern right now is nuclear cardiology, where these guys,

basically, want to read films. They say, you know, we are not involved in the day-to-day operation of the nuclear medicine department of this hospital. We have been trying to read films. This is our specialty, now, why can't we do that? But we still require them to go through this radioisotope handling technique stuff, 500 hours of teaching somewhere. If we are just going to allow any physician to call up and send a patient down there, do a scan on him, and if a technician is the only one that does it, I agree with that nuclear cardiologist who questioned why in the world do I have to have that?

MR. FLETCHER: I see his point clearly. I don't have anything to add.

MR. TELFORD: Let's go to prescription, then. Lloyd had a suggestion here.

MR. WHATLEY: We are going to skip misadministration?

MR. TELFORD: We will come back to those. Referral and prescription are kind of related and I didn't want to leave that hanging too long.

Now, we specify in prescription what the information content must be.

MR. WHATLEY: Is this a standard definition from FDA?

MR. TELFORD: No.

MS. BLACK: Isn't that what was brought up at one of the public meetings? One in California, I believe.

MR. TELFORD: The American College of Radiology, for instance, if they were defining prescription for teletherapy they would ask for more than total does, number of fractions and treatment site. They would want to know what's the disease, what's the stage of the disease, what do the lab reports say, what is the relevant history of the disease, what are the physical findings. Their prescriptions go much further into the practice of medicine than what we have. What we really have here maybe should or should not be called a prescription. What we have is a written directive that says write this thing out, date it and sign it. That is by authorized user. And, by the way, it has to contain these groups of information whether it is diagnostic, radiopharmaceutical, teletherapy or brachytherapy. Perhaps prescription was the wrong term to use.

Lloyd, do you mind coming in here.

MR. BOLLING: Yes. Again, I said prescription has kind of a different connotation than requisition. Requisition means consult. It means referral by one physician to another. In fact, it could wind up that referral was unnecessary or perhaps some other kind of a scan rather than a nuclear was needed, maybe a CT scan or

ultrasound, or none at all.

MR. TELFORD: Yes. So that's for diagnostics. But for therapy, we are saying give us a written directive. Even radiopharmaceutical therapy.

MR. BOLLING: Would requisition, from your mind or definition, replace both prescription and diagnostic referral.

MR. FLETCHER: For diagnostics.

MR. BOLLING: For diagnostics, I would think so, yes. As far as therapeutic, from what I understand of the field these days, they no longer call themselves therapeutic radiologists, for the most part, it is usually radiation oncology, kind of a real field unto itself. And the doctors actually physically examine the patients, they look at their charts, they look at their blood work, and they do a lot more than they did years ago which was just to mark the outline of the border to irradiated and check for any unusual reddening of the skin, and perhaps look at some doses on the dose chart. This is a completely new field now, much more comprehensive. There, again, I think we can probably benefit from using the same kinds of terminology that the medical community uses and use words like referral or requisition but I would try to stay away from prescription.

MR. TELFORD: Okay.

I think we left off with Kirk.

MR. WHATLEY: Well, here in this one, my comment is I don't particularly care for "physician under the supervision of the authorized user," allowing that individual who may have minimal training in the use of radionuclides to be prescribing doses to be administered to patients by an authorized user.

MR. TELFORD: Okay. Roland?

MR. FLETCHER: Well, looking at the teletherapy, a lot of the comments you made would be the same ones we would make. We would want to have more required information.

MR. TELFORD: For Maryland.

MR. FLETCHER: Yes.

MR. TELFORD: Well, is this sufficient for our purposes?

MR. FLETCHER: Oh, yes. We could always expand on that.

MR. TELFORD: Well, for C here, for teletherapy, that information content. Is that a minimum content?

MR. FLETCHER: Yes.

MR. TELFORD: Any other comment?

MR. FLETCHER: I am still wrestling with the fact that we can take these definitions as independently as they may be presented. We have to think about ways to satisfy our need to make sure that we don't by-pass the trained

people in both prescription, as is written with this "or physician under the supervision" and diagnostic referral seem to have a road around an established or trained individual and I don't like that. I have problems with that.

MR. TELFORD: Okay. That speaks to the referral.

MR. FRAZEE: I think for the diagnostic studies a referral, maybe one that's oral, is reasonable because the program has been established by that authorized user. For therapy, clearly, a written prescription from the authorized user is needed. So that is kind of going both ways on this one. Easier for diagnostic but, clearly, may be more restrictive for therapy purposes.

MR. TELFORD: Okay. Could you indicate where you would be a little more restrictive or how? I would hate to think that we have a big hole here for therapy.

MR. FRAZEE: A big hole?

MR. TELFORD: I would hate to think that we were insufficient in providing information.

MR. FRAZEE: Well, back to Kirk's comment about "physician under the supervision of."

MR. TELFORD: We understand that. We got that.

MR. FRAZEE: Oh. Okay. That would be how I would make it tighter.

For therapy purposes, authorized user.

MR. TELFORD: Okay.

MR. FRAZEE: As Lloyd was indicating, radiation oncology, the authorized user who is examining the patient, making the diagnosis and prescribing the treatment to be followed.

MR. TELFORD: Okay.

MR. FRAZEE: The physician who is learning, until he has been adequately trained, he is not responsible.

MR. TELFORD: That's a good point.

How about information content for B, C and D?

MR. FRAZEE: I think those are appropriate for the aspects that we are considering which is radiation safety. It doesn't continue on into the practice of medicine. This is clearly radiation therapy and how you are going to apply it.

MR. TELFORD: Let's go back to "misadministration" now.

Yes?

MR. WHATLEY: Has your medical committee given their comments on these terms, your advisory committee? I would think that would be a good source for -- I'm sure you will.

MR. TELFORD: During the public-comment period, we would schedule a meeting with our ACMUI and get their comments on the whole thing.

MR. WHATLEY: They are certainly more aware than I am of what they need to have on a prescription. I would encourage that.

MR. TELFORD: Okay.

All right. "Misadministration". We have defined "misadministration" in the same way that it's defined currently. That is, we give a list of events and say if you make one of these mistakes, you have a misadministration, and when we go through the reporting requirements in 35.33 and 35.34, you'll see exactly which ones.

Does anybody have any comments on defining the word that way? Is it okay?

MR. BOLLING: Do you mean by referring to a reg?

MR. TELFORD: No. What this does is define "misadministration" by example. It gives you examples of the mistakes you made, and it's on the list. If it's on the list, you made a mistake, you have a misadministration. It doesn't really tell you what a misadministration really is. It defines it by example. Is that okay with you?

Kirk says yes?

MR. WHATLEY: I say yes.

MR. TELFORD: Okay.

MR. FRAZEE: It gives you the opportunity to increase the number of examples if you find a new one, and in fact, I have a new one for you.

MR. TELFORD: You do? Okay.

Roland?

MR. FLETCHER: Once again, if we want to be more specific, we can. I mean this just lays the groundwork.

MR. TELFORD: All right.

The next -- actually, let's take both of these together, the "prescribed dosage" and the "prescribed dose".

Both of these speak to the radiation safety of the activity. We just wanted to be able to distinguish between a teletherapy dose and a radiopharmaceutical dosage in our discussions and our requirements. So, we put these two definitions in there so that we would make ourselves clear when we use those terms.

Do either of these definitions -- let me ask a positive question. Are both of these all right?

MR. FRAZEE: I think so.

MR. WHATLEY: I don't have any problems.

MR. TELFORD: Okay.

The final one is, then, "therapy event". Now, that's the analog to the diagnostic event, where we have -- we will see in 35.34 -- 35.34 is all about therapy reporting or recordkeeping requirements. So, we have split that into either an event or a misadministration. So, when we get to 35.34(a), you'll see exactly what -- that's our list.

I note that it's 12:20. We're about 20 minutes

behind schedule, I guess, according to the agenda, which is not too bad.

Would there be any objections to breaking for lunch?

[Whereupon, at 12:20 p.m., the hearing recessed for lunch, to reconvene this same day at 1:20 p.m.]

AFTERNOON SESSION

[1:35 p.m.]

MR. TELFORD: Back on the record.

We're on page 1447. Is everybody ready to begin again?

Okay. Let's go.

What we will do this afternoon is go through the reporting requirements, beginning with 35.33; then go through 35.34; then the draft reg guide, if we want to and if time permits and if you particularly have some comments to make about it; and then at the end, we'll have some individual air time for you to state your summary views or remarks or things you feel strongly about.

35.33 is divided into record and reporting requirements for events and misadministrations, and part (a) here is the part that covers events. So, what we've been doing is just taking off a piece of this, like 35.33(a), then letting each person make comments about it.

So, let's choose 35.33(a), start with that, and start with Kirk.

MR. WHATLEY: I don't have any comments on that one.

MR. TELFORD: Okay.

Rita?

MS. ALDRICH: Well, we've had two meetings with

the AAPM groups in New York State, and they find the whole concept of creating this new class of things called "events" to be unnecessarily complicated.

It seems to us that there are and will be violations under the regulation. We expect any licensee to try to detect violations and, once they detect them, correct them, but I think it's unnecessarily complicated to create an extra class and extra action limits, and I think it tends to blur the overall intent here, where you want people to try and detect important events and set them apart by making them recordable or recordkeeping.

The other comment that was commonly made was that anything requires a record, whether that's kept in or not, that for a diagnostic misadministration or anything for which you're only requiring the record, the record requirement should be simplified, maybe the identification of the patient, description of event, and action taken.

MR. TELFORD: Reduce to that.

MS. ALDRICH: Yes. It would probably be sufficient, and we found, too, when you require things that are extremely detailed, you're sort of setting up a boobytrap for somebody. You know, they could do the detection, make the record, but they don't have all the information in it, so zap, you know, you're in violation anyway, that kind of thing.

So, I think that if you keep the requirement simple and practical, so that people will understand them and implement them, but I do think that creation of the "events" classification historically is a mistake.

MR. TELFORD: Just call everything a misadministration.

MS. ALDRICH: I think that you ought to consider that these are all violations, and that you expect them. You know, we already expect licensees to go looking for, detect, and correct violations. I don't think we need to single out some violations that happen in a medical program and say now these are events, and now we want you to make separate records and do special things. That's all.

MR. TELFORD: Okay. Good.

Roland?

MR. FLETCHER: My comment is probably minor. Basically, you've redefined "diagnostic event", and you've already got that on the page. You would just have to describe those things that you consider a diagnostic event.

Other than that, I don't have anything to add.

MR. TELFORD: Terry?

MR. FRAZEE: I guess I don't have a comment at this point.

MR. TELFORD: Okay.

MR. WHATLEY: Let me add there -- when I said I

didn't have a comment, I meant I didn't have any problem with it.

In support of it, let me just say that several people that I talked to were in support of defining a "diagnostic event" and separating that from a "misadministration". They felt it was a good idea to distinguish between the two.

MR. TELFORD: Let's go on to (b).

Let me just point out that we will have a paragraph for particular record content and notification content, (c) and (d) and (e). So, keep in mind you will have the chance to look at those.

Now, (b) is for misadministrations, and in item (1) under (b), we've got the usual things that we've had currently in 35.2 of the wrong radiopharmaceutical or the wrong sealed source, wrong route of administration, and in (2), that's the 50-percent error; the administered dose is 50-percent different from the prescribed dose.

So, let me stop there, and I could say our intent is to capture what we have now in 35.2.

Kirk?

MR. WHATLEY: I'll share one comment that was given to me by the State of Texas. Cindy Weber called me, and these are her comments from the State of Texas.

She said they still have problems with diagnostic

dose differing by 50 percent and therapeutic by 10 percent. The difference is so insignificant that it does not make a difference. It's too prescriptive.

The example they gave was the difference between thallium doses; doses of radiopharmaceuticals where relatively small quantities are used.

MR. TELFORD: Let me see if I understand this. They're saying that for some diagnostics radiopharmaceuticals that a 50-percent dose -- just because you're 50-percent difference is an insignificant difference, it doesn't make a difference.

MR. WHATLEY: Doesn't make a difference.

MR. TELFORD: Did anybody have a suggestion for what it should be?

MR. WHATLEY: I asked that, and there was not a suggestion. Apparently, the committee from the State of Texas is reviewing his right now, misadministration as far as their regulations are concerned. I can't speak for the State of Texas. This is all that was shared with me.

MR. TELFORD: Do you have comments of your own?

MR. WHATLEY: No, I don't have anything else to offer on that.

MR. TELFORD: Okay.

Rita?

MS. ALDRICH: I don't have any comment.

MR. TELFORD: Okay.

Roland?

MR. FLETCHER: It runs very close to what we currently have in our regulations. So, I don't have any problem.

MR. TELFORD: Okay.

Terry.

MR. FRAZEE: With respect to the 50-percent overage, I know Carol Marcus was referring to the FDA, and they have a misadministration rule, and basically, it says don't bother reporting it as a misadministration unless it kills somebody.

MR. TELFORD: Okay.

MR. FRAZEE: Now, is there a parallel here that -- you know, don't bother reporting anything unless it goes from a diagnostic-range study to a therapy? That is clearly a misadministration. Can we do that kind of a distinction?

MR. TELFORD: Well, when the staff was working on this particular reporting requirement, we talked about various ideas, like saying -- putting in a quantity level -- you know, a dose below this quantity X, don't report. But we ran into difficulty with -- you know, because it's -- both the isotope and the patient's condition and several other factors would have an effect on the kind of reaction a patient might have.

Now, it may be that there is a level, a quantity level that could be used here. The State of Texas is saying even 50-percent different for any of the radiopharmaceuticals that they use, their licensees use, is an insignificant difference.

It is a workable concept, if we could know what quantity we should use and basis for it.

MR. FRAZEE: What's the basis for 50 percent and .0 percent?

MR. TELFORD: Well, right now, it's precedent and 35.2. If we went back further than that, we would probably find that -- or looking back further or looking at the present intent here of having a quality-assurance program and saying how much different should it be before some record is kept or a report is given.

If you look at 35.35 as being a quality-assurance requirement of creating a record that you said you would do a certain job and you did it, you can prove it. Then you could look at the reporting requirements as kind of an error band in which you can operate. As long as we're radiopharmaceuticals, you're within that 50-percent error band. You don't have to keep a record or report.

So, it's kind of a quality-control idea, but at some point, you know, 10, 20, 30, 40, 50, 60, 70, 100 percent, you would say, gee, if I make a lot of these kind

of mistakes, could that be looked at as evidence of kind of a crummy program? Do they need to do a better job at audit time and say -- to look at all these reports and say is there something wrong here and does something need to be fixed?

So, the real short answer to your question is surely there should be a level that would require some recordkeeping and reporting requirements, but the first idea was that -- to look at the consequence to the patient, in terms of the dose received. If it's truly small -- I mean a lot of x-rays get given each year, and those are on the order of maybe 100 millirem.

So, one question that could be asked is if this misadministration results in that kind of a dose -- 100 millirems -- to the patient, should we bother requiring it being reported?

MS. ALDRICH: Am I misunderstanding here? Fifty percent isn't reportable, is it? Fifty percent is just for recordkeeping, right. A 50-percent error, you make a record.

MR. FRAZEE: Fifty percent or over is reportable as a misadministration.

MS. ALDRICH: That's not the way I read it in my copy.

MR. TSE: It is not reportable to NRC.

MS. ALDRICH: Notify management. That's all.

MR. TSE: It's only if you exceed 2 rem or 500 millirem.

MR. TELFORD: It's a report. This report does not go the NRC.

MR. FLETCHER: I thought that also contributed to determining whether the diagnostics misadministration was 50 percent or more of radiopharmaceuticals. That is a diagnostic misadministration.

MR. TSE: That's correct. That may not need to be reported to the NRC. It's really complicated.

MR. FRAZEE: Now it is.

MR. TSE: No. Currently, it's also this way, and the current regulation also says you need to report to NRC if you exceed 2 rem. There's a couple of other items, too.

MR. FRAZEE: By and large, though, the practice of nuclear medicine is sufficiently precise that within a few percentages, they're going to get their dose, and the experience, I think, Kathleen was saying as she went out the door, that like 400 diagnostic events a year, out of a million or whatever it's estimated, that's a pretty good -- pretty low error rate. So, maybe 50 percent isn't such a bad deal, because it's not getting a lot of reported misadministrations.

MR. WHATLEY: Do you have an example of how

misadministration reports have been used to change rules or whatever? How are these reports going to be used? For what purpose are we collecting them?

MR. TELFORD: Well, that's a different question. I don't think we collect these in order, necessarily, to change rules.

One of the things that they're used for is to show that the licensee is doing a good job, that if they're having very few misadministrations, either reported to their management or the NRC, they have an adequate QA program.

On the other hand, if they repeatedly make the same mistakes over and over again, year to year, something must be wrong.

So, the purpose is to be able to audit and/or inspect the licensee and assess their performance.

Does that seem reasonable?

MS. ALDRICH: I'd say if you're talking about a report to the regulating agency, there should be some significance to the event that's being reported.

Have we spilled over now into (d) or have we approached that yet? It sounds like --

MR. TELFORD: I think we're still on (b).

MS. ALDRICH: Okay. Then I'll save my comment.

MR. WHATLEY: Can I just share -- and this goes back to the definition of "misadministration", but it fits

here, also -- a comment from Stuart Rosenberg, and I will quote.

"I believe that the word 'misadministration' should be restricted to situations where the patient's risk increases or their health is jeopardized, rather than utilizing the word 'event'. I think both the medical community and the public would be best served by utilizing the word 'deviation'."

I'd just like to enter that in our record as Stuart's comment.

MR. TELFORD: Okay. "Deviation" instead of "misadministration".

MR. WHATLEY: Yes.

MR. TELFORD: And instead of "event". Okay.

MS. ALDRICH: It sound like he's saying instead of "event" but maybe not necessarily instead of "misadministration".

MR. WHATLEY: I think he's saying "misadministration", yes.

MS. ALDRICH: Okay. Does he mean just diagnostic?

MR. WHATLEY: I don't think so.

MR. FLETCHER: He is replacing the term altogether with "deviation"?

MR. WHATLEY: He specifically referenced 35.33. So, that does relate directly to diagnostic events or

misadministrations. So, without knowing further, I'd leave it at that.

MR. FRAZEE: What about for orders of magnitude differences in dose where it's no longer diagnostic, just therapy? Does he mean to include that as being just a deviation, or is that still --

MR. WHATLEY: He said, "'Misadministration' should be restricted to situations where the patient's risk increases or their health is jeopardized." The word "misadministration" is not done away with, but it's used only where the patient's risk increases or their health is jeopardized. That's misadministration.

MR. FLETCHER: That's more likely to occur in therapy anyway.

MR. FRAZEE: Right. Or a diagnostic dose that got carried away.

MR. FLETCHER: Really carried away.

MR. TELFORD: A thing like a dose resulted -- a diagnostic dose resulted in a dose in the therapy range.

MR. FRAZEE: Right.

MR. TELFORD: How would we define "therapy range"? The concept is clear. You'd have to arbitrarily declare that above this dose, that's therapy, and below it, it's not, and then somebody comes along with a counter-example in the next 2 minutes.

MS. ALDRICH: It sounds like we are on (d).

MR. TELFORD: Well, let's make sure we talk about (c) here. The intent of (c) is that if a 35.33(a) or (b) happens, then the RSO shall investigate, make a record, and notify the licensee management.

Kirk says okay.

MR. WHATLEY: Yes.

MR. TELFORD: Okay.

Roland?

MR. FLETCHER: Yes.

MR. TELFORD: Terry?

MR. FRAZEE: Yes.

MR. TELFOR[illegible]ody says okay.

Now, we're on (d).

Now, here we have to notify the referring physician and appropriate regional office if we've got a fivefold difference where we'd have 2 rem whole body or 1/2 rem -- 2 rem organ, 1/2 rem whole body.

Then we have a content of the report about the licensee's name, the prescribing physician's name, brief description of the event, why the event occurred, the effect on the patient, what improvements are needed to prevent recurrence, and actions taken to prevent recurrence.

The notification of the patient is at it is now. You go through the referring physician, and the referring

physician has to determine if it's a larger impact.

MR. TSE: And in therapy.

MR. TELFORD: Okay. As currently required under therapy misadministrations.

MR. FRAZEE: The organ dose at 2 rem -- isn't that pretty common to have a normal exposure at or exceeding that?

MS. ALDRICH: Yes. I was questioning the rationale for that. We don't see -- we've looked at it, and we just can't see where the rationale for that comes from.

The 2 rem and the 500 milligram falls right in the range of some diagnostic doses.

MR. TELFORD: Okay.

MS. ALDRICH: All MDMs would be reportable. Why would you want to know about MDMs administrations and not necessarily bone scans?

So, if you were going to use a dose-related thing like that, I'd set it well above the normal diagnostic range.

The only one we feel we will take is the fivefold.

MR. TELFORD: The fivefold difference?

MS. ALDRICH: Yes. If somebody suggested tenfold instead, that might be -- but fivefold we can live with. I don't really see, you know, what the exact rationale for it is, but that I could see. But not the whole body and the

organ doses.

MR. TELFORD: Should we not have those, or should we just greatly increase those?

MS. ALDRICH: I think, from our perspective, since we're going to have to apply the same criteria to x-ray, it would be simpler to use something that's -- what we're saying is a fivefold error from the prescribed dosage or a -- what are we calling it? Or misadministration that involves Iodine 131 or 125 -- 125 just to be on the safe side. Because it seems that's really what you're trying to capture here, isn't it? Something that's either grossly overdone, as far as the routine diagnostic radiopharmaceutical or an iodine.

MR. TELFORD: Yes.

MS. ALDRICH: We would be interested in any misadministration that involved iodine in the form of iodide and we would be interested in a report on something that's on the order of five-fold over the intended dosage but then we would feel we would want to take action and investigate. Below that, we wouldn't be doing anything in respond to the report so I think like Kurt said, what do we want the report -- we only want the report if it's something we think is important enough that we're going to be acting on it.

So those are the two that we would keep for use.

MR. TELFORD: This requirement, it says differing

by at least five-fold.

MS. ALDRICH: Right.

MR. TELFORD: From the prescribed dosage or administration of a byproduct material. So you can go either way. It's an "or" statement.

MS. ALDRICH: It sounds as though that's both.

MR. TELFORD: Yes.

MS. ALDRICH: I take it as meaning both. Everybody who read it did.

MR. TELFORD: Yes.

MS. ALDRICH: So we would keep only the five-fold and we would add in anything that involved radioiodide administration in the form of iodide.

MR. TELFORD: At what level?

MS. ALDRICH: Any.

MR. TELFORD: Any?

MS. ALDRICH: Yes.

MR. TELFORD: Any departure from prescribed?

MS. ALDRICH: We think it would just be simpler to do it that way, even if it's an uptake. If they did an uptake on the wrong patient, it could still be significant, especially if it's a relatively young patient, or at least that FDA report that I haven't yet got a copy of, that following the adolescents and children who had diagnostic uptakes of iodide, there seems to be some correlation with

increased thyroid nodules.

MR. TELFORD: That's the wrong patient. What if it's the correct patient?

MS. ALDRICH: Like I said before, I try and keep it simple. I don't think we're going to get many errors like this involved in radioiodide. What's happening now is our licensees know everything is in flux and they tend to be calling us for anything that goes wrong and we -- to my knowledge, we've gotten reports of I think three iodine incidents in the last four or five weeks. One of those was the typical patient supposed to be being assessed for hyperthyroidism was given a therapy dose instead. One was a patient who was getting an uptake and the wrong patient responded to the name and as he said, I think you would still want to report something like that. Anything that involves iodine, I think the jury is still out on how important even a diagnostic misadministration -- I mean an uptake dose could be and we would just want that data.

MR. FRAZEE: At the 50 percent level.

MS. ALDRICH: At any -- I would say we would keep the five-fold error and we would say any misadministration involving radioiodine. Rather than have people try to figure it out and misreporting something we wanted, we'd rather get over-reporting on radioiodine rather than underreporting. We won't be requiring them to make reports

to the patient except with the five-fold. The other would be left up to, you know, review by the Department and if we considered it significant, then we would give it to our radiological health advisory committee. If they considered it to be significant to the patient, then we'd make it reportable to the patient, but I think in this scheme of things, the patient's going to be notified about things that are really probably going to be quite trivial, no impact on the patient, but they're going to think there is.

MR. TELFORD: That depends on the opinion of the referring physician, in this case.

MS. ALDRICH: Maybe. See, we have another complication in New York State. Probably anything that we make reportable is going to have to be reported to the patient because we have a sister agency, Office of Health Systems Management. The patient's bill of rights was amended in January of last year to make it pro-active. Now, the patient must be notified of any change in health status as a result of treatment and if we go saying that something's important enough to be notified, then we have to argue with the sister agency about, well, it must be an impact on the patient's health or why would you want to report it and you can see where that can lead.

MR. TELFORD: Okay. Let's back up to Curt.

MR. WHATLEY: I don't have anything to add to

that.

MR. TELFORD: How do you react to the 2 rem organ and .5 rem whole body?

MR. WHATLEY: One of the things that we had picked up on 2 rem. There are a lot. That was a question we had also regarding the basis for that. I think, 2 rem, if you look in your package insert for doses, that would cover a great deal -- almost anything to some organ.

MS. ALDRICH: We said it would include some thallium, even some tech administration.

MR. WHATLEY: This does not specify the organ though.

MS. ALDRICH: Yeah, any organ.

MR. WHATLEY: You give a dose of technetium, bladder or something's going to --

MS. ALDRICH: No, that's what I said. Even some tech compounds. I think sulfur colloids.

MR. WHATLEY: Sulfur colloid, for instance.

MS. ALDRICH: India compounds, thalliums -- in a lot of studies, thalliums would be over.

MR. WHATLEY: Can you live with 1.3 rads for millicurie? Spleen, 3.4?

MR. TELFORD: So those are two --

MR. WHATLEY: If it's a child, pediatric, it jumps way up.

MS. ALDRICH: Yeah, that's the other thing. That's a whole other category.

MR. WHATLEY: Depends on the age of the child, greatly.

MR. TELFORD: Okay. So we have -- Curt says that's too low and Rita says that's too low. Move to Roland.

MR. FLETCHER: I have to agree.

MR. TELFORD: All right.

MR. FLETCHER: I was just going to say the five-fold -- I think --

MR. FRAZEE: I agree that the organ dose and the whole-body dose are unnecessarily restrictive in terms of defining the reporting level because of what Rita's saying. We're inclined to say hey, you know, if there's something wrong, you report it to the patient. We don't care whether the doctor's trying to protect his backside or not. If there's a problem, report it to the patient. If it's reportable to us, report it to the patient.

Perhaps -- but on the other hand, even a 10-fold variation or deviation in a diagnostic study as Texas was indicating may not be significant. Now, there may be a point to be made about the type or the age of the patient. If this is a 70-year-old man, we've got lots of studies like that, invariably they all come back, I don't think I've seen

a single diagnostic misadministration that's been reported to us where they don't say ep, no harm, no harm. I mean either they're stringing us along or indeed, there's no harm. Unless it's a pediatric patient. If there's a distinction to be made here, maybe that's where it should be made. Maybe it's five-fold for the pediatric patient and 10-fold for everybody else or some such.

MR. WHATLEY: The way this is written now, a dose of sulfur colloid administered to the wrong patient would be reportable under this.

MR. TELFORD: Yes. That's wrong patient.

MR. WHATLEY: Those too.

MR. TELFORD: Yeah. No question.

MR. WHATLEY: Just looking at the dose.

MR. TELFORD: Right.

MR. WHATLEY: However, that patient could be scheduled for some other doctor that decides to give him a -- scan. He gives him the same thing and there's no -- I think what Texas was saying was, what's the problem? Is it significant?

MR. FRAZEE: In this particular vernacular events, so something went wrong. Let the RSO, let the facility investigate it, make a determination, make a corrective action, keep a record of it and only if it's something that's really significant, a large dose, 10-fold or

whatever, okay. Then it needs to be reported because it was significant as far as the patient's health was concerned and then, because it's reported to us, we're not collecting data for data's sake. We should be collecting this information and saying, okay, what can we do about this? Is there a trend? Is there a rule that needs to be changed? Not just collect it because it's interesting and on the basis of what we collect, then propose to do some fine tuning.

We're willing to let the licensee fine-tune their internal quality assurance program up to a point and the point is when they start to really doing damage to patients, then it's our turn.

MR. TELFORD: How do you define --

MR. FRAZEE: Therapy range.

MR. TELFORD: Therapy range.

MR. FRAZEE: I don't know. There are some package inserts and there's information that I'm sure is available on the types of doses that are common from the various agents. Has anybody taken a look at the range, to look at what kind of doses do we expect to see down in the diagnostic studies versus -- hopefully there's a gap -- the kind of doses that you expect from clearly therapeutic uses. If there was a nice distribution, we could cut and establish a threshold for one or the other. That would be the way to do it. Now, I don't know that there is such a study that's

been conducted.

MR. TELFORD: We looked at the therapy doses for teletherapy and boy, the range that you can -- for tumor in this organ, the range is huge -- from hundreds to thousands of units.

MR. FRAZEE: That's fine, but how big is the range from the diagnostic end because that's really where we're trying to save --

MR. TELFORD: If a patient has already had their thyroid out and now you're looking for mets, you give a pretty large dose. That's diagnostic. That's I-131. So you can't say that's therapy range. It's really diagnostic.

MR. FRAZEE: Rita was alluding to just say, hey look, we're interested in iodine. We're going to specifically name iodine. If you do anything funny with iodine, we want to know about it.

MS. ALDRICH: Something else that's come up, as I said, we have to apply these rules in some fashion also to X-ray. There are a lot of X-ray procedures, fluoroscopy procedures, say cardiac cath, where you're looking at 50-R per minute to a small part of the patient's body because you're using high resolution film. How far do you go on that before that's a misadministration? They see white blood cell changes after some of those studies. So we have to use the same standard. We can't make -- just because

it's radioactive material, it doesn't come from another planet. It's the same -- it should be the same benefit risk or risk reportability kind of ratio.

So we keep that in mind. That's why we stuck with the five-fold because it at least makes it relative. You're talking about a patient who's come to have some kind of a study, so you expect some radiation dose. So maybe that would be a place to peg it.

MR. TELFORD: How do you do five-folds for a cardiac patient?

MS. ALDRICH: Well, for example, if the patient wasn't supposed to have that study. Now you know, there's another thing involved, of course. For that kind of a study, probably the biggest risk is the catheterization. It's not the radiation. So that's another thing. We're focusing only on the radiation. When you get over into X-ray, you get into a whole other realm of things. What if the wrong patient gets contrast material? What is the wrong patient gets a barium enema or if the patient -- the wall of the intestine is incompetent and you puncture it or something. It gets really complicated when you try and say I'm going to apply the same standard to everything.

MR. BOLLING: Also, you're dealing with physicians who need only a license to practice medicine. That's all. They don't have to know what an atom is. They don't have to

know what anything else is. Quite often, most physicians from personal experience, have a heavy foot on the pedal of the X-ray machine. They just put their foot down and they keep looking and they just sit there and you're getting zapped and zapped and zapped.

MS. ALDRICH: See, the way it's approached on the X-ray side now is you look at retake rates. So we're not really looking at individual harm to an individual patient. You're looking at the overall quality assurance program. What's your retake rate. How often do you do a study that's not worth it, whether it was the wrong patient or you didn't get diagnostic results. You're looking to optimize and a lot of this regulation is looking just for the error and not to optimize.

So if there was a way that could be built into it, that would be helpful. I don't have a good answer for that.

MR. TELFORD: Okay. I think we are on D.

Did we allow everybody to comment on that?

Okay. E is retaining records. We would like a record of each prescription or the diagnostic referral of the administered radiation dosage. And E(2) says, in essence, if you change your clinical procedures manual you retain the old page for three years. Then 3 is you retain the report of each event or misadministration for ten years. Its content is specified in that last couple of sentences

which we used before. So that's all of E.

Kirk?

MR. WHATLEY: I have no comments about that one.

MS. ALDRICH: Well, we always have a problem with the referral concept. We have a problem with that.

MR. TELFORD: Kirk had a problem this morning on that this morning.

MS. ALDRICH: All right. Whatever he said, I probably would agree with.

MR. WHATLEY: I just said I don't like it.

MS. ALDRICH: We require a prescription. And, from what I have seen, almost every misadministration that NRC has reported involving iodine the missing person in the chain was the physician who was supposed to be the authorized user. And what you are doing here is saying well, this thing that was the cause of a lot of problems in the past, let's recognize it because we know what's going on and, in this case, I think it's a bad move. I think it is moving further and further away from the original concept that we are different from x-ray because we review the credentials of the person who orders the study and we ask for special qualifications and we say that person, because of his special knowledge, can make a benefit/risk judgment for this patient. And once you start saying a diagnostic referral, I believe, personally -- in New York State, we

feel there are far too many x-rays taken. I guess everybody feels that way, FDA, and certainly our Commissioner of Health.

Partly, I think why it's not the case in nuclear medicine is because of this requirement that, you know, you name on the license, you review their credentials and you really are focusing attention on the importance of that prescription and the dose to the patient. So, that is something I feel strongly.

MR. TELFORD: Well, let me see if I understand your point. You are saying that all diagnostic procedures and all therapy procedures should be done under a written directive signed by an authorized user.

MS. ALDRICH: Yes. Now, we realize that, in reality, some of these are not going to be made in advance or they will be done over the phone. But what we want is the concept that that person who is named, or someone who is named on the license, or someone under their supervision or tutelage is responsible for every one of those patients. In hospitals, it is not a problem. You know who is coming in the next day and physicians can look over these things. We have been doing this with private offices too, and it's kind of an uphill battle because everybody knows it's a little different in the country which surrounds us.

We have had physicians cited for not fulfilling

that function. What a lot of them want to do is come in in the evening and read films just like x-ray offices function. And we say, if you come in in the evening and you read films, you can review the cases for the next day, you know, take a look at these patients and if something looks, you know, inappropriate or you know what other studies have shown -- the other thing is that, I think, this takes away from something that we think is important that for diagnostic workup of a patient, there should be some kind of hierarchy or logic tree instead of this you are going to get eight tests, you're going to get all of them today, then will look at them tomorrow, you probably didn't need four of them, but you know, instead of saying first we'll do this, then we'll do that and then we'll do the other thing.

I think the most common thing I have heard in nuclear medicine departments about patients who have been referred for a study and it's not done is because the physician or authorized user determines that the patient should have had another study first or, because they had another study first, that study should be looked at before they go through with nuclear medicine, or that the patient hasn't been properly prepared for the study.

The authorized user, if he has a presence in the department or in his office is going to do that but if you are going to now rely on referrals, all you have -- in New

York, anyway -- is an unlicensed person, technician, taken off the street and given a week's worth of instruction. That's the only thing that stands between the patient and the administration of this material. In New York, we do license x-ray techs but not nuclear medicine techs. That is another distinction I would make. I have been in x-ray offices when I have heard techs on the phone, the call came in that the referring physician wanted this study, this study, and this study and the last one is ultrasound. The secretary took the call but the technician was standing talking to me and she turned around and said, wait a minute, you know, took the phone and said what's the ultrasound for and he said possible pregnancy. The first thing he wanted done was a lower spine. But, you see, that person has some training. This is a very different situation. We can rely on that. Should we? I don't think we should.

MR. TELFORD: All right. Anything else about E? Rita?

MS. ALDRICH: The simplification of the reports from ten years sounds like a long time. I would say three years would be adequate. That is the usual time that you use in your other regulations for keeping records.

MR. TELFORD: Review is three and five.

MS. ALDRICH: Three and five. Well, one or the other than. But I think ten is a long time. It elevates it

to an importance that I think we agree is not really there.

MR. TELFORD: Not there for diagnostics?

MS. ALDRICH: No.

MR. TELFORD: Roland?

MR. FLETCHER: Well, much of what Rita said, you know, we had talked about the definition of diagnostic referrals so I agree with her apprehension in the context of what we talked about earlier. Ten years does seem like a long time.

MR. TELFORD: Terry?

MR. FRAZEE: Okay. I think I am already on the record earlier this morning in sort of the counter position. As far as this particular section is concerned, it certainly falls in line so that if you have all the other requirements that this certainly makes sense. I do agree that ten years is a long time and five is better at any rate. Three years for normal records, is that standard with the NRC?

MR. TELFORD: Three years. Every major hospital will get inspected once a year. Some of the smaller ones, every three years. As a matter of fact, three years may not do it for us because, see, what if you come to a small hospital and you find the problem by auditing the records and you say what are you going to do about this and they tell you and they say, we'll do it. But you come back three years later and the records you looked at before are gone.

It may be something like five or six that we really need.

MR. FRAZEE: Wait a minute. We have a program here that says, Mr. Licensee, you are on your own, you audit your program every year, you keep a record of that and you continue making improvements in your program. We come in and we are going to do an inspection. We check their program, number one, because that's real critical. We will go back and look at the last year's worth of records, the last two years' worth of records, again, we are auditing, we are not looking at 100 percent of the records, our function is to get a feel for this program, is it working.

MR. TELFORD: Okay.

MR. FRAZEE: If they have been good boys in the last year and it looks like everything is progressing normally why would we have to have ten years worth of records, or even three years' worth of records.

MR. TELFORD: You are saying we could rely more strongly on the audit requirement.

MR. FRAZEE: Absolutely.

MR. TELFORD: Let's see. We keep those three years so you would get three years of audited records which ought to be pretty sufficient for judging a program.

MR. FRAZEE: Yes.

MR. TELFORD: Okay. Good point.

Is that all on E?

Let's skip F and go to 35.34. This is a similar structure to 35.33 in that we first start with events. So we will pick up A first and this is a record or report to the licensee management if, number one, you have some material and use it and you are not supposed to have it, is that right?

MR. WHATLEY: No.

MR. TELFORD: I'm sorry. I misspoke. Number one here is therapeutic use without a prescription and a prior review of the patient's case by the authorized user.

We have Kirk's favorite phrase here "physician under the supervision."

MR. WHATLEY: I don't like that. And I will restate that again that I don't think that a physician under the supervision of an authorized user, who may or may not have any training, should be authorized to write a prescription for a therapeutic does of radiation, period.

MR. TELFORD: Okay.

MR. BOLLING: So it should just be authorized user.

MR. WHATLEY: It should be strictly for authorized user.

MS. ALDRICH: In New York, we don't use "supervision", we use "tutelage" and we say that part of the definition of tutelage is that that person who is the tutor

by licensee has to determine that that person in tutelage is receiving all the required training leading to license. We feel it would be legitimate for a person in those circumstances to authorized. Under the supervision of seems to be an open-ended, eternal kind of arrangement when a person isn't necessarily progressing toward being licensed. I think if you had interns or residents -- at some point they are going to have to be ordering studies in order to even sit for the boards, don't they? You know, couldn't swear to that but, at some point, in a program like that, the person does order treatments and then the supervising physician or, in our case, the physician who is tutoring this person, should make regular checks on what kind of treatments have been ordered, whether they have been done properly and whether the patients have been followed up, in other words, if the person is in training progressing towards becoming an authorized user. I don't expect you to change it because you have been using it for a long time but "under the supervision of" is sort of a paper tiger, I think.

As I understand it, the way you would inspect against that you would ask the authorized user if he is responsible for these people. If the person had just made a mistake, I think I know what the authorized user is going to say. But what we are saying is that tutelage should be a

formal program and what we would expect to see in any kind of a training program for radiation oncologists.

MR. WHATLEY: I would have no problem with the physician under the supervision of an authorized doing that, as long as, prior to the administration of the radiopharmaceutical to the patient, you get a concurrence with an authorized user to do so.

MR. TELFORD: Okay.

Roland?

MR. FLETCHER: I think I could go along with concurrence, but you know, in my heart of hearts, my feeling is if there is a need to have, say, a sufficient number of physicians available to administer the therapy procedure, then why not give them all training or get as many trained as you can?

I realize that that's going to require some time, but every time you put down "under the supervision of", everybody has their own idea of what "supervision" means, and people make mistakes. Even people who are trained make mistakes, and I don't like to leave that open-ended supervision out there.

MR. FRAZEE: I agree that an authorized user should either make the prescription or concur with whoever is under his tutelage or under this supervision.

I also would like to point out that this requires

both a prescription and a prior review. A prescription, as defined, is a written whatever by an authorized user or someone under the supervision of, and the prior review is also by the authorized user or physician.

Is this meant as a double review?

MR. TELFORD: No. The prescription means a written direction or order for medical use for a specific patient. It does not necessarily require a review of the records of the patient before you write it.

So, you're correct. In (e), it says -- I'm sorry -- (a)(1), we have both a prescription and a prior review of the patient's case by an authorized user.

MS. ALDRICH: What I was wondering about was the documentation. How would you expect a licensee to prove they're doing this? I mean, to me, that's what the prescription is. It indicates you've reviewed the patient's case and you have made an order.

First of all, we're saying, I think, amongst ourselves that this is either going to be a physician who is named on the license or it's going to be somebody in a training program and that if they write a prescription, that has the force of the person who is writing it, and I take it for granted they reviewed the patient's case, and I don't see how you could prove or disprove that they had done it, except to question people in the department and say did you

see him looking at the patient's folder.

I think it makes it unenforceable.

MR. TELFORD: Okay. So, I think I'm hearing that it's not necessary, because the prescription is evidence that that was done, and secondly, it's not enforceable. So, therefore, it should be taken out.

At least, I have two heads nodding over here. Rita and Terry are saying yes.

MR. FLETCHER: If I know what you just said --

MR. TELFORD: It would be the clause that says "and a prior review of the patient's case".

MR. FLETCHER: Okay. That would be taken out?

MR. TELFORD: I think that's what I'm hearing as a suggestion.

So, the question is should that be taken out?

MR. FLETCHER: I'd take out everything after "authorized user".

MR. TELFORD: Okay. Well, that's a different thrust. See, this is an "and" statement. It says you have to have both a prescription and a prior review of the patient's case.

MR. FLETCHER: But my only problem with what you're talking about, if you stopped after "prescription" in (a)(1) and you go back and look at the definition of "prescription" on 1447 --

MR. TELFORD: No, you don't stop there. You just take that out, and you would say -- what they're saying is without a prescription by an authorized user, and that stays.

MR. FLETCHER: Okay.

MS. ALDRICH: I have one more comment, of course.

MR. TELFORD: Let Kirk reflect on this "and" statement here.

MR. WHATLEY: Well, a prescription has to be written by an authorized user or a physician under the supervision of, and my interpretation of how someone could write a prescription would be it involves an examination of the patient's case by either the patient himself, reviewing the patient, consulting with referring physician, and reviewing the patient's chart.

So, I guess if you look at it that way, it's redundant, if that's understood what's involved in writing a prescription.

MR. TELFORD: Okay.

MR. WHATLEY: So, if that's the understanding, I would support it. I have no problem taking it out. I have no problem leaving it, either.

MR. TELFORD: Do you have another comment?

MS. ALDRICH: Yes. The same reasoning as before -- I think that we're creating another hole. We're getting

into an unnecessarily complicated scheme of what people are going to record, report, and I have talked to at least six physicists who have totally misunderstood this entire thing, even after explaining it to them, and these are not dummies.

I think, again, that these are violati[illegible] ther are or will be, depending on whose regulations yo[illegible] looking at. You're going to require prescriptions. So, any use without a prescription is a violation. We expect the licensee to identify and correct violations. I don't think we need to make a separate category and say we're going to call these types of non-compliances events. I just don't see why it's being done. I don't understand the logic or the need, and I think it just confuses people. It's going to make it hard.

You know, there's a lot going on in therapy departments, and I think you want them to focus on -- you know, if you want certain things reported, you think they're really serious, that those ought to stand out. Not that I expect that there would be a lot of these, but on the other hand, I'm picturing somebody practicing on a day-to-day basis and trying to keep all these things in mind, and it seems like it's not working.

MR. TELFORD: The intent here was to allow the licensee to report back to their management. So, this is an internal report. It doesn't have to go to the NRC.

MS. ALDRICH: But as I said --

MR. TELFORD: Just because these occurred doesn't necessarily mean something bad happened to the patient.

MS. ALDRICH: Oh, I understand that. That wasn't the point.

MR. TELFORD: Okay. I think I understand your point, that it's unnecessarily complicated, but as we go through this, let me accept your point, but do me a favor, and tell me the ones that you would put in paragraph (b), which are misadministrations and which you would have reported to somebody.

MS. ALDRICH: Okay.

MR. TELFORD: Meaning other than licensee management.

MS. ALDRICH: Right.

MR. TELFORD: Okay?

And I think I hear you saying you would keep (a)(1) and have that reported.

MS. ALDRICH: No. What I would say is if you felt you needed to say anything that it would be sufficient to say that the licensee must identify any noncompliance and follow it up and that management is supposed to audit -- regardless of the new audit requirement, management is supposed to audit the program annually anyway and look at all of these things. So, I see that it will be captured.

So, I don't really see what this is accomplishing that isn't already in place or could be covered by saying you've got to optimize your program. Instead of just looking for mistakes, optimize your program. Look at it, you know, regularly, if you want to specify an interval. Look for evidence of a lack of prescription, a lack of daily recording, a lack of weekly chart checks. That's going to be part of their whole quality-assurance program. And identify where people have failed to comply with that and do something about it. That I expect to be part of their whole -- rather than prescribing all of these little individual things.

MR. TELFORD: Good point. If this were part of the audit requirement, to check for this occurrence, you don't need to report. That would be your point.

MS. ALDRICH: That's the way I see it, yes.

MR. TELFORD: Good.

MR. FRAZEE: The only advantage this has is that as you're going along, you're making a notation. I mean not a full-blown, 15-page report, but a notation that we forgot to record the dose, and then, when the audit comes along, you've simplified your audit, because they can sort of a shorthand, quickie look for all the check-marks and notations and make a determination of whether or not they're compliant or how well they're compliant.

Now, the disadvantage to that is they're sort of red herrings. You get out there and you just start looking at the little notations and you forget to got back and look at the detail, but it is a --

MS. ALDRICH: Yes, I can see that. I just would tend to approach it more saying you should be, on a regular basis, looking for noncompliance with all of the aspects of your quality-assurance program and detecting them and seeing that they are corrected, not necessarily waiting for your yearly audit, but your yearly audit is to look at the whole program and see whether you have been doing this.

If you go back at the end of the year and see that records from the beginning of the year show occasional lack of summing of daily doses or a lack of a chart-check or a lack of this, you not only just say we need to correct this, but you're going to say how come nobody has been looking at this? Our quality-assurance program isn't something we do once a year. It's something we do every day.

That's the way I'd like to get them to think. It's something you do every day, and then it's not necessarily because you're Sherlock Holmes looking for things that have to be made reports of or sorted into this category or sorted into that category, but it's just part of your overall program, and you should be looking for those things and identifying them.

MR. TELFORD: Okay.

Shall we go to (2)? This is just the daily recording of the administered dose or dosage.

MR. WHATLEY: I have no comments on that one. That's fine from my point of view.

MR. TELFORD: Would you keep this report, Rita, or throw it away?

MS. ALDRICH: No, I was talking about that whole section. So, I'm finished with my comments, really.

MR. TELFORD: Roland, any comments on (2)?

MR. FLETCHER: Well, I like recording done as frequently as possible, even if it's a check, because your memory gets bogged down in so many things and you go back and try to recapture things and you're more likely to make errors or leave things out. So, I would lean towards requiring daily recording of some kind or specifying a frequency period, so that it wouldn't be left to the end of either an audit period or a -- a yearly audit period or an inspection, some kind of frequent recording.

I'm not sure I understand what "an appropriate record" -- what does that mean to you? I think everybody who looks at "an appropriate record" will --

MR. TELFORD: We didn't want to specify a particular record, because it be wrong for some hospital. We would probably be happy with them recording the dose in

however manner they're currently recording it, or if they're not currently recording it, heaven forbid, they would create a record.

MR. FLETCHER: I would even be willing to have them specify their frequency of recording and let us know what it is, and if we thought it should be more frequent, either by experience or something like that, we could let them know that.

MR. TELFORD: Well, if you go beyond one day, your memory may get kind of dim.

MR. FLETCHER: Right. That's what I was speaking of.

MR. TELFORD: Terry.

MR. FRAZEE: I like Rita's concept. Your quality assurance program, you are doing it on a daily basis. And certainly, requiring that they have a record, daily record, or at least a day of use, a day of dosage, somebody makes the record right away. And if it is on an appropriate form and it is a nice little blank, it becomes really obvious as you go along. You wouldn't even have to make a notation. There would be a blank. It's not a heavy-duty, have to write up a report each time; but it is clear that something has or has not been done as you are going along, which I think facilitates doing the audit in the long run.

MR. TELFORD: Okay. Three is the teletherapy

administration. What we are capturing here is an administered dose that is 20 percent different from the prescribed dose.

MR. WHATLEY: I have no comments.

MR. TELFORD: Rita would delete this. Okay.

MR. ALDRICH: Yes.

MR. TELFORD: We are on Number 3.

MR. FLETCHER: Isn't that a change from what was previously in effect?

MR. TELFORD: Yes.

MR. FLETCHER: By more than 10 percent, from what was previously in effect?

MR. TELFORD: You will see that. You will see several requirements for teletherapy doses below, in Item 3.

MR. ALDRICH: This is in one fraction.

MR. TELFORD: This is one daily fraction.

MR. FLETCHER: I think I could live with that.

MR. TELFORD: Okay, Terry.

MR. FRAZEE: I guess it is back to the significance of this on a daily basis or on an occurrence basis. I guess I really don't have a big problem with it.

MR. TELFORD: I tell you what. I will give you a chance at this one when we get to 3, then you can put it in perspective a little better.

Okay. Let's go down to (b) now, where we are

talking about therapy misadministrations, and records and reports. Reports are required to the NRC, and licensing management, of course.

Now, Item 1 is, is the therapy medical use other than what you stated in the prescription. For instance, you have treated the wrong patient or the wrong radio pharmaceutical, the wrong source, wrong target organ, wrong site, or wrong route.

MR. FLETCHER: Or the wrong level of intensity.

MR. TELFORD: That's dose, isn't it?

MR. FLETCHER: That's dose.

MR. TELFORD: Okay.

MR. WHATLEY: I support that.

MR. TELFORD: Rita?

MR. ALDRICH: That's fine.

MR. FRAZEE: Fine.

MR. TELFORD: Everybody says yes. Okay.

Now, 2 is, this is the radio pharmaceutical therapy, where the administered dose is 10 percent different from the prescribed dose.

MR. WHATLEY: I have already shared the comments from the State of Texas on that, and my personal comments are that I don't really feel I have enough knowledge to know whether 1 percent is good or not.

MR. TELFORD: Wait a minute; let me see if I

understand this. Texas was talking about the diagnostic.

MR. WHATLEY: And therapeutic.

MR. TELFORD: And therapeutic, too?

MR. WHATLEY: About the 10 percent, yes.

MR. TELFORD: So they are saying that a 10 percent error is probably no big deal?

MR. WHATLEY: As I understood her to say.

MR. TELFORD: Okay.

MR. WHATLEY: I received that on the phone, I did not receive it in writing. But it was my understanding that was what she was saying, also.

MR. TELFORD: All right.

MR. WHATLEY: I may be corrected on that.

MR. TELFORD: All right. And you said you don't have personal views on that. Okay. Rita.

MR. ALDRICH: We have had a number of debates on the 10 percent with the AAPM, as it applies to teletherapy as well as radio pharmaceutical therapy. And I can see a better basis for it in teletherapy, because you can find references for certain cancer sites where 10 percent results in a significant change in the tumor control or late radiation effects, but not all cancer sites. But they haven't come up with a better number. So they're going to be stuck with that number.

As far as the radio pharmaceutical error is

concerned, I would be interested in knowing where that number comes from. Is it just because it is the same as the teletherapy, because that seemed like a reasonable percentage; or similarly, can you find references in literature that indicate either a loss of tumor control or a significant increase in side effects at 10 percent? I'm not aware of it, if it is true. I just really would like to know where that comes from.

MR. TELFORD: Yes. One basis for the 10 percent is it is well outside the bounds of what you can deliver, so that the state-of-the-art can do a lot better than that.

MR. ALDRICH: No, I understand that. But --

MR. TELFORD: So it is a clear departure, that something is wrong, an error has been made.

MR. ALDRICH: So it is just set at 10 percent because that is an error that they should not be making?

MR. TELFORD: That would be one rationale, certainly. But if any medical society wants to give us a rationale that says 10 percent or, or no, "and," and above a certain effect or dose on the patient of some quantity, then if they can provide a basis for that, then gee, that may be acceptable, too.

Anything else, Rita?

MR. ALDRICH: Not on that one. Just that I wondered whether the number had any significance.

MR. FLETCHER: I haven't found any problem with that, and we've been using 10 percent.

MR. TELFORD: Yes. It is currently in 35.2.

MR. ALDRICH: I'm aware of that. What I'm asking for is really is there --

MR. TELFORD: Is there a better basis for it than that?

MR. ALDRICH: Is there, like I said, is there a radio-biological basis for that number? That's the number that we've had with the AA Board, that they have had with us, I should say.

MR. TELFORD: Did we skip Roland?

MR. FLETCHER: I said 10 percent is fine. I don't have another number.

MR. TELFORD: Okay. Terry.

MR. FRAZEE: Likewise, I don't have another number. Ten percent is, I think, certainly achievable with the current quality of dose calibrators on the market. And as far as Texas was concerned in their comment about 10 percent doesn't make any difference, they are probably right. If you're already dosing a patient, and there is, well, you are already dosing a patient, and so there is some risk involved already. And even if you were to double the dose, you are doubling the risk. But that patient is already willingly submitting to the risk that they are

taking for the benefit that they are achieving. And of course, typically, these patients are -- typically, not always -- but typically, they are older. And by the time the cancer effect may or may not show up, it may be beyond their normal lifetime anyway.

So from that standpoint, I can see where Texas is coming from, in either diagnostic or the therapeutic range.

So, only because the number is commonplace and because from the technical standpoint it is easily achievable, would we let 10 percent stand. We can do it. If you miss it by more than 10 percent, something has gone wrong.

MR. TELFORD: Okay. Let's move to 3. Now, this is a multipart requirement on teletherapy. And the first one is, the administered dose is 10 percent different from the prescribed total dose. Maybe an example would be useful here. What if we had 5,000 rads over 25 days and the 10 percent would be of the 5,000, so (i) says you have to get 5,000 plus or minus 500.

Now, for any treatment fraction, (ii), that fraction has to be either greater than half of what it is supposed to be or less than twice of what it is supposed to be, for each daily fraction.

And (iii) says that it is a cumulative sum, a cumulative sum as you go along, a daily sum, that if you

have 200 per day and you are at the third day, and you should have been given 600 the patient should have been given 600 so far, and the margin of error that they have to play with is 10 percent of the prescribed total, or that same 500. So at the beginning of the first dose, it is very loose. But as you get further along, it tightens up. No, I mean, if you used up, if you had a margin of, if you missed it by 50 --

MR. FRAZEE: If you miss it by 50 --

MR. TELFORD: -- on the first day.

MR. FRAZEE: -- on the first day, you are out of compliance with (iii).

MR. TELFORD: No. It's 10 percent of the total, total dose, not just that daily dose. See, the total dose is 5,000. So the first day of the dose is 200. So it's plus or minus 500. (a)(3) says 20 percent on that single fraction. So that is where that comes in. So it is 200 plus or minus 20 percent from there. And then (b)(3)(iii) has this cumulative sum as you go along.

So the 20 percent really operates on each fraction until you get further along. But you see, what if you were only -- 200, 20 percent is 40 -- what if you were 40 over for the first 10? Now you ar 400 over. Okay. So you are still not violating (iii) yet, but pretty soon you will be. But (iii) allows you to correct your next day's dose to be a

little bit more or a little bit less, depending upon if you need to.

MR. WHATLEY: Again, I just don't feel confident in commenting o whether or not these numbers are significant or not. Let me share a comment by Stuart Rosenberg on 35.34(b)(3)(ii) and (iii). And I quote. He says: "If these errors can be compensated for, they should be classified as an event or deviation."

MR. FLETCHER: Can or can't be compensated for?

MR. WHATLEY: If they can.

MR. FLETCHER: If they can be compensated for.

MR. TELFORD: Yes. Like on (ii) i you are given a single fraction, and it is only one half or less of what it is supposed to be, this comment says if that you can make up for it in the next several days worth of doses, it ought to be an event, not a misadministration. Correct?

MR. WHATLEY: That's correct.

MR. TELFORD: Any other comments?

MR. WHATLEY: That's all we have for now.

MR. TELFORD: Rita?

MS. ALDRICH: If I believed in events, I would agree. But I think again it is unnecessarily complicated. It is amazing the number of physicists who get thrown by that (iii). They expect there to be some internal logic to this, and there doesn't seem to really be, it just seems to

be regulatory fine-tuning.

I think that what you really want is if the 10 percent is the only number that anybody can come up with, you want the 10 percent. Anything that exceeds the 10 percent of the final prescribed dose, you want that reported.

Other than that, I just think you want a simple requirement for something that relates to the fractional dose, whatever kind of logic you want to apply to it, just one requirement, instead of this, you know, complicated series of things.

What we have done is say we would like to know if you exceed 50 percent, plus or minus 50 percent of the fractional dose. If there is an error like that --

MR. TELFORD: That is (ii).

MS. ALDRICH: No. Yours is 100 percent.

MR. TELFORD: Excuse me. Excuse me. You are right.

MS. ALDRICH: So you could keep that. I don't know.

We took 50 percent because, and we haven't got that as being reportable to the patient. It is one of those things that is reportable to us, and then we will refer it out to our committee and ask them whether or not this is significant enough that the patient should be informed about

it, because it has come up in the misadministrations that we have had. We have had patients that received double dose for a period of time. They didn't exceed, they didn't ever get the full dose. We had a patient fairly recently -- it wasn't [illegible]alt, it was an accelerator patient -- that received twice the intended dose for six treatments. So that certainly would have been reportable to either you or me.

MR. TELFORD: And what happened after the six doses?

MS. ALDRICH: That's when they caught the mistake. They did a weekly chart check. And by the way, that dose was doublechecked. The dosimetrist made a mistake. The second dosimetrist did an independent calculation. And it was caught by the original dosimetrist in the weekly chart check of the week that followed. So it was about the sixth treatment that it was caught.

It was a stupid mistake. And a comment that was made by someone in the regional office where it happened in health systems management made a comment that stupid mistakes are the ones that are easiest to make. I mean, they are the ones that are most common.

MR. FLETCHER: The ones you can't legislate against.

MS. ALDRICH: Yes. You just want to catch them.

And so they did both things. They did a double check and they did the chart check. And that second level caught it. So I think that is a heartening thing. So that if you have some redundancy in the system, it is a good thing. You are going to be more likely to catch it. A second check isn't necessarily going to do it.

But anyway, that, and the previous, the series of misadministrations we had, there are a couple of patients, more than a couple of patients where the final dose was where it should have been to the organ, or much less than, because treatment, in this case, for example, that patient was terminated at 1,800 rads; the original prescription was for 3,000. So he wouldn't have exceeded, they would not have exceeded the 10 percent, and we would not have heard about it. I haven't run through your calculation here to see whether it would have met the (iii). But it certainly is something we wanted to know about.

MR. TELFORD: They received double the dose.

MS. ALDRICH: They received half, they received 1,800 total rads.

MR. TELFORD: Oh, but on each single fraction it was double. That would be here, this would be (a) --

MS. ALDRICH: Except the treatment, what happens then is, of course, the physician says oops, an error has been made and we have to change the prescription.

MR. TELFORD: Yes.

MS. ALDRICH: And in some cases, if the deviation wasn't that great, like Kirk said, quoting Texas, I guess, you can make it up and it is not going to have an impact. But as the dose gets further and further out of line, as your fractionation schedule changes, you could easily have an impact on the patient, much more serious than the 10 percent overall.

So that is what we wanted to capture and I assume that is what you want to capture, too. I just think that this is unnecessarily complicated. I would set one reporting level for an error in fractional doses and require that.

MR. TELFORD: One for total, one for fractional?

MS. ALDRICH: Yes. And as I said, we don't make the fractional automatically reportable to the patient because in some instances it isn't going to be all that important.

MR. TELFORD: Okay. Roland?

MR. FLETCHER: I can see, as Rita has indicated, some degree of confusion in fact, to deal with dosage. I guess in a way I have been fortunate. The misadministration case we had was a 75 percent error and we didn't have to worry about this level of specificity.

I am a little concerned that this is, either the

explanation needs to be made clearer, or I know what is meant, and I was just trying to do some little doodles here, but I can see that this could cause some confusion in the community. And I think it needs to be clarified. I am in full agreement with the intent. But I think the presentation needs to be cleaned up a bit.

MR. TELFORD: Okay. Terry?

MR. FRAZEE: Yes, I agree with the previous statements.

MR. TELFORD: Okay. Off the record for a minute.

[Discussion off the record.]

[Brief recess.]

MR. TELFORD: Let's commence.

That means we are on (b)(4). This is the home stretch. Take a deep breath. This is the brachytherapy administration, where the sealed source is leaking or lost or unrecoverable during the treatment

MR. WHATLEY: How would the source get lost? What do you mean?

MR. TELFORD: Temporarily lost. Lost in the patient. You put in so many seeds, but you only took out N minus 2. There's two left in there.

MR. WHATLEY: Okay. I just had a question, that's all.

MR. TELFORD: It could be lost in the room, and

you don't know that it is lost in the room, so you check the patient to prove it is not in the patient.

MR. FRAZEE: You implant 10, you pull out nine. Did you lose it before you implanted or after you implanted?

MR. FLETCHER: Are you sure you implanted?

MR. TELFORD: Right. Is this something that should be reported, might be a question?

MS. ALDRICH: When I read it I thought it sounds like things that are already reportable. Leaking sources are reportable, whatever the circumstances, and lost sources are reportable.

In fact we had something sort of similar to this. We had a case where a patient had a breast implant, iridium seeds, and pulled off the dressing, and threw away the gum wrapper, as she described it, and the gum wrapper went into the waste and the waste went to the dump and we didn't get called until they wanted to bury it. And meanwhile, the radiologist removed the rest of the seeds and counted out exactly the number she put in.

So I think that is what you would find happening here. We got the report because there was lost material. Meanwhile, the radiologist was merely filling out the log as though all of it had been recovered. And I won't go any further. But I think that is more likely to happen, that we are going to get a report because they have lost track of

material. And I would leave it at that. Again, I guess my feeling is that the reg. should be simplified wherever possible in that.

MR. TELFORD: Meaning you would take this out?

MS. ALDRICH: If we are required to write a report for a sealed source already, if they have a sealed source that is involved with brachytherapy, they are going to run to the phone, really. Nobody is going to try and keep that from being reported.

MR. TELFORD: Roland?

MR. FLETCHER: Well, I guess in following along with what Rita is saying, you could probably make a concise statement that any lost, leaking or unrecoverable source should be reported in a manner as prescribed in so and so, and be done with it.

Everything in here is already required. I agree with that.

MR. TELFORD: Okay.

MR. FRAZEE: It is unnecessary, we don't need to have it here at all.

MR. TELFORD: Okay. Number (5) is a brachytherapy administration that is 20 percent different from what is prescribed. Currently, in 35.2, there are six items listed there and number (6) currently covers this, but it says 10 percent, currently.

So the 20 percent here is a recognition that brachytherapy is part art, part science, and there is a certain ability that you have to deliver a dose. And the limit we set, the 20 percent, we wanted it to be well outside the ability, to be clearly distinguishable from that.

Kirk?

MR. WHATLEY: I have nothing to add on it.

MR. TELFORD: Rita?

MS. ALDRICH: The physicists we have talked to are uniformly upset about it. We put the 20 percent in our draft regs knowing that that is what NRC was proposing.

One of them, as an example, gave me an actual dosimetry report -- I can't think of the word -- isodose curves, to illustrate that he got in a program, software program where there was some discrepancy between the classic definition of the points (a) and what the program was calculating as being points (a). And he said that the difference in the dose, doing a hand calculation, was 15 percent.

So he has been in touch with the software manufacturer and they are going to correct the software. But he said that that is an illustration of how easy it is.

Now, this was just a question of where we are specifying these classic points. And if you change that a

little bit, it is 15 percent.

MR. TELFORD: Okay.

MS. ALDRICH: And he went on to say that a 2-millimeter shift using either the simplest applicator can produce a 25 percent change in dose, and his personal feeling was, set the misadministration level at 50 percent.

Some of the others just generally felt that there shouldn't be any reporting level for brachytherapy because, well, I guess because of the foregoing, that a very slight difference, the dose rate is just so steep, it depends on what do you want the report for. And as one of them said, any physician can just change the point that he is specifying as being the prescription point. And just about any kind of deviation could be taken care of like that.

I wonder if perhaps wording it differently -- The way this is worded, it turns it into kind of a calculational issue. I remember one of the earlier versions that specified a 20 percent difference in the milligram hours. You know, it had the three different usual ways of specifying dose.

That, I think, they would not have a problem with. If you loaded the wrong sources, and that is the cause of a 20 percent difference, that is one thing. But when you start to get into this business of where do I specify my dose to the treatment point, that is when you start to get

into these hairsplitting things. I think that is what they are really saying, you know. Put it differently. I don't think anybody would object to something like that.

But this gets into the realm of it is just so hard to be very precise about where that 20 percent error is going to be.

MR. TELFORD: Well, with that as background, where would you set the limit?

MS. ALDRICH: I think I would go back and make it a variation of the original wording that you had used, where you had -- I'd have to go back and look at it. And it sticks in my mind. That has not, that is not a suggestion of the physicist. But we had that in an early version of hours, and we didn't get objections to it. It is, I think when it comes down to something that is a dosimetry issue, you know, how the radiographs and where do you set your Point A and Point B, and how you calculate the dose to those points, that gets, I agree with them, that gets to be extremely difficult to resolve. But if you said, you know, 20 percent error in the source that was loaded, I mean the prescription says that after we have done all of this, we are going to load these sources, and if you make a mistake in that, that is a clearcut breakdown in procedures. You've got a problem that needs to be corrected.

But if you have a competent dosimetrist who is

doing his best and a physician who is doing his best to specify dose, and you have a difference of 20 percent because the applicator winds up being not exactly where it was intended to be, that is where I see the problem. That is where they, I think, see the problem.

MR. TSE: I think this particular proposed rule is not really addressed. The errors, or the differences, not errors, the differences you are describing address the errors made.

Somebody makes an error, for example, forgot about the wedge factor calculation or forget some other factors in their calculation.

MS. ALDRICH: That I can see in teletherapy, but where is that going to happen in brachytherapy?

MR. TSE: Okay. In brachytherapy, there is also the calculation may be, a number of sources may be in error. And if the calculation and the sources are in error and they do not find out and use it, then of course it becomes --

MS. ALDRICH: I think that is exactly what I am saying. If you put it back, it would be clear what you wanted. This doesn't say that.

MR. TELFORD: Well, I remember some guidance from the American College of Radiology, that I think when we were trying to say it three different ways they said you can get into trouble by these other ways, and you should just focus

on one, and say it is a function of the dose, because if you look at the isodose curves, and the 100 percent line is the one that circumscribes the tumor. That is what they want. That is the objective.

So if you can't deliver that by X percent, then you have an error.

MS. ALDRICH: You said the ACR said that?

MR. TELFORD: Yes. They're a lot tougher than you think.

MS. ALDRICH: Yes. But, you know, these are the diagrams he gave me showing the, you know, it is a 25 percent change in dose, and he is using a Burnet applicator and he says it is about the simplest one you can use, 2 millimeters.

MR. TELFORD: 25 percent change.

MS. ALDRICH: Yes. So you know, and this says --

MR. TELFORD: That depends on the activity of the sources. If they are pretty hot, that's true.

MS. ALDRICH: Yes. So what kind of a loading is he using here? I don't see it. Three cesium-137 sources. I don't see the activity.

So this is the physicist that said he thought no less than 50 percent, if this is truly what you are intending to pick up, because he just thought that, you know, because this says errors in treatment plan or

execution, which is going to be positioning.

MR. TELFORD: Right. Well, he has given us a perfectly good counter-example for why 20 percent is too tight.

Now, is it a good counter-example?

MS. ALDRICH: I don't know. I think the physicists all agree on this, at least the ones that we have talked to. I don't know about the American College of Radiology.

MR. TELFORD: It could be that this number needs to be 50 percent or higher, if that is the best the state-of-the-art can do.

MS. ALDRICH: And as he pointed out, he is the same one who pointed out that the treatment program -- this is only something that happened in February, I saw the date on his fax -- but says that: although I don't wish to attach unfounded importance to the points A that are commonly used by radiation oncologists, and in the recent case you and I consulted on, the overage dose for each point A determined by the computer program is 51 centigrade per hour while the dose rate to the true Point A was 60 centigrade per hour, and had I applied your program's dose rate I would have had a misadministration in excess of 15 percent.

So I think he has two concrete examples of why he

feels that that is too restrictive a limit. And I let him speak for himself.

MR. TELFORD: Is 15 percent over, does that mean that it was 35 percent over total?

MS. ALDRICH: No. He is saying it would have been a total misadministration of 15 percent. He did not use --

MR. TELFORD: This 20 percent?

MS. ALDRICH: -- he didn't use what the program indicated, he did his own calculation.

MR. TELFORD: Yes.

MS. ALDRICH: What he is doing is reporting back to his software supplier that they have an error in their software about specifying at Points A to B, or to be, to be located.

MR. TELFORD: Okay.

MS. ALDRICH: And he is just pointing out that a little error like that, which could be a matter of definition, it is a classic concept, the Points A, results in 15 percent error.

MR. TELFORD: But we all have to recognize that that is an unproven technology here, and what he is saying is you have a new piece of software in, and he explored it and found out that there is a 15 percent inherent error. But after you get those bugs out, his other example with the 2 millimeter distance change results in a 25 percent change

in dose.

MS. ALDRICH: Right.

MR. TELFORD: I think that is a very relevant example.

MS. ALDRICH: I think the first one is, too, because apparently this is not so much in error as the difference in where they are specifying it. As he says, maybe he doesn't need to attach unfounded importance to it. But the classical definition is you go to, what is it, 2 centimeters or 2 millimeters, and you follow a prescribed protocol.

MR. TELFORD: Yes.

MS. ALDRICH: But I think what he is saying is valid. You do that, you've got your program, then you've got your orthogonal films and by the time you get finished, I wonder, in brachytherapy, whether your tolerances are really all that tight. So as I said, I think if it was something that was specified so that the error part was clear, that they would feel much more comfortable with it.

I think right now, the physicists who really work at their dosimetry would have a problem with it.

MR. TELFORD: Is it too tight?

MS. ALDRICH: Yes. That is what they were saying to me.

MR. TELFORD: Let's let Roland have a shot here.

MR. FLETCHER: I will be perfectly frank with you. Right now, if I were having to present this to my Radiation Control Advisory Board and was asked why 20 percent, I couldn't tell them And if they asked why not 50 percent, I couldn't argue for it or against it. I'm not sure what it should be, and I would just need more, I would need more experimental evidence or a little more background for me to even intelligently discuss it.

MR. TELFORD: Okay. Terry.

MR. FRAZEE: If we are going to break this down into the various stages or parts to this, clearly there is the planning. They know what dose they want to deliver and they can calculate the positioning of the sources. And it seems to me that ought to be a pretty precise bit of business. They do it.

Now, in the step between having planned it and execution, we can run into some problems with picking the wrong sources or putting in the wrong places, and those are the errors that you want to catch, and probably report.

Now, the saving factor is usually they go and do a film afterwards to determine that they did it in the right place. And of course then, they can adjust the, they can go back and adjust it or they can change the treatment time, until the dose is delivered that they want to do.

So it is a real mixed bag here. this particular

statement probably isn't going to cut it because for parts of this schedule, you can hit 100 percent accuracy. For other parts, such as the positioning, you have real problems. A 2-millimeter difference in the positioning makes a big difference. But if they catch it and correct for it, then is that still a misadministration? I mean, they are still trying to execute the treatment plan.

MR. TELFORD: We covered that in the guide.

MS. FRAZEE: Okay.

MR. TELFORD: What we're saying in the guide is you should take the film in order to calculate, in order to know the position of the sources; then you do your calculation, and you have a final dose that you are going to give. And at that point you are just watching the clock, so you don't leave them in too long.

MS. ALDRICH: I have to run. I'm sorry. I enjoyed it. I really regret this.

But I will say one thing about the Reg. Guide, since I'm going to be passing through the door, and since you mentioned it.

The comments on the brachytherapy part of the Reg. Guide was that fixed geometry applicators don't require radiographs to calculate dose. I give you that for what it is worth.

Afterloading procedures are often based on the

location of dummy sources. The way the guide is written, it doesn't say anything about the dummy sources, whether it was intended or not.

And in general, the guide reads more like a regulation, and the regulation, our counsel's office is telling us that we are going to have to be more specific in what we have, which we at least specify under the quality assurance program of things you have to address, you know, you have to have a policy and procedure for. They are saying we have to build in to that a test, a criteria. You have to do it to what extent, or establish something, not just that you have to have a procedure for it.

But most of what I saw in the guide doesn't even appear in the regulations. And we could never adopt that. That would be considered using a guide in place of a regulation.

And I would be happy to send you the other comments. I really hate to move on. And I hope I get a copy of this.

Sorry to interrupt.

MR. TELFORD: Terry, did you have any other comments on the brachytherapy?

MR. FRAZEE: Strictly editorial. The order in which you have administered dose and prescribed dose, isn't that reversed? Treatment planning or execution result in

administered dose different from the prescribed dose?

MR. TELFORD: Oh, could be, yes. Okay.

MR. FRAZEE: Editorial only.

MR. TELFORD: All right. Now we are up to (c), which is the same as, or very much like (c), from 35.33, where we have an event or misadministration, where the RSO will investigate, make a record, obtain the record, and notify the licensee management.

Would your comments from (c) before be equally applicable here?

MR. WHATLEY: Yes.

MR. FLETCHER: Yes.

MR. FRAZEE: Yes.

MR. TELFORD: Okay. The (d) is also very much like the (d) from before, with the exception of we are talking about therapy here instead of diagnostics, so we don't have the 2 rem and half rem or the five-fold.

MR. WHATLEY: You require notification of NRC possibly before notification of the referring physician.

MR. TELFORD: In (d)?

MR. WHATLEY: I don't have a problem with that. I just point it out.

MR. TELFORD: Okay. Yes. The licensee shall notify by telephone the appropriate NRC regional office, and no alter than the next Federal Government working day after

discovery of the therapy event, or misadministration.

Does anybody else have any comments on that?

MR. WHATLEY: What is going to happen with that referral? Suppose just a doctor in Baltimore calls and says we have a misadministration that fits some of this criteria. What are you going to do?

MR. TELFORD: Well, the next day is a frequency of reporting, of course. Just how often do we, how quickly do we want to hear about this? And it goes to the regional office. If it is a sufficiently bad event, we could say we'll send an inspector. If it is not, we could say we'll be looking at the report, the written report.

MR. FLETCHER: And the term "sufficiently bad" becomes a judgment call?

MR. TELFORD: Yes. Of course. Well, like the Cumberland event. If that were an NRC state and this rule were in effect, we would probably say okay, we'll have an inspector there tomorrow. Let's figure out what is wrong with your program, your computer program, your procedure. Be prepared to tell us what you are going to do to fix it.

MR. FLETCHER: You know, in that light, one of the, a lot of the comments I made dealt with the time delay in that situation, because the initial misadministrations had gone on and we had not received a report, because the quote "licensee" wasn't aware that it had happened until

they actually did some audits.

So when you start leaving gaps in the audit time, in the checklist, that is when I become concerned, because that is exactly what happened there. The person authorized on the license was performing the administrations essentially without supervision.

MR. TELFORD: Yes.

MR. FLETCHER: And there was no one in the hospital that was checking on her work. And therefore, she assumed for one reason or another everything was being done correctly. Nobody doublechecked to be sure, until sometime later.

MR. TELFORD: Terry?

MR. FRAZEE: I'm fine.

MR. TELFORD: Okay. And (e) is just the written report, within 15 days. We specify the information we want. It is very much like before.

No comments on that?

MR. WHATLEY: I don't have anything on that.

MR. FLETCHER: No.

MR. FRAZEE: No.

MR. TELFORD: And (f) is the records that have to be retained. It is very much like the requirement from 35.33, the prescriptions case, the record of the administered dose or dosage, and the report of any events or

misadministration. Ten years is in here again. So maybe that is too long again.

So that completes 35.34. Let's go to the Guide. I will note that it is 20 minutes of 4:00. Why don't we discuss this for a few minutes, depending upon how long you want to talk about this.

Are there any parts of the Guide that you particularly liked or didn't like? Rita has already said it reads too much like a regulation. That is because there is a change between this guide and the guides that are currently used in medical use. The ones we have currently are more like a directive, or more like a recipe.

. . WHATLEY: My first comment is on Page 4.

MR. TELFORD: Page 4, okay. Go ahead.

MR. WHATLEY: On the 1.2.

MR. TELFORD: Yes.

MR. WHATLEY: Audits will be conducted following approving policies and procedures by qualified personnel -- my comment is who is qualified -- who are not involved with the activity being audited.

And my question here relates again to the small hospital, the one-man operation, of the individual doctor, who is the only one involved with is program. I just throw that out as a comment.

MR. TELFORD: Yes. It seems the only possibility

there is the guy has to go to another hospital or somebody nearby or hire a consultant or something to do the audit.

MR. WHATLEY: Qualified personnel. What does that mean?

MR. TELFORD: Well, we were actually trying to be a little bit less prescriptive there.

MR. WHATLEY: Show some flexibility.

MR. TELFORD: Yes. Show some flexibility. Let the licensee use their good judgment to know that two nearby hospitals could exchange RSOs or that you could pick one person who is a qualified technologist and a senior person or something, senior technologist, or your chief technologist, let that guy, let that person go do the audit. Or maybe it is one of, it is a technologist plus a nuclear physician.

MR. FRAZEE: Including some examples might be useful.

MR. TELFORD: Examples. Okay.

MR. WHATLEY: In a footnote. That is a good idea.

MR. TELFORD: Yes. Include examples of acceptable cases. Do you like that?

MR. FRAZEE: Yes.

MR. TELFORD: Okay.

MR. WHATLEY: If you don't, that is going to be a constant argument.

MR. FRAZEE: The idea is to help them comply. Feed them the information we want.

MR. TELFORD: Does anybody else have a comment on that page?

MR. FLETCHER: Since this is the Reg. Guide, I don't think it is necessary to say available for NRC or agreement state inspectors.

MR. TELFORD: I am sorry, I missed that.

MR. FLETCHER: This is 1.2. Down here you say audit results will be documented, reviewed by management and available to the NRC inspectors.

Just asking the question --

MR. TELFORD: We should say available to inspection.

MR. FLETCHER: Or available to inspection, for NRC or an agreement state inspector.

MR. TELFORD: Okay. I understand.

MR. WHATLEY: All NRC guides are written this way, I believe. We in agreement states just make changes --

MR. FLETCHER: Well, that's what I was saying, that's what I said, since we can draw from it and be more specific.

MR. TELFORD: It seems like we can make a simple change and just say for inspection.

MR. FLETCHER: You can make a footnote, when we

refer to inspections this means so and so and so and so.

MR. TELFORD: Okay. All right. Where is the next comment?

MR. WHATLEY: I have one on Page 5.

MR. TELFORD: Okay.

MR. WHATLEY: 3.1. It goes, the same thing that was said many, many times today: "... a physician under the supervision of an authorized user..." comments apply there. It applies in 3.3 also.

MR. TELFORD: Okay.

MR. WHATLEY: And down in 3.5: "After administering a radiopharmaceutical, a qualified person under the supervision of the authorized user will make, date..." and so on.

I don't want to be nitpicky, but does that mean the authorized use can't do these, too?

MR. TELFORD: The qualified user can, certainly.

MR. WHATLEY: It says a qualified person under the supervision of the authorized user.

MR. TELFORD: Oh, you think we should say the authorized user or this qualified person?

MR. WHATLEY: Maybe I was tired when I read it, that's what I read into it.

MR. TELFORD: Well, I think we could agree to that.

MR. WHATLEY: Okay. Just reword it.

MR. TELFORD: What we are really trying to say is if you are doing this procedure, I think we will put it this way, because we have been told that here is the physician with their gloves on and they don't want to take their gloves off to make the record. So we said okay, let a qualified person make the record.

MR. WHATLEY: Say he can do it, too, that's all.

MR. TELFORD: Okay.

MR. FLETCHER: You know, we still have a concern every time, in looking at 2.2, once again we have this, "or a physician under the supervision," as just pointed out.

MR. WHATLEY: I won't mention that any more.

Before we leave 3.3, just a grammatical thing there. "Any change in the prescription will be made by the authorized user or physician under the supervision of an authorized user..." -- and -- "will be recorded..."

MR. TELFORD: All right. Thank you.

All right. Next page, or next comment?

MR. WHATLEY: On 4.3.

MR. TELFORD: 4.3.

MR. WHATLEY: On 4.3, it is the same comment as was on 3.5. It's the way it reads.

MR. TELFORD: The authorized user "and." All right.

MR. WHATLEY: On 4.4.

MR. TELFORD: All right.

MR. WHATLEY: I would suggest that 4.4 be reworded to say that: "Any change in the prescription will be recorded in writing in the patient's chart or in another appropriate record and will be dated and signed by the physician making such change." That already defined, who can make a prescription.

MR. TELFORD: So the rest of it is unnecessary?

MR. WHATLEY: Again, I don't think the guy under the supervision, but the guy that originally might have made the prescription should be able to come in and make a change without getting approval of the authorized user.

MR. TELFORD: All right. I understand.

MR. WHATLEY: Same basic comment.

MR. TELFORD: Allright. Shall we go to the next comment?

MR. TSE: May I ask a question?

MR. TELFORD: Sure.

MR. TSE: This has to be the physician who originally signed the prescription to make a change. What happens if he is somewhere else and wants to make a change?

MR. WHATLEY: I don't see a physician making such change.

MR. TELFORD: He's saying that physician A, you

are saying physician A is off somewhere else.

MR. TSE: Is somewhere else.

MR. TELFORD: Physician A calls physician B and says make a change in this prescription, and physician B then makes this change, so the physician making the change is physician B in this case.

MR. TSE: Right.

MR. TELFORD: Kirk wants it to be a physician that makes the change. And we already defined in the definition who can make a prescription. So he wants an authorized user there.

MR. TSE: But I thought Kirk said that to have the physician who originally -- was that it?

MR. WHATLEY: Did I say that? If I did, I didn't mean to.

MR. TELFORD: Okay. Next page.

MR. WHATLEY: I have a comment on Page 7.

MR. TELFORD: Page 7, okay.

MR. WHATLEY: In 4.9, I know, I am sure I know what "prescribing physician" means. At least I think I do. And there may not be a need to do anything with that. I circled it when I first read it and I said well, hey, here is a new term, but after looking at it maybe that's not even worthy of comment. The prescribing physician is the physician that wrote the prescription. Fine. That's fine.

MR. TELFORD: Okay.

MR. WHATLEY: At the end of 4.9, though, okay? "...within two working days of the treatment." Does that mean two days from the end of the treatment, or what? "The checks of the calculations will be performed within two working days of the treatment."

MR. TELFORD: Yes. After the treatment is over.

MR. WHATLEY: After the treatment is over.

MR. FRAZEE: In brachytherapy, what is a typical treatment, a couple days?

MR. WHATLEY: Oh, yes, 72 hours.

MR. TELFORD: The treatment here is the insertion.

MR. FRAZEE: Okay. That's the question he was asking. And it appeared to me that the answer given was within two days of the end of the treatment.

MR. TELFORD: Not a good answer.

MR. FRAZEE: Of the inception.

MR. TELFORD: Okay.

MR. FRAZEE: Or beginning of the treatment.

MR. TELFORD: All right. So we should work on that word "treatment." It should say, two days from the beginning of the insertion, or implant, I guess is the better word.

MR. FRAZEE: Or it could be surface application.

MR. TELFORD: All right. Implant or surface

application.

Okay. Page 8.

MR. FRAZEE: We need to check something with you. This is brachytherapy and this is delay in treatment. We're waiting to determine the dose calculations, because a delay would jeopardize the patient's health, because of the emergent nature of the patient's condition.

Oh, okay. Wait a minute. This is just dealing with checking the dose calculations, right?

MR. TELFORD: Yes.

MR. FRAZEE: So that a dose calculation would be done; ordinarily it would be checked before treatment begins. But for some reason this is an emergency case or perhaps the physician who is going to do the check would not be available, so they are going to proceed with the treatment?

MR. TELFORD: This is an emergent condition, emergent nature.

MR. FRAZEE: Okay. What is an emergency in a brachytherapy case? Is there such a thing?

MR. WHATLEY: There probably is.

MR. FRAZEE: Is there?

MR. WHATLEY: One of the chambers are blocking some critical organ off.

MR. FRAZEE: All right.

MR. TELFORD: Okay. Does anybody have anything on Page 8?

MR. WHATLEY: Just a little old grammar thing. Do you want these kind of comments, or not?

MR. TELFORD: If you want to make them, sure. We'll take them.

MR. WHATLEY: You'll catch it.

MR. TELFORD: All right. Give me a hint. Where is it?

MR. WHATLEY: 5.4.

MR. TELFORD: 5.4. Okay.

MR. WHATLEY: After "dose administered."

MR. TELFORD: Okay.

MR. WHATLEY: That semicolon shouldn't be there.

MR. TELFORD: All right. Page 9.

MR. FLETCHER: This is going to have to be my pet, I think. Under 5.7, dealing with calibration measurements, particularly 5.7.1 after source change. In the situation that we went through, we required that they place a statement that all teletherapy treatments controlled by the computer be updated at the time of the source change. No option. All that were capable of being used. I don't know whether you need to prepare that as an additional sentence or as a guide. What happened i our case --

MR. TELFORD: You are saying program here.

MR. FLETCHER: All programs must be updated with the source values. Because what happened in our case was that the one program that wasn't updated was the one that turned out to be used. That resulted in a misadministration.

MR. TELFORD: I think we say that in 5.10. "Before the first use of a computer program for dose calculations or after performing fuel calibration measurements pursuant to 10 CFR 35.632(a)(1) and (a)(2), depth dose calculations will be made with each computer program...," "each computer program." I think that's what you said. It could be used for therapy dose calculations following exposure conditions. And then we give some examples of what we would like. We agree with you.

MR. FRAZEE: Same section, 5.7.1. You are saying: After a full calibration measurement..." following source change.

Refresh my memory. What is involved in the full calibration that is required in other sections, I mean other regulations?

MR. TELFORD: Currently.

MR. FRAZEE: Currently. Already.

MR. TSE: You mean what kind of condition provides full calibration?

MR. FRAZEE: Right.

MR. TSE: This is source change after 5, if it is a spot-check indicating 5 percent error.

MR. FRAZEE: Which is already in the regulation.

MR. TSE: Correct.

MR. FRAZEE: And here it appears again.

MR. TSE: Here it says the industry makes an independent check after the full calibration.

MR. FRAZEE: So they are already checking. Isn't that involved in the full calibration check?

MR. TSE: There is a spot check and there is a full calibration measurement. If you change the source, you need to perform full calibration measurements.

MR. FRAZEE: Right.

MR. TSE: And also, if you spot check, your monthly spot check, if the output is different with more than 5 percent also, then you do a full calibration measurement.

MR. TELFORD: This sets up a condition, 5.7.1. It says when you discover this, when you have this 5 percent difference, then you perform this independent check.

MR. FRAZEE: Sure. That makes sense.

MR. TELFORD: Okay.

MR. FRAZEE: But automatically after you just, you change the source, you automatically do a full calibration on the unit.

MR. TELFORD: Yes.

MR. FRAZEE: And now you come back and you are doing more?

MR. TELFORD: No, this tells them what to do. This sets up the condition. This is after full calibration measurement that results from changing the source, or whenever a spot check indicates that you've got a 5 percent difference.

MR. FRAZEE: But after a full calibration measurement, you are going to do an independent check of the output. Do you do that full calibration? I mean, I guess that is what I am trying to clarify here.

MR. TELFORD: Oh. I see where you are going.

MR. TSE: Full calibration measurement is a set of measurements done by the licensee. Currently, once you have done that, that completes the calibration. The proposed requirement was saying after that, after you have done the full calibration, you need someone else to check, independently check against your full calibration. But that is not required for annual full calibration, only required for the change of source or when your spot check indicates it is more than 5 percent difference.

MR. TELFORD: See, we are having the independent overcheck in the guide.

MR. FRAZEE: Right.

MR. TELFORD: Okay. Now that you understand it --

MR. FRAZEE: If you spot check varies more than 5 percent, then okay, we better check one of our parameters here and see what is going on.

MR. TELFORD: Right.

MR. FRAZEE: But to me, if you do a full calibration, don't you do an output for a specified set of exposure conditions, if you are doing an independent, do you do it again?

MR. FLETCHER: No.

MR. TELFORD: No. Here's a good example. Cumberland, Maryland.

MR. FRAZEE: They can't get around it?

MR. TELFORD: Now that you understand it, what do you think about it?

MR. FRAZEE: Okay. Well then, we've move on to the picayune. The independent check will be performed within 30 days after the full calibration measurement.

What about after a spot check? No time limit? Immediately? 30 days? Or what?

MR. TELFORD: Good point.

MR. TSE: There are two, three conditions, maybe three conditions you need a full calibration measurement. For instance, annual full calibration measurements and also change of source. Also, if your monthly spot check has 5

percent difference or more, you need to conduct a full calibration measurement.

For those two cases which you are involved, your source may be a new source or some sources, there may be some problem.

After you finish your full calibration measurement, you need to have independent check of this full calibration.

MR. TELFORD: No, his question is what if you have a spotcheck and you have a 5 percent difference? We are implying you do it immediately. We just don't say that. What if you have this?

MR. TSE: If you have this 5 percent, more than 5 percent, then you need to do a full calibration measurement.

MR. FLETCHER: When?

MR. TSE: That's in the current regulation.

MR. TELFORD: The answer is do it now. But it is a current requirement. Okay. So the route is circuitous here. You have to know all the requirements before you can figure out that this sentence is really meaningful. Okay.

MR. FLETCHER: Or maybe you can just say, immediately as prescribed in, and then --

MR. TELFORD: You're right.

MR. FLETCHER: That will keep people from having to look. The "immediately" will take care of the when.

MR. TSE: The current regulation 35.632 states that the licensee shall perform full calibration measurement on each teletherapy unit before certain, under certain conditions, like what is before the first medical use of unit, before medical use under the conditions whenever spot check goes to exceed 5 percent change of source, and so on, you need to conduct, perform a full calibration measurement. It does not say when.

MR. TELFORD: Is that all on that page?

MR. FLETCHER: 5.7.2 refers to 10 CFR 36.630.

MR. TELFORD: Okay. Now, we have 632 over in 5.10. Okay. Anything on Page 10?

[No response.]

MR. TELFORD: Okay. If there is nothing on Page 11, then that's the Guide.

[No response.]

MR. TELFORD: I promised you that you would have some individual air time. Why don't I gave you each, would 15 minutes be appropriate? Is that sufficient for everybody?

MR. FRAZEE: At this late date, that's more than enough.

MR. TELFORD: Is that more than enough?

MR. FLETCHER: If it takes all of us together more than that, you are in trouble.

MR. TELFORD: I want to show some regulatory flexibility.

Kirk, would you like to start?

MR. WHATLEY: Well, I have voiced most of my comments that I want to make today, but I will just say a word or two.

I think we ought to say, and it should be made part of this record, that I think what we have heard here today is that the medical community has done a good job. When you consider the number of studies that have been done over such a long period of time, and the number of misadministrations or events or whatever you want to call them that have been reported in what are many if not most times very trying situations in a hospital and medical setting, I think the medical community is to be commended for the record that they have in this area. And I am sure we are all thankful that they are there. I am certainly glad that they are.

I think that the community wants to do a good job. I think that they are willing to cooperate. I think their concern is ours, and hopefully ours is theirs also, and that we just want to try to do a better job of what we are doing.

I would like to hope, and I am sure it will be the case, that it is evident about publishing these comments in the "Federal Register" that there has been an effort to

solicit comments from all interested parties. And I would sure like to encourage that. I think we in the states need to be more responsive in submitting comments. I sent out a letter regarding this meeting and asked for comments. And I received very few from states. But I can understand that. Because I have the same problem as they do, and it is just simply the fact that most of us in the states do not have a staff or personally ever sit down and really spend the time necessary in reviewing in detail the volume of information that comes over our desk. And I understand that. But I would like to solicit as much information as we can from our states. I think we need to have input.

My comments today were based on my past experience and information that was available to me. And if someone has information or has a different opinion than I do, I would certainly welcome their comments. They might enlighten me. My mind is still open on the subject.

And I would just like, in closing, I would like to commend the NRC staff for your efforts in this area, and I would like to thank NRC for providing us an opportunity to express our concerns and to be more informed on the subject by being here today.

MR. TELFORD: Thank you. Roland?

MR. FLETCHER: I think I am going to reverse it. I am going to start by thanking the NRC for giving us this

opportunity. And I also want to thank NRC for having at least a number of states where ideas and situations are different so that we can see some of the unique problems that we run into in this very broad area.

I have found, in my limited experience, because unfortunately from my position, I can't dwell on any particular area. I have to look at things program-wide. So I kind of feel like I am only this deep in this area today.

But an actual event is one facet of a teaching point. And you know, it was unfortunate that the event occurred. But from my perspective, I learned more from just going through the investigative process and the enforcement actions related to this multi-event in Cumberland. I learned more there than I probably would have learned in all of the time scanning the references. And that, I think that helped me appreciate what things needed to be done. And hopefully I have contributed to the conversation from that perspective.

I do agree with Kirk that the medical community is to be commended. But, once again, I have to look at it from a broader base. And that is, it is not those that are doing the things that we want them to do and they want to do that we are concerned about. It is that little percentage who either aren't as familiar as they need to be with the way things do or they try to cut corners or they think they are

above reading instructions. And unfortunately, there are a few in that situation, and I think those are the ones that we are really always aiming at.

I hope to do a better job. Thank goodness, in a few months I will be permitted to add about six members to my staff. So this, hopefully, will give me the opportunity to respond more to other state's solicitations and to NRC rulemakings. I did circulate this through my staff and I didn't get a lot of input because, like the rest of us, they are running off on other missions, too.

But, once again, I appreciate this opportunity. And I have learned a lot today and I enjoyed this process.

MR. TELFORD: Thank you. Terry.

MR. FRAZEE: I would also add my appreciation to the NRC for supporting my attendance here. I also agree with Kirk and with Roland about the medical community and the good job that they are doing and they are trying to do. And I believe we share a common goal. They don't want misadministrations, they don't want bad PR. They don't want to have patients that are impacted. And certainly, what has started out is certainly a laudable rule. It is clearly going in the right direction. Basic quality assurance, I don't think there is any question that it is needed. I don't think the medical community disagrees. In fact, they probably support the quality assurance approach.

The problem is, as I stated earlier, the dichotomy in our viewpoints of the medical profession. And some of that has to do with our own perceptions of risk. Those of us who have become familiar with the medical profession and the types of studies that they are doing tend to think that particularly diagnostic risks are certainly well within the acceptable range and it is no big deal. Others, who have a slightly different perspective, are saying hey, radiation is something that we have to reduce to zero, not necessarily reasonably achievable, but zero.

And our task is to take something that has clearly started out in the right direction and to work with it to achieve a middle ground, common ground, that they can live with. It is the area of the detail that we need to address. Certainly today has been a learning experience for me, because I am getting more information than I had before I came. And as the whole process goes on, I think that the licensees as well will gain a greater appreciation for where we as regulators are headed and likewise we will learn more about the kind of impact this type of document would have upon them. And in the long run, I think we will achieve a meaningful and working rule.

MR. TELFORD: We have been joined by John Glenn, Branch Chief in this area. John, do you have any comments to make or reactions?

MR. GLENN: I guess not, at this point. I am just here to welcome you.

I guess I will reiterate the comment about us needing the states to come in early with their comments. It is a help to us. So I again encourage you. And I realize the competing interests. But we do appreciate your comments.

MR. TELFORD: Mike or Susan, do either one of you have any comments you want to make?

MR. WEBER: Glad you are here.

MR. TELFORD: Okay. I want to thank you all for coming. It has certainly been informative and helpful to us. You know, of course, that you can send in your written comments and also there is still an open invitation extended by state programs that if your state or any other state would like to have a round table discussion, maybe there is a collection of states in your area that, based on your experience here today, you could convince them that it is informative, and they have some things to say, that you can respond to that request if you would like to. The quote "rule writing staff" is available, willing and able, hopefully.

MR. WHATLEY: Let me just say one other thing. At the Conference of Radiation Control Program Directors in Salt Lake City in May, the Nuclear Medicine Task Force will

be meeting. Terry is a member of that. Lloyd is NRC's representacive on it. I hope Lloyd will be able to go. And regardless of whether he does or not, we are going to have a meeting. And if you will provide us what you have, if you have anything you would like us to comment on or to review at that committee, we will be happy to do it at that time.

MR. TELFORD: Okay. Great. Well, if that is all, let's stand adjourned.

[Whereupon, at 4:15 p.m., the meeting was adjourned.]

REPORTER'S CERTIFICATE

This is to certify that the attached proceedings before the United States Nuclear Regulatory Commission

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NAME OF PROCEEDING: MQAP Roundtable Discussion

DOCKET NUMBER:

PLACE OF PROCEEDING: Rockville, Maryland

were held as herein appears, and that this is the original transcript thereof for the file of the United States Nuclear Regulatory Commission taken by me and thereafter reduced to typewriting by me or under the direction of the court reporting company, and that the transcript is a true and accurate record of the foregoing proceedings.

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