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

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NUCLEAR REGULATORY COMMISSION

New York Workshop on the Pilot Program
For Proposed Rule 35.35: Basic Quality Assurance Program
For Medical Use of Byproduct Material

Holiday Inn Crowne Plaza
104-04 Ditmars Boulevard
East Elmnurst, New York

Thursday, March 29, 1990

The above-entitled workshop convened at 9:10 a.m., when were present:

John L. Telford, Office of Nuclear Regulatory Research, NRC
Anthony Tse, Office of Nuclear Regulatory Research, NRC
Lloyd Bolling, State Agreements Program, NRC
Josie Piccone, Region I, NRC
Darrel Wiedeman, Region III, NRC

PARTICIPANTS:

Edward Kaplan, Brookhaven National Laboratory

Charles Meinhold, Brookhaven National Laboratory

Kevin Nelson, Brookhaven National Laboratory

Suresh Brahmavar, Baystate Medical Center, Springfield, Massachusetts

Andrew G. Bukovitz, Armstrong City Memorial Hospital, Armstrong, Pennsylvania

Tom Doring, Samaritan Hospital, Troy, New York

Linda Franklin, Chandra R. Polam, M.D., Pittsburgh, Pennsylvania

Eugene Graham, WCA Hospital, Jamestown, New York

Frank Kearly, Washington Adventist Hospital, Takoma Park, Maryland

Nellie Kelty, Schultze, Snider & Associates, Baltimore, Maryland

Sarah Kirtland, Naval Hospital, Bethesda, Maryland

Susan Moore, Samaritan Hospital, Troy, New York

Jerry Rosen, University of Pittsburgh, Pittsburgh, Pennsylvania

Ken Strubler, Greater Baltimore Medical Center, Baltimore, Maryland

PROCEEDINGS

[9:10 a.m.]

MR. TELFORD: Good morning. My name is John Telford. I want to welcome you to this first workshop. I want to thank you for participating and agreeing to participate in the pilot program. I'm sure your participation will be very helpful to the NRC, and in particular to the group of people within NRC that's trying to write a rule and produce a guide that will be helpful.

The agenda was passed around.

In introduction I will ask everyone to just state their name so that we can get to know one another just a little bit.

We're going to talk about the proposed rule, and then we want to talk about what the pilot program is all about, what you can expect, what we expect. Then -- it says 1:00 here, but it's really whenever we get there -- we'll talk about any conflicts that the agreement state licensees may potentially have following the proposed rule. Lloyd Bolling from State Programs at NRC will address that. Then we'll have Charlie Meinhold talk about evaluation criteria and what the form will look like for the feedback that we desperately want. Then we'll review the guides in case you have any questions about what might be -- I won't say "acceptable procedures" because you're really on your own,

but I will say we'll talk about what we had in mind, so that you can understand our thinking. We intend this guide to be helpful to everyone.

You'll notice that we've put in a lot of items within the agenda that say questions and answers on this and questions and answers on that, so I think that's the heart of today.

Let's start over here for introductions.

MR. MEINHOLD: Charlie Meinhold, Brookhaven.

MR. NELSON: Kevin Nelson, Brookhaven National Laboratory.

MS. KIRTLAND: I'm Sarah Kirtland. I'm from Bethesda Naval Hospital.

MR. ROSEN: Jerry Rosen, University of Pittsburgh.

MR. KEARLY: Frank Kearly, Washington Adventist Hospital.

MR. GRAHAM: Gene Graham, WCA Hospital, Jamestown, New York.

MS. FRANKLIN: Linda Franklin. I'm from a private cardiologist's office in Pittsburgh, PA.

MR. KAPLAN: I'm Edward Kaplan, from Brookhaven National Laboratory.

MS. PICCONE: Josie Piccone, from the NRC Region I.

MR. TSE: Anthony Tse, NRC.

MR. WIEDEMAN: Darrel Wiedeman, from the NRC Region III office.

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

MR. STRUBLER: Ken Strubler, Greater Baltimore Medical Center.

MR. BRAHMAVAR: Suresh Brahmavar, from Baystate Medical Center, Springfield, Mass.

MR. BUKOVITZ: Andy Bukovitz, Armstrong Hospital, from north of Pittsburgh.

MS. KELTY: Nellie Kelty, from a private radiology group in Baltimore, Maryland.

MR. DORING: Tom Doring, Samaritan Hospital in Troy, New York.

MS. MOORE: Susan Moore, Samaritan Hospital in Troy.

MR. TELFORD: Again, welcome.

Some of you had the experience of hearing me give a talk at some point last year about the proposed rule and the pilot program. I described the pilot program as being a chicken test for the rule. Since we don't have any aeronautical engineers here, you probably haven't heard what the chicken test is.

When you design a high-performance jet engine -- A couple of years ago, they spent a few million dollars and

five years and designed this very-high-performance jet engine. It passed with flying colors in all the tests, and they were getting ready to put this engine on airplanes and sell it, but there was one test that they didn't do, and that was the chicken test. This sounds funny, but you go down to the supermarket and you buy about twelve gross of chickens and you put it in a large gun, with a six-foot diameter, you turn on the engine and point the gun into the engine, and you fire the chickens. The engine has to literally inhale the chickens and keep going, because it's a military aircraft, and if it's on take-off or something, you have to have your engines keep running. Well, the engine failed.

So, rather than put out this rule and have it fail, we'd like to give it the chicken test. We'd like to -- There's no inference here.

[Laughter.]

MR. TELFORD: This to see if there's something wrong, and let's fix it before we hang it on an airplane.

To sort of bring you up to speed, rather than just jump right into the rule: We started working on this in '87 with a very prescriptive rule, and the medical community came in in April of '88 and said, we really don't like this prescriptive rule; basically, we don't want to be told how to do it; we would rather you just tell us what to do, and

we'll figure out a better way. That led to a recommendation to the Commission that we have a performance-based rule.

We had various meetings with the medical community, invited licensees to a workshop, and the American College of Radiology. Eventually we got to a proposed rule. We gave that to the Commission in August the second time. This is the briefing in June.

Since August of last year, the Commission has deliberated on this rule a lot, and it was December 21 of last year that the Commission gave the Staff what we call a staff requirements memorandum that said, here's what you do with the rule before you publish it, and it was published in January of this year, and it was about then that we started looking for volunteers.

I'd like to congratulate Brookhaven and Ed Kaplan on having gotten a goodly number. Nationwide, there are 22 NRC volunteers and 46 agreement state volunteers. There was what I would call a scientific selection procedure to try to proportionally represent each agreement state or each region and each type of licensee, each type of facility. We paid attention to whether you were rural or urban. This was on a stratified random-sampling procedure. We've gone to a lot of trouble to get to each of you. It was a lot of work, and Ed Kaplan deserves the credit.

The first item on your agenda is to talk about the

proposed rule. We have a handout for you.

[Handouts distributed.]

MR. TELFORD: Whenever you got a letter from the NRC requesting your participation, you received a package just like this that has the proposed rule, 35.35, and the guide. Just to have a reference, we're going to quickly go through that.

You have a page of definitions.

What we asked you to do is to take the proposed rule, 35.35, and develop a written quality assurance program and to bring a copy with you today. The whole objective is to prevent errors in medical use.

You have your handout for the eight objectives that are in the rule. By now you're hopefully intimately familiar with these objectives. I'd like to run through them quickly, because we can have a question-and-answer session on that.

What we intended by number 1 is that there be some thought process by the nuclear physician before a patient is given byproduct material or radiation from a byproduct.

What we intended by number 2 is that you use a prescription whenever you're going to have more than 30 microcuries of I-125 or I-131. Part of this thinking is that we know several cases in which the switch has been made from micro to milli. Therefore, if the patient gets 30

millicuries of iodine when they should have gotten 30 microcuries, then it's not so good, but if this number were larger and the switch was made, then the consequences are worse. Selection of that number is somewhat arbitrary, but that's the best we could do. We hope, as a result of our pilot program, that we'll be able to have a better number or defend it in some way.

Yes, Ken?

MR. STRUBLER: What was the rationale for the selection of iodine, without discussion of the other isotopes in medical use?

MR. TELFORD: Well, iodine is taken up selectively by the thyroid.

MR. ROSEN: No, it's not.

MR. TELFORD: Okay.

MR. ROSEN: Iodohipuran is not taken up by the thyroid.

MR. TELFORD: Okay. That's a special case.

MR. ROSEN: It's covered by number 2. A hundred microcuries of iodohipuran is covered.

MR. TELFORD: Okay. That's one thing that we hope to measure, or hope to find out in this pilot program, that we should possibly have an exception for this.

MR. STRUBLER: Well, I realize, number 1, the NRC is limited to byproduct materials, but since there is a

larger number of agreement state here as well -- and that's going to influence us ultimately -- we're obviously dealing with a large variety of radioactive pharmaceuticals, and the focus on these two items here is on iodine alone, but you still have similar consequences if there is an error made in between micro and milli.

MR. TELFORD: For example?

MR. STRUBLER: Well, I'm just saying, in any other usage that you may have where a microcurie dose was prescribed and interpreted as milli. I don't have any specific examples.

MR. TELFORD: Another isotope?

MR. STRUBLER: Yes.

MR. ROSEN: A good example is indium-111, because you're delivering 20 or 30 rads to the liver and spleen and a higher dose for the white cells. Iodines are not the only high-dose procedure. The speaker's correct, over there, from the standpoint that whatever standards you set or recommendation will have to be adopted by the agreement states and will have be applied straight across the board.

MR. TELFORD: These are diagnostics or therapy?

MR. ROSEN: Diagnostics.

MR. TELFORD: That's a good point.

MR. BRAHMAVAR: I think the 30 is the limit for hospitalizing a patient or not hospitalizing a patient, and

that's where that 30 comes from for iodine.

MR. WIEDEMAN: I think it's 30 millicuries.

MR. BRAHMAVAR: Millicuries, that's right. That's why I said 30 microcuries or millicuries. If it is more than 30 millicuries, then the patient has to be hospitalized. Maybe that is why you've chosen that 30 as your guiding light.

MR. TELFORD: Well, that may be an indirect effect.

MR. WIEDEMAN: The very first time I read that 30 microcuries, I thought, oh, there's an error. What we really meant was 30 millicuries, but I found out, no, we really meant 30 microcuries, because you find that most of the thyroid uptake studies with iodine-131 are done with less than 30 microcuries, but when we start going into various different nuclear medicine studies about 30 microcuries, then you have more. When there is an error in the judgement of the person selecting the dose, now we start getting into biological damage.

MR. BRAHMAVAR: But other nuclear medicine studies, if they're more than 30 millicuries you don't hospitalize the patient. It's not required to be hospitalized.

MR. WIEDEMAN: That's correct.

MR. BRAHMAVAR: But lung scans or any other

studies, you may give more than 30 millicuries and not require to be hospitalized.

MR. WIEDEMAN: Correct.

MR. ROSEN: A 30 microcurie uptake study on a normal-functioning thyroid will deliver about 50 rads to that person's thyroid. If you slip the micro to a milli, you're talking about 50,000 rads. Certainly that is not a negligible dose. It seems to me more like a tenth of a microcurie might be appropriate.

MR. WIEDEMAN: You want to lower it even lower?

MR. ROSEN: Oh, I'm not saying we even need a standard. I'm just saying that simply just saying 30 microcuries of iodine is obviously highly in question. We would like to really know what the basis of the 30 was. It can't be a random selection. It has to be done with some positive decision.

MR. TSE: The idea of introducing such a limitation is to avoid not just a switch from 30 microcuries to 30 millicuries. In addition, it will prevent that any microcurie amount of any -- any millicurie amount, even 5 millicuries, should be prevented, because under this proposed rule the physician would have to give a direction to the technologist, and therefore the technologist cannot say, the referring physician says this patient needs a whole-body scan; therefore it needs 5 millicuries. The

technologist should not do that under this provision, but without this provision, some technologists do that, and therefore give the patient 5,000 rads, 5 millicuries to the patient. We're trying to prevent those kinds of situations.

MR. TELFORD: Let me in a way back up, but in a way cover another one of these. The thought was diagnostic procedures, those that are almost inherently safe, we could allow to be referred to the department with what we're calling a diagnostic referral, trying to incorporate the way that business is done in most cases. Now, the procedure requested in the referral needed to match the clinical procedures manual, so the authorized user would approve the clinical procedures manual and therefore have control over what gets done to the patients, because the authorized user, physician, having approved of the clinical procedures manual, then the technologist follows that.

So in comes a referral. The technologist matches it with the clinical procedures manual. It matches. He knows exactly what to do. All is well and good. Of course if it doesn't match, then the technologist goes back into, what do I go, so the authorized user is still in control.

Now, we thought that certain procedures deserve a prescription, like therapy procedures or certain diagnostic procedures like this. That's not good. I accept that. We're going to learn how to do better, and we're going to

keep this; that's great. That's the thought. If we've our number is not any good, I'm sure we're going to learn that.

That's basically these two.

Four just says to make sure the responsible individuals, meaning the technologists or anyone involved in administering diagnostics or therapy, make sure they know what to do, that they understand the procedures manual, then make sure that the dose or dosage is in accordance with the prescription or the referral and the procedures manual. We were thinking that the prescription stands alone as the directive; the referral and procedures manual make a pair.

Number 6 we put in because we see too many cases of the wrong patient.

Seven was to identify unintended deviations. That's because in the rest of the rule, which we didn't send you, there's the requirement for an annual audit, so that licensee management has to have a finding that the program is sufficient at the end of the year, so that the audit goes back and looks at these and says what was wrong, what needs to be fixed, and the rule apparently requires that licensees make any modifications to ensure that the same mistake doesn't occur again.

Yes.

MR. ROSEN: How does an unintended deviation differ from a misadministration?

MR. TELFORD: Probably by degree, amount. These are all deviations.

MR. ROSEN: Twenty percent instead of the 50 percent?

MR. TELFORD: Okay. An unintended deviation could be 5 percent or 2 percent. A misadministration could be 50 percent or 100 percent.

MR. BUKOVITZ: But 2 percent or 5 percent is a normal clinical procedure, though. You ask for a 20 millicurie does, and you may get 18; you might get 18.5, depending on the time of day that you use it.

MR. TELFORD: Okay. You're saying, no big deal.

MR. BUKOVITZ: Right.

MR. TELFORD: Well, this does not imply, big deal. All this implies is that this is a way for the licensee to have a feedback loop, so that they can improve their own program. If you were the chairman of the department and you saw a lot of these that were 2 percent or 5 percent, then you would know whether or not anything needs to be fixed.

MR. BUKOVITZ: You're going to see that almost all of them are going to be 2 percent and 5 percent.

MR. TELFORD: Okay. Maybe you're telling me a couple of things here. One is, the intention is so that deviations will be recorded, so that they can be evaluated. I think what you're telling me is, most times it's not a big

deal, and that you would know that according to what was done and how large the deviation is.

MR. BUKOVITZ: Well, most times you're going to see it. Not necessarily that it's not a big deal, but you're going to see it, especially if you use a radiopharmacy and they calibrate all your doses for 12 noon, and you start patients at 7, or you do a patient at 4 o'clock.

MR. TELFORD: But this says unintended, so if you use a dose calibrator and you know what you're about to give the patient, that's --

MR. BUKOVITZ: But your clinical procedure says, for this procedure I want to use 20 millicuries, and your dose is calibrated at 12 noon for 20 millicuries, but when you use it, let's say it's 15, or it's 23.

MS. PICCONE: That's why, in fact, most clinicians in the procedure manual do not see 20 or 3 or 5. There is an acceptable range over which they will do a study. If you're doing a bone scan and the ideal is 20 but you will accept 18 to 25 or whatever, then certainly there is no deviation from what is acceptable to the clinician.

MR. BUKOVITZ: But most procedure manuals, when they specify the dose -- and the procedure manual does say, a nominal dose is 20 millicuries or 10 or whatever -- I've seen very few procedure manuals that give you a range for

doses. Most normal clinicians that I've had experience with will give you the nominal dose, and they'll assume if it's within plus or minus 50 percent you're okay. This may not be correct, but this is what normally is seen in the field.

MS. PICCONE: And I've seen as many with acceptable ranges. This is what people have posted in their hot labs, as well, for the dose. I see a lot of heads nodding, so I have to assume there's at least that kind of situation as well, because the clinician, when he says 20, doesn't mean that's his only acceptable dose, so it might be that the clinician should put . is acceptable dose.

MR. BUKOVITZ: Oh, yes. They'll accept 15 or they'll accept 25, but the thing is, if you have a clinician who has a number, you may want to specify that he's better establish a range then.

MR. TELFORD: You're making a judgement about these things, I think. The intention here is just to identify them. If it were teletherapy and you were giving daily doses, the patient is supposed to get 200 and they got 205, the next day it was 200 and they got 195, or whatever, just identify them so that the authorized user can say that's okay.

Jerry asked about the criteria for reporting requirement, which is different. This just says, identify what they are. If you've seen the Federal Register notice,

you've seen this particular proposed requirement, but it's for an annual audit so that the licensee management has a feedback loop where they can look at their own program and say what's right and what's wrong, does something need fixing.

That's the intention behind identifying.

MR. ROSEN: Can I ask for a quick favor?

MR. TELFORD: Yes.

MR. ROSEN: It is certainly unacceptable at our institution to have 100 percent error in dose. Let me just use that number arbitrarily. Certainly that is a misadministration, and we report that, but for the vast majority of nuclear medicine procedures, in terms of the health outlook for that patient, it is in fact absolutely no big deal.

MR. TELFORD: Diagnostics.

MR. ROSEN: I don't mind it so much in this room, but when we discuss these things in public, we raise the same aura that any amount of radiation is a big deal, and a one-rad or a half-rad dose that all of a sudden gets doubled does not exactly put anyone at any significant risk.

MR. TELFORD: Okay.

MR. ROSEN: From a regulatory standpoint, from the operation of our department, yes, it's a big deal, but not from a health standpoint.

MR. TELFORD: This is from the standpoint of the operation of your department.

MR. ROSEN: I know. I'm as guilty, tending to use words like that, talking to patients and the general public. One of the problems is that we don't choose our words carefully.

MR. TELFORD: You mentioned reporting requirements. This afternoon we'll give you a copy of what appeared in the Federal Register. That contains the reporting requirements, which we purposely didn't send you in this package. The reason is we want to hear your comments about the reporting requirements; after the actual test period we'll have another workshop, and it's at that workshop that I especially want to hear your suggestions on how to redo the reporting requirements: 10 percent, 20 percent, 50 percent; what's the number?

However, for now, all we're saying is that we're requesting that you have a program that you tell us meets proposed 35.35. This an objective of the program. This is a performance-based rule, so we're not telling you how. We're only suggesting to you that this ought to be an objective. Now, it could be, at the end of this test period and all these workshops we find out it's not a good thing. Okay. We'll learn that if that's the case. For now, let's just say that we want the unintended deviations to be

identified. We don't attach any stigma to those. That's a feedback loop.

Number 8 is that we want the treatment planning to be in accordance with the prescription.

We intended all these to be very straightforward and almost intuitively obvious. I can see that number 2 very possible needs a little work, and maybe others.

MS. FRANKLIN: I have one question about number 6. Do we document that we've checked the patient's identity? Does each patient sign something, saying that they are that patient?

MR. TELFORD: This doesn't really require documentation per se. What it requests is that each institution have a program that includes some measure of how to identify the patient. In other words, the mechanism used at one institution may be different from the other one, but the people dealing with the patients in your institution should be told to follow a given procedure for how to identify. Maybe you ask them their name; maybe you ask their birth date, their social security number, their mother's maiden name, or something. Any number of things they could do.

This is a giant experiment in letting licensees implement the proposed rule any way they want to, as long as you say, we think it does. Now, you'll hear a little bit

more this morning about how we want to find out for a small number of licensees how that's really implemented in practice.

MR. BUKOVITZ: JCHO already has number 6.

MR. TELFORD: Okay. What else?

MR. BUKOVITZ: Are you interested in the redundancy?

MR. TELFORD: No. About 78 percent of the hospitals in the U.S., out of 6,000, belong to JCHO. The other 22 percent get inspected by the PRO, the peer-review organization -- that is, if they want reimbursement. The JCHO are largely voluntary standards. What's flexible here is how you meet a requirement like number 6. See, if you allow a performance-based rule and you allow each institution to meet that in their own way and give them an annual audit, then the licensee management will learn whether or not they're doing a good job with that, and if they need to they can fix it.

MR. STRUBLER: Well, I think the question raised here raises a number of questions, in the sense that if this is intuitive obvious on many of these things we all accept -- for example, number 6 -- then the problem goes down, because it's entering the regulatory process, then you have to make some kind of documentation in some form. Saying, are you Mrs. Smith; yes, I'm Mrs. Smith, may not be

sufficient, as it has been in other patients; other patients say, sure, I'm Mrs. Smith, and he has a low voice.

[Laughter.]

MR. STRUBLER: It becomes a problem when it enters the regulatory process. We can establish measure and say, yes, this is intuitively obvious; we're going to find out who this patient is in some manner, but if there's going to be audit of that by regulatory agents or other outside consultants, then we have to come up with some mechanism. That's where the difficulty, I think, creeps into a few of these processes: the documentation and to what level that must occur.

MR. TELFORD: If this proposed rule became final and it had the requirement for annual audit to be performed by the licensee, and this does not mean an outside organization --

MR. STRUBLER: Well, I thought one of the statements, though, said it had to be someone other than the user.

MR. TELFORD: Other than the person doing it. In other words, you don't audit yourself.

MR. STRUBLER: Right, but in many small institutions there are no other qualified people to do the audit.

MR. TELFORD: Okay. For the small, three-person

operation someplace in Iowa, it may be that they have to do something different. What this tries to do is grant maximum flexibility. Two nearby hospitals can exchange RSOs, or you can figure out a scheme internally if you have a large enough department to audit various parts that you didn't actually do. In some cases -- There was a doctor in Oklahoma that has an oncology department, and what they do is they just take turns. He'll designate one technologist that will do the audit, and they do it monthly. I'm given to believe that it could work various ways.

A little later in the program I'll tell you about 18 site visits that we will make, but we're there just to see if you're doing that you say you're doing. The documentation is, I think, necessary for procedure. Your written quality assurance program should contain a procedure that says, what we do to identify patients is as follows: a,b. That's it.

MR. ROSEN: That's not auditing. That's written down. I could write almost anything bizarre in the manual. but that's really not the issue. If you don't have a written response, how in fact do you audit? My going into our nuclear medicine department, standing there and watching the technologist interact with the patient is in fact a form of audit. On the other hand, I would be highly surprised if they were not on their best behavior when I was standing

there looking over their shoulders. In effect, that makes it a non-audit.

MR. TELFORD: Okay. And if this rule were a final rule and if our inspectors came to a hospital, we might observe the same behavior. While we were standing there, people would probably be doing it according to the manual. What you're implying is that that doesn't happen all the time, necessarily.

MR. ROSEN: Well, everyone in this room is aware of the fact that technologists ask for Mr. Jones and Mr. Brown gets up and gets a scan every once in a while. They ask for the patient identifies himself, and the wrong person gets up. You can ask them to take out their wallet and their driver's license, but when people are in a hurry, things go wrong.

Now, this is an easy one, by the way, to deal with, because this one in particular always shows up with a misadministration. The wrong patient got the wrong dose.

MR. TELFORD: Or the right dose, as the case may be.

MR. ROSEN: Or the right dose for the wrong patient.

MR. TELFORD: Yes.

MR. ROSEN: It is in fact very auditable, but not in the manner in which I think we normally consider an

audit.

MR. TELFORD: How do you prove that all the cases that were done right were done right?

MR. ROSEN: Well, you bring in a team of people and you invest about a thousand man-hours a year, probably, looking over every piece of paper in a busy department.

MR. MEINHOLD: Part of the problem, Jerry, I think, in all of this is that the NRC is trying to make this a performance-based standard. Your comments are saying, no, you don't want a performance-based standard; you want it to be laid out, which is the reverse. All this guide is saying is that, in fact, you have a procedure to make sure that the right patient gets it, and you're saying, we don't do that very well.

MR. ROSEN: I didn't say we weren't doing it well.

MR. MEINHOLD: I can give you some techniques to use if you want them. Every ten patients, somebody goes and says, were you asked what your name was when you got this procedure, all that kind of crap. We don't want to tell you that. That's been the whole point of this exercise, and to say that you can't think of any way to do it, you're really saying, all right, we'll tell you how to do it.

MR. ROSEN: Oh, I can think of ways to do it. I'm just figuring out a way then to audit it, how to audit something without a written record.

MR. MEINHOLD: That's the pilot program. Tell us it needs a written record when you comment back, if that's how you feel about it.

MR. TELFORD: Well, I hadn't asked you to come to a conclusion. It's a good point.

MR. ROSEN: This is certainly one line item that everybody in this room, I think, has. Probably every licensee nationwide has a written requirement to identify the patient.

MR. TELFORD: As part of your package you got a copy of the draft guide, and it has some suggestions. Is there something wrong with allowing each licensee to do it their way in their institution, and letting us learn from that before we finalize our guide or change this objective in some way.

MR. BUKOVITZ: Well, it's a commendable attitude.

MR. TELFORD: It's the way we're trying to go, a performance-based rule. It's very difficult. If we tell you to do the following 12 things, by definition you do them, you've got an acceptable QA program. We're not doing that. We're giving you eight objective with the requirement to have a written program and with the requirement for an audit, and a requirement to make prompt changes annually.

I think what you're saying is, gee, how do I prove I did it right.

MR. ROSEN: That, I think, is the major issue, not the fact that we have a program to identify the patient.

MR. MEINHOLD: But, still, Jerry, you want to solve it; you don't want the NRC to solve it.

MR. ROSEN: That's my point. Each institution wants to solve this problem in its own way.

MR. MEINHOLD: Or else you're crazy.

MR. ROSEN: Well, I want to solve it in a manner that will not result in a citation at the end of the year when I'm inspected, also. I'm asking for some guidance in this room, or perhaps some suggestions in this room, in this particular case. We're doing 80 or 90 percent of all of this already; we have no problems -- I'm not saying this is a bad policy overall. This happens to be a relative troublesome one from the auditing standpoint, our internal audit.

MR. TELFORD: Well, we just have two of the best inspectors in the NRC here -- Now that I've put you on the spot: In part, we don't want to give you too much guidance at this point, but is there something that you would say to a licensee after inspection, to say what you look for or what you think they ought to have, or think about.

MR. WIEDEMAN: One point I'd like to make is that every institution is different in how the physician prescribes what he wants versus the procedure on how it gets

to the nuclear medicine department. In some hospitals, they use nothing but requisitions, and they verify only by arm bands, and we've run into problems where they report a misadministration -- they gave it to the wrong patient -- and their corrective action was, well, gee, now we're going to bring the chart down to the nuclear medicine department with the patient and verify that that was truly what was ordered. They think, gee, this is a great idea that they came up with, but, yet, you go to another hospital; they routinely do that stuff.

Sure, there's going to be some that slips through the cracks because of a matter of communications: A physician will order a scan as a whole-body scan, and the technologist has it in his mind that this is a bone scan, or another technologist has it in him mind that this is a thyroid cancer scan with iodine. It's a matter of terminology. If we implement the QC-QA program, where it has specific guidance to the technologists on what is truly a whole-body scan, and get the word out to the physicians that refer to the nuclear medicine department that a whole-body scan means this, and this is what we're going to do. And so it's very difficult to say, this is the solution to your problem, because your situation is different from a little hospital in Iowa. You've got to look at what is available in resources at your facility and what would be

the best solution to the problem.

MR. ROSEN: Most of these problems in reality stem from outpatient diagnosis, I presume, where there are no arm bands; there are no charts.

MR. WIEDEMAN: Exactly. It's a bigger problem down in the southern states, where you have a lot of Latin Americans, Spanish people who do not speak English, and you have a communications problem. That was a big problem.

MS. PICCONE: You see the problem everywhere. It's not just outpatients. There are inpatients that come with a chart. The facilities generally have procedures, and the procedures encompass more than asking the patient the patient's name. I think it's a given at most institutions that that's not a way to verify patient identity, especially depending on your particular patient population, because you may have the whole room answering to the name that you call. Most facilities do have more than this already. The problem is that the individuals aren't following the procedures that are already in place in the institution.

So I think in response to your comment I would only reiterate what Dr. Meinhold has said, in that that is one of the purposes of your participation in this pilot study. You are to develop an audit program; you are to develop the procedures you're going to use to audit. This is a performance-based rule. When we come in, how are we

going to audit? Did you have a misadministration that resulted from the wrong patient? In that case, why did that happen? Was your procedure followed, or was it not? There are performance-based items in part 35 already.

MR. TELFORD: Okay.

Part of the handout is a list of definitions. I just want to go over those so that you can ask questions and make comments about them. Probably nobody has any trouble with the basic quality assurance definition.

For the clinical procedures manual, we wrote down our understanding of what a clinical procedures manual is.

Let me back up a step. The purpose of this would be so that you understand what the intentions are for these things, rather than try to make them perfect at this point.

For the diagnostic referral, it's just a written request dated and signed by a physician, not necessarily the authorized user, and not necessarily a nuclear physician. Probably in most cases it's not. It's someone sending a patient for a diagnostic test. What we're really asking here is that it be in writing, that referrals come in to you in writing.

Let me skip the prescription. First of all, if you don't like that word "prescription," just think of it as a written directive. The intention here is to have the description of what you're about to do to the patient

written down, rather than giving it as an oral directive.

I skipped over a footnote that was on the first page for emergent conditions. If you have an emergency, of course you do whatever you need to do, and you write whatever you need to write after the emergency is over.

The basic idea of the prescription is just to have it written down. This is the same thought as, when somebody tells me a phone number, if I want to remember it I write it on a piece of paper, because I want to call that person in 15 minutes, and I'm not sure that I'll remember that. It become doubly important with radiation, of course.

For prescribed dosage and dose, we're just merely trying to distinguish between radiopharmaceutical use or radiation, typically therapy, for dose.

Any questions about the definitions? Are all these fairly understandable, and can you work with them?

MR. ROSEN: It's not so much a question as an operational problem. A diagnostic referral: The orthopedist says, I want a bone scan. Item number 1 on the list says, insure that any medical use is indicated for the patient's medical condition. There is no authorized user present in my department, nor does there have to be, from my understanding, so a nurse might be reviewing, the tech might be reviewing this referral. I have a choice now: I either get the referral or a prescription. The authorized user has

to document the dosage, et cetera, et cetera. The referral does not. This implies that the clinical procedures manual will have to have a list of clinical indications in it for when this particular scan or procedure is done. If it's not, the system in fact will break down.

MR. TELFORD: Okay. That's a way of letting the authorized user approve a procedure. See, in a prescription we're asking for the authorized user, or a physician under the supervision of the authorized user, to sign that.

MR. ROSEN: But a prescription is not required for the non-iodine, less-then-30-microcurie procedures.

MR. TELFORD: Correct. What you're saying, I think, is that a referral comes in from a non-nuclear physician for a bone scan, so you ant to put a list of indications in your clinical procedures manual so that, if these match, then in effect the authorized user will be approving of the procedure.

MR. ROSEN: I really can't think of any other way of doing it, quite honestly.

MR. TELFORD: Okay.

MR. ROSEN: It assumes that every referring physician has intimate knowledge of the nuclear medical process, the diagnostic process, otherwise, and I know that's not true.

MR. TELFORD: Well, no. Recall what I said a

while ago, that when a referral comes in, the technologist must match the requested procedure with the procedure in the manual.

MR. ROSEN: Someone says a bone scan, and they give tech-labelled phosphate, and they do the bone scan. The doctor may have said, do a bone scan, and the patient's got a brain tumor, but that's what was requested.

MR. BOLLING: I think part of the responsibilities and duties of the authorized user would be to review the requests. At the hospital that I worked at, technologists were not allowed to touch a patient unless the authorized user or his deputy has initialed some part of the upper corner of the requests indicating that the night before, before the patient was even scheduled, the request was reviewed and the authorized user indicated, yes, go ahead.

The procedures manual that was used by the technologists was just an additional check. Just as you said, a patient presented with a certain diagnosis may in fact need some other test that's not specifically anatomically related to what they have.

MR. ROSEN: This is one of these things that, again, does not apply to our particular institution. We have three full-time physicians in house at all times. But I have seen practices operate where the physician only comes into the department at the end of the day to read out his

films. There is in fact no one, no authorized user, present as part of this process, so it is in fact up to a nurse or a technician. Maybe as part of that institution's plan, they can assign that responsibility, and a nurse would, perhaps, be a better choice, since they're more familiar with medicine than a tech.

MR. BOLLING: Well, I just had occasion to review the duties and responsibilities of the authorized user yesterday in writing a letter to a physician in Texas. Prior to the '87 comprehensive revision of part 35, the regulatory guide, 10.8, revision 1, I believe it was, clearly indicated that there were three things the physician was to do: choose the patient, choose the dose, and interpret the results, be they image or data. We dropped the last one in incorporating the requirements into the regulation from the regulation guide; we dropped the interpretation one, but we still do have the selection of patient and radiopharmaceutical. How they do that, we don't get too much into that, but it would seem to me that it's a very easy thing to do for the physician to just review x number of requests the night before, of course allowing some provision for emergency lung scans or whatever.

I don't think it's asking too much for a physician to review those requests the night before and give some indication as to whether or not a scan is needed, because

quite often we received misadministration reports where the patient really needed a sonogram, or perhaps a CT scan. There's a lot of scanning jargon going around along with these new modalities of imaging, so we really want to be clear as to whether or not the patient even needs something nuclear.

MR. MEINHOLD: I can't help looking at the regulatory guide as we come to each one of these questions, because I think it focuses more on what we're after here. What it says is, "Before writing a prescription, the authorized user or the physician under the supervision of an authorized user will personally review the patient's case in order to establish that medical use is indicated." You're saying sometimes that doesn't happen.

MR. ROSEN: Well, if we don't have a referral, then that has to occur, but if the referral is there, the prescription isn't an issue.

MR. MEINHOLD: I understand all that. What I'm saying is that what we want to get out of the pilot program is an idea of whether or not this particular requirement is met in most institutions, if it's difficult, expensive, time-consuming, helpful, whatever. I think that will answer, sort of, the opinions we have of this problem, rather than discussing it. What normally happens with this particular issue is that radiologists and nuclear medicine

physicians almost always think this is a good idea, and endocrinologists think it's dopey, because they're aren't the authorized user. Well, we need to find out how everybody handles this issue and see what it looks like and find out if, in fact, in order to have a good program, this is an element. Is that an expensive, time-consuming, helpful, or is it not helpful, terribly expensive; what is the issue here? That's what we want to find out.

MR. ROSEN: Maybe I should ask a simpler question, then. In the stratified selection process, are the kind of practices that I'm talking about represented?

MR. MEINHOLD: I hope so.

MR. ROSEN: In this room?

MR. TELFORD: Small guys?

MR. MEINHOLD: Ed Kaplan can tell you how successful we were in each category.

MR. ROSEN: It's interesting. This came up with a colleague of mine who asked me the question.

MR. MEINHOLD: I'm sure it did.

MR. ROSEN: I said, why don't you call the local or regional NRC office and ask them the question, and as to where does the physician have to be during this process, the response was, someplace on the face of the earth.

MR. MEINHOLD: Let's find out.

MR. ROSEN: I just want to make sure that area's

covered and if we're represented in that area in the room, fine.

MR. TELFORD: Okay.

MR. WIEDEMAN: One other point that I wanted to bring out is on footnote 5, about the emergencies. In my review of the misadministration reports for the last three years in Region III, this seemed to be a big problem, and it's on emergency lung scanning. The first thing you think of when they order an emergency lung scan is that they're probably looking for a pulmonary embolus. The first thing that comes to mind with a nuclear medicine technologist would probably be an MAA lung scan. However, once again, it's the communications between the referring physician, the authorized user and the technologist. Sometimes we find out he really wanted a CT scan, or he really wanted a xenon ventilation study, or a DTPA aerosol study. There's one thing that you want to kind of keep in mind in your procedures manual: what we have to do to get those three, four, or five different medical modalities straightened out when you get this emergency lung scan order.

Maybe the procedure should call that the physician or the technologist contact the emergency room physician, the referral physician, and ask them, do you want this or do you want that. That way it will be straight in everybody's mind. I remember seeing something like 10, 12 cases in

about two and a half years regarding that.

MR. TELFORD: Okay. Let me ask for a show of hands of people that think they understand the proposed rule and understand the definitions well enough that they can implement a QA program during the 60-day period that, in their opinion, would meet this. Just at your institution.

[Show of hands.]

MR. TELFORD: Okay. Everybody said yes. Good.

Let's move on to the next item on the agenda.

MR. KEARLY: John, could I ask one question. Hopefully you're going to tell us how you want this reported to you, that we've demonstrated that we can implement this program. Is that right? That's the aim of the workshop. That's one big question of mine.

MR. TELFORD: Okay. Hopefully, when we come out of this this time.

I'm moving on the agenda to the discussion of the pilot program, what participants can expect and what is expected of the participants. I think that's your question, right?

[Handouts distributed.]

MR. TELFORD: Does everybody have one of these?

I just wrote down some objectives. This is not necessarily inclusive, but I was trying to capture the intent of what's going on here. The overriding issue is how

to do this, how to do this in a way that you use the performance-based rule but you test it and you find out from licensees how to do it better, how to have less impact on your institution, how to be less of a problem as far as administration procedures or paperwork or something.

Number 1 is that we want to understand how you view your program. We want to learn from you.

Number 2 is that we will want to understand how licensees actually conduct their program in actual practice. I'll tell you about a small number of site visits -- small compared to the total number.

Number 3 is that we want to determine of these performance objectives are any good, and they have a chance of preventing or catching small mistakes that can lead to misadministrations. Maybe it's just on the way to the door, and it's part of the treatment, calculations, or maybe it's identification of patient steps.

Fourthly, to determine, if these proposed objectives and the proposed rule are implemented properly, can they provide high confidence that errors in medical use are being prevented.

Now, this is more of the details and a chronological description of what has happened and what is about to happen. Upon publication of this proposed rule in the Federal Register back in January, we started sending out

invitations for the licensees. We found that, as undoubtedly all of you know by now, we sent the letter, and sometimes we get the thing saying, this guy doesn't work here anymore. So we sent other letters, and finally we contacted you, and we said, would you please consider being part of this pilot program. You said, let me think about it, and then you said, well, it sounds like a good idea; let me check with three other people. Okay. Now the approvals are in. Well, that took a while. That took about a week and a half, two weeks, sometimes three weeks for any given licensee, so it took until maybe March 9 to round up everyone, get all the approvals for the ones we have on board.

Secondly, we invited volunteers to review this proposed rule, which we've gone through. Once you determine that your program meets 35.35, your existing program or modified if needed, or in the rare event that you don't have one, you develop one. That's during March. That's the grand scheme of things. Toward the end of the month, you should have the program committed to writing and give Ed a copy. I'll tell you what happens to those in a minute.

Now, we're going to have workshops, five of them, around the country. Today we're in New York. On April 4 we'll be in Chicago. On April 6 we'll be in Atlanta. On April 18 we'll be in Dallas. And on the 20th we'll be in

San Francisco. So you know what's happening.

The fourth item is, during April you use April to develop or modify any written instructions that you use every day. Perhaps it's patient identification, or it's instructions to nurses ensuring that the medical use is indicated, or whatever. Please change your instructions, please train your personnel, if that's required. If your program already is ready to go, then you don't have to do any of that. April is for that purpose.

Now, for May 1 to June 30, we would like to do an operational trial. We would like you to put this modified program into place, test it for 60 days, so that's number 5: to conduct a 60-day trial.

Now, to retain specific records: Those records are of prescriptions or referrals and the administered dose or dosage. That's it for now.

I don't know if I said on here, but let me tell you what happens to your QA program, the copy that you give to Ed. For 18 of these, we have what we call our QA team that will review these 18 programs and evaluate them, kind of a licensing process, but this is fault-free. At the next workshop we'll tell you the criteria we used to evaluate those 18, so that you get an insight into how we do that or how you can appear to be better, in the event that a rule like this ever becomes final. Secondly we'll express to you

what we think of each of those 18 programs, in a very non-fault-finding manner. We'll express to you what we think is good, what's positive, what's negative, and what maybe needs a little work; it's just insight to you. I mean, you want to get something out of all this, right? That's one of the things we're going to give you.

The second thing is that this QA team will visit those 18 sites. There will be 12 NRC and 6 agreement state sites that we will visit, randomly selected from that large number I mentioned, 22 and 46. Now, this will be a one-day visit. It will not be an inspection, but will rather be a site visit. We will evaluate your program. The principal question we want to ask is, are you implementing the program you say you are. We just want to come in and maybe observe some procedures, examine some records, whatever the magic is that our inspectors. No citations -- you can't be cited against a proposed rule. We're there only one day, focusing just on this. We just want to get the impression of how well you're doing because we want to learn the effectiveness of the program.

Now, it could be that one hospital has a great program on paper, and you get there and it's either great or it's not. Another hospital could have a program that does not look so good on paper, but you get there and you find out, gee, they're doing a great job. That's really

important information to us, because if it turns out that everybody's doing a great job, regardless of what the paper looks like, that tells us something.

Let's see what number 6 is all about.

MR. ROSEN: John, excuse me one second.

MR. TELFORD: Yes.

MR. ROSEN: Can you repeat those specific records.

MR. TELFORD: I think we sent that to you, but let me go through it. It's the diagnostic referrals -- Now, this is for the purpose so that when the QA team gets there they can say, let me see your diagnostic referrals; let me sample those; let me look at your clinical procedures manual; let me look at your prescriptions; let me look at your record of administered dose or dosage.

MR. KEARLY: This is only for I-131 for this; is that correct?

MR. TELFORD: This will be all referrals; keep a record of all referrals. You file these things someplace, right?

MR. BRAHMAVAR: Including teletherapy?

MR. TELFORD: Yes, including teletherapy. In teletherapy we visited Johns Hopkins, and they keep their records on each patient until that patient dies, so they know the complete diagnosis; they know each treatment that patient's ever gotten, et cetera.

What we're trying to do, in part, is number 7 here, where we could -- not leave, but so that the program could identify any deviations. Is that what we're asking.

MR. KEARLY: For teletherapy, that would amount to the entire chart for each patient that's treated on a cobalt unit for that 60-day period.

MR. TELFORD: Well, you have it.

MR. KEARLY: That's what you're asking us to compile and prepare for you?

MR. TELFORD: Not necessarily compile and not necessarily prepare; just retain. For you, it's no different. You've got the prescription; you've got the administered dose.

MR. KEARLY: But we just don't file it away, I guess is what you're saying, or at least we could keep a list of everybody we treated for that period. Usually the process is you treat the patient, the chart's reviewed, and that's it's filed for the future massive filing.

MR. TELFORD: All right.

MR. WIEDEMAN: We wouldn't expect you to have them piled up in a corner, saying, now this is what we've treated in the last 60 days, because we're not going to look at all of them. Some of these places run 30 to 50 patients a day, and that's a lot of records. We're just going to take a random sampling of the records.

MR. KEARLY: We'd just maintain a running list of those patients who were treated on that machine, and that would be okay?

MR. TELFORD: Yes, that's fine. This just a request to keep a record of the cases treated -- referrals, prescriptions, administered dose or dosage, and of course you'd have the clinical procedures manual -- so that if your institution is chosen for the one-day visit, then we take a random sample of those and look at them.

Now, what I'm calling the post-test workshops, after the 60-day trial period, Charlie Meinhold will talk about the evaluations later on on the agenda. He will appear after Lloyd Bolling; I apologize for not putting him on. We want to hear about your evaluations during the post-test workshop. We want to hear about your experience and your suggestions for improving 35.35 I can tell that some of you -- well, I should say all of you -- have thought about this a great deal, but for some of you it's very obvious that you already have suggestions, and I appreciate that. We'll also talk about the guide. This is what I said before, that the QA team would tell you about the criteria that we used for two things: one is for the evaluation of the program and for the results of site visits.

Now, everybody's program will get evaluated, not just the 18. I failed to mention that. You'll get some

f edback on your program, guaranteed.

Also at the post-test workshop, we'll tell you about the findings of our 18 site visits.

Any questions or comments on that?

[No response.]

MR. TELFORD: Some of the things that I hope you get about all this is to not only know what the criteria are but to understand what we will have used to evaluate your program. You'll get the results of the evaluation of your program. We would want you to understand the criteria that we used to evaluate the program on site, and to learn those results. Maybe you can profit from other people's experience, other people's insight -- I don't want to say mistakes; I want to say insight or better ways of doing something.

Number 5 is that, very honestly, we want to listen to you very carefully on your evaluation of this proposed rulemaking, because at the post-test workshop you will be an extremely valuable resource. Not only will you have thought about the proposed rule, you will have tested it in your hospital for 60 days. That is what is intended for a performance-based rule. If you find part of it that's not useful at all, doesn't do any good, I want to hear it. If you find that it's not sufficient and want to do something different, I'd like to hear that, too. Your input will have

an extreme effect on the people writing the final rule, so that's the reason I put down 5.

Six is to assure that your suggestions will be listened to and used, because we would like to simply have a performance-based rule with some good objectives in there and give all the licensees a good guide and say, okay, we're not convinced everybody can do this. We have to have a good proposed rule to do that with. That's where you come in.

This is what we would like you to do, develop your program to meet the proposed 35.35, attend the pre-test workshop, provide written instructions to your personnel as necessary, and prepare for the 60-day trial. You say you've already committed your program to writing, you've changed your instructions, your procedures, and your training to get read, and you conduct a 60-day trial, and evaluate it -- and we'll try to make that easy for you, give you a handy-dandy rm -- and attend the post-test workshop to give us the benefit of your experience and your findings and your suggestions.

Questions? Comments?

MR. KEARLY: John, this is kind of a general comment. The NRC is the sixth or eighth agency or group with the power to put us out of business, telling us to do something different in quality assurance. In the past three years, we've jumped through hoops over quality assurance.

JCAH told us one thing. ACR came out with a recommendation for another thing. We went through a year's worth of development on the first one, a year of development on answering what on earth to do for the ACR. The JCAH inspected and said they don't accept what the ACR said, and they told us to do it differently. The state comes in, reinspects, and tell us to do something else, the state licensing group. The state radiation control group tells us to another thing. There's a group in the state that tells us something else about technologists, which is marginal to this but still have an impact. Now you come in and say we're supposed to integrate what you want into our quality assurance program, and you've made no attempt -- None of these groups have made any attempt to integrate this entire mess into one whole. You've caused us an enormous amount of time. You're going to cause us a huge amount of time, and there will be no reimbursement for this to speak of. We can't get more people to do this work. It's frustrating. We want to do the best job. There's no question everything you're asking us to do is good practice, but it's very hard on all of us to try to response to all of these things without a real effort on your part to try to integrate it into what we've been told already by massive and very powerful forces.

Part of my comment is, I have a quality assurance

program. It's the fifteenth draft over the last three years. It may or may not incorporate everything that you're saying in a form that you can recognize. For us to complete our quality assurance program is going to be a -- Until we get through this, we probably won't know how to incorporate your stuff in some way.

I don't know. You may get reactions like that from elsewhere in the country, too. I don't know if anybody else has that feeling, but we have felt really hammered, and this is one of the latest.

MR. TELFORD: I'm tempted to ask, what do you want me to do, but let me answer the question first. As far as coordination with states goes, if a rule like this becomes final, then it would be a matter of compatibility for each agreement state, for all 29 states, so that the state would be telling you the same regulation that we are, in the sense that it's at least that much. Other states, like New York could say, do that plus some other things. That's their power as an agreement state. We will coordinate with the agreement states.

Now, with reimbursements, just this week we met with a gentleman from HCFA to talk about, what if the NRC requires these programs, what does this mean; how do you go about reimbursing for equipment, personnel, and procedures. We're exploring with HCFA just how they do that to find out

if we can make any logical and convincing arguments that certain things ought to be allowed or not.

You mentioned JCAH. We have talked to them previously, and we will have more discussions with them on what they require versus what we require. My understanding currently is that they have gone to all of their members and said, you tell us what you want to measure in your department, or what should be an indication for whether or not your program is working very well. They have general guidance as to what they may want you to do. That's for all departments, and I would not feel too uneasy about making the statement that they're not as specific as we are.

MR. ROSEN: That's one of the problems, by the way.

MR. TELFORD: Let me come back to that.

With the American College of Radiology, we met with them during the time when they were developing their model QA program. In fact, some of the things in their model QA program you'll find in our guide, especially in teletherapy. I would note that what they would ask for in a prescription is about four times as much as what we have. They ask for a lot of stuff in the prescription. That was useful to us. We are coordinating with the ACR, and we will continue.

Could you expand on the problem with JCAH?

MR. ROSEN: In a moment, but let's get back quickly to something. When the state comes in, in a state of Pennsylvania they come in from a regulatory standpoint of radiation. It's the Department of Environmental Resources. But it may be the Department of Health putting the demands on you, in terms of the quality assurance, and believe me, if you think it's a problem with you interfacing with the states and JCAH, you ought to see the problems within the states. We had inspectors come in from the Department of Health and say, we don't give a damn what the regulations are; this is the way you'll do it, even though it's not what we referred to.

MR. TELFORD: Sorry about that.

MR. GRAHAM: Well, it's the ubiquity of the way the rules and regulations are written and leave so much to the interpretation of the individual inspector, so consequently you'll find two- or three-men teams coming in, all saying various things, and you can't even get that group together, let alone trying to coordinate the various things.

MR. TELFORD: Okay.

MR. ROSEN: The level of people, we deal with, by the way, you haven't lived through a close-out with a Department of Health group this size, having someone turn to you and say, how many cases of leukemia did you have in the biology department last year. It really tells you they

have a very firm understanding of what goes in the world.

Want to hear about the pregnant pause?

By the way, the answer is zero.

[Laughter.]

MR. MEINHOLD: I was wondering, Jerry.

MR. TELFORD: Your question was about JCAH.

MR. ROSEN: Yes. I'll give you an example of how they operate.

They're requesting in diagnostic radiology -- by the way, that's where all of our radiation problems are, not in nuclear medicine -- In diagnostic radiology they're asking you to take the more common diagnostic procedures -- radiographic, not fluoroscopic -- and provide doses so that we can tell the patients what their receiving dose was, and so that we can compare between institutions to find out how we all were doing. They do not tell you how you might go about that. Within the city of Pittsburgh we've taken some straw polls, and the bottom line is that everyone it slightly differently, and I dare say if I invited all the medical physicists in Pittsburgh to come into one of my diagnostic rooms, we would all generate somewhat different numbers.

As a result, you can't compare from facility to facility. To me, the only sensible dose to give to the patient is something called H-sub-B. I would hate to tell

them they get 200 millirems from this picture and that picture when they are not additive, because the same tissues are not necessarily in the same view. They're asking us to generate a number that will be further confusing to the general population. It's one area where I guess I would prefer something more prescriptive. They won't even define what a common procedure is. We do 40 percent of our general radiography in portables. We don't even do it in the radiology department. It's something like 200,000 films a year.

MR. TELFORD: Well, we wouldn't touch dose with a ten-foot pole, because that's the purview of the authorized user-physician. We want that person to be in control.

MR. ROSEN: Right, but they drop this on you and say, this is what we want you to do, but with absolutely no guidance. Sometimes some guidelines in fact are more than welcome.

MR. TELFORD: Any other points?

MR. BRAHMAVAR: The QA program that they want us to submit, I would say that most of us would have those programs in place for many years now. We really mean 85 to 90 percent of what you're saying, but they may not be in the exact format that you want. Do you want us to reconstitute in the format that is given and submit, or submit the way it is, and when you come for the site visits you will see

whether it meets or not?

MR. TELFORD: Well, what we want to do is, quote, "evaluate your program." It would help us if you could give us an outline that says, for the eight objectives, look to this section for this requirements -- for this objective, or look through this other section for this other objective. If you could give us a little road map through it, it would certain help our reviewers.

MR. BRAHMAVAR: For teletherapy, you know, the chart is kept until the patient dies, and even after his death we keep them, for medical and legal reasons later on. In the chart, the prescription and the daily dose delivered, the weekly checks, the treatment plan, and the total dose delivered, and the summary that is sent by the physician to attending, that's all in that chart. That is the record, so there is no other place where it is recorded in a separate lot.

MR. TELFORD: Don't send the records, just the program.

MR. BRAHMAVAR: But if you are given the copy of that chart as our documentation, will that suffice, or will we have to mark it.

MR. TELFORD: Or a blank chart.

MR. BRAHMAVAR: Right. Okay.

MR. TELFORD: If you have a blank record that you

append to your program and say, we keep the records on this chart, and you identify the deviations, okay.

MR. WIEDEMAN: Yes. "This is where we do our weekly chart check, and this is the prescription that the user physician has filled our, and here's where we put our treatment plan. This is where the fractionated doses would be entered, this is where the total dose would be entered, that type of thing.

MR. KEARLY: John, can I put my other comment in a little different perspective.

When JCAH came in to inspect us last year, and they took a look at our program -- which was very nice; according to what the ACR had recommended, we were doing everything -- they said, that's not what we want to see; we want to see what we call our ten-step program for monitoring and evaluation; how do you fit your requirements into that ten-step program? That's your job, it seems to me, to tell us how this is to fit into what's already been required of us by somebody else whose authority is as great as yours.

MR. TELFORD: Well, all we're really asking is that you have a written QA program that meets these objectives. JCAH is going further, and so is ACR. All we want you to do is to look at your program, look at the proposed rule, and say, yes, it meets the objectives, and if it didn't, I modified, I added a little thing here, a little

thing there, so that these eight objectives are met.

You're looking at various requirements and saying, other people are requiring more of me, and that may be true.

MR. KEARLY: In different format, in different ways.

MR. TELFORD: Well, we didn't say anything about format. All we asked for was a copy. We didn't say, write it a specific way. Now, if you would be so kind as to give us an outline as to what parts of your program meet which objectives, we will appreciate it very much, because we want to review your program. We want to both give you feedback and learn from it, so that would help us. But you don't have to give us the ten-point evaluation that JCAH wants.

MR. KEARLY: That's the program.

MR. WIEDEMAN: Your JCAH evaluation that you're commenting on, are you talking about for the entire radiology department, or are we talking specifically of nuclear medicine?

MR. KEARLY: We're talking about the hospital, and specifically radiation oncology, which is where I spend a good time.

MR. WIEDEMAN: And that's where they said that you're --

MR. KEARLY: For the whole hospital. They want every quality assurance program in the hospital cast in what

they call their ten-step program for monitoring and evaluation.

MR. WIEDEMAN: And they want you to be very specific on these, or like motherhood statements that "we plan on delivering quality medical care"?

MR. KEARLY: You have to be monitoring things which specifically address the quality of patient care.

MR. TELFORD: That's above and beyond what we're asking for.

MR. BRAHMAVAR: JCAH's emphasis is physician-drive quality assurance, patient care, whereas this is equipment and quality control.

MR. KEARLY: But they stepped over the line with this. This is not just equipment that they're talking about. NRC has stepped into the patient care aspect.

MR. TELFORD: Could you point to an objective?

MR. KEARLY: Just by asking that the medical use is indicated by the patient's condition. Is that an equipment question? Certainly not. That says the physician must review the case for appropriateness, which is one of the JCAH -- sort of the heart of what JCAH wants people to do.

MR. TELFORD: It didn't say how.

MR. KEARLY: I'm just answering the question that this really isn't just equipment-oriented or even specific

-- [Pause.]

MR. TELFORD: Would anybody object to taking a little break?

MR. TSE: Just one point related to this question first, and then we can take a break. If the JCAH requests you have similar objectives, then that would meet the NRC objective also, with the same procedure.

Second, this trial, therefore, is not really a true requirement yet, and therefore really does not impact very much.

Third is that we are talking to JCAH, and JCAH said they're going to look very carefully at what we propose, and they will consider whether they should be integrated together, or some words like that they indicated to me.

We are not just in a vacuum, but it is complicated.

MR. KEARLY: It's not a simple matter of just implementing.

MR. TSE: Right.

Well, for the pilot program period, thought, it's not really a QA program. It's just a trial.

MR. TELFORD: Let's take a 15-minute break.

[Break.]

MR. TELFORD: Next on the agenda is any

considerations for the agreement state licensees. A large number of the volunteers are from agreement states, and some states have requirements that have the potential of either being in conflict with the proposed objectives or being in addition to those objectives or procedures. Lloyd Bolling is here from our office of state programs to tell you what to expect and to give you a couple of examples.

MR. BOLLING: Those from agreement states -- I guess mostly they'll be from New York and Maryland -- will be expected to follow the license conditions and the regulations of your state, while keeping in mind the objectives of the QA program. Of course, while you're doing this kind of work, if you come across any violations of your regulations or any leaking sources, misadministrations, you are to treat them as though you would without the QA program in effect. This is just a trial.

Beyond that, I should focus more on New York State, I guess, because New York has an existing regulation which, according to what I've read, is quite general. I'm hoping in negotiations with New York State that we will be able to convince them to come a little closer to what our reg is. Our regulation will be what we call a matter of compatibility -- that is, that New York will have to adopt certain parts of the regulation verbatim. We will have to talk a little more with New York State as to how their

regulation fits into ours, but the thing I'd like to just remind you is that you're operating under a current license, and all of the license conditions are still in effect, and you are to follow those license conditions. They take precedence over anything else that you might be doing.

If there is in your mind a conflict, you can either contact me or contact the state, and we can discuss it and work it out.

Are there any questions from the agreement state licensees?

MR. STRUBLER: I presume that, again, with the agreement states this ultimately will come under -- the jurisdiction of linear accelerators will also come under this, because the proposals for teletherapy, technically for cobalt, and maybe there's a smattering of cesium units still there, would still be applicable to linear accelerators as far as agreement states are concerned.

MR. BOLLING: Yes. Very early on in this QA process it was pointed out to the NRC management that there's a whole area of activity that we do not control, and that would be lin accs and NARM material, accelerator-produced, not naturally occurring. The response was that, yes, we hope that the agreement states would adopt similar regulations to also control those materials and help to reduce problems and misadministrations in that area as

well, but we are not in any way, nor can we, advise them to also adopt these regulations for those materials, because the Atomic Energy Act is silent in those areas, so legally we can't say anything about it.

MR. ROSEN: You are requiring those who have adopted cobalt teletherapy.

MR. BOLLING: For byproduct material, yes.

MR. ROSEN: Does anyone know of any states that have not adopted them across the board? Is there a state without a misadministration report requirement?

MR. BOLLING: Oh, yes. April 1 is when the compatibility clause goes into effect, and as far as I remember, there are only about seven or eight states out of the 29 agreement states that actually have a regulation in place. A number of others are doing it by license condition until they can get their regulations up to speed.

MR. ROSEN: Where they'd done it, have they applied it across the board, both to byproduct and to non-byproduct material, to accelerators as well as to cobalt teletherapy?

MR. BOLLING: I don't know.

MR. ROSEN: I would like to think there isn't going to be a double standard.

MR. BOLLING: Yes. It would be unfortunate if there was.

MR. ROSEN: We're solving part of this problem right now, in effect. We're building four accelerator rooms and probably will phase one cobalt machine out next year and the other one the year after. I still expect to see a requirement for QA, though.

MR. BOLLING: I would be very surprised if New York didn't apply it to both, but there could be the odd state out there that would concentrate only on what NRC has told them that they have to apply it to.

MR. BRAHMAVAR: But there are many more linear accelerators than cobalts at this point.

MR. BOLLING: Yes.

MR. ROSEN: And the vast majority of drugs used for diagnostic purposes are not byproduct anymore. The majority are now accelerator-produced.

MR. BOLLING: And it's growing, yes.

MR. ROSEN: I guess the point is, every time the NRC makes a ruling or considers the impact, they look at the byproducts.

MR. BOLLING: Right.

MR. ROSEN: And that's only the tip of the iceberg. If, for instance, as an example in the non-nuclear area, if the NRC drops occupational-exposure limits, which certainly people have requested be done, that impacts diagnostic radiology, which is where, in the medical

community, the real exposures to personnel occur. They will have a severe impact, but the driving legislation will not take that into consideration, presumably.

MR. BOLLING: Well, when we go out for a rulemaking, we do have the public input process, and we get a lot of questions and comments along those lines. There are factored in, to the extent that we can. We have the NVLAP requirement for dosimeter processors, and we know that that had an effect on the X-ray area as well. We hope it was a positive effect.

Any other questions from the agreement state licensees?

[No response.]

MR. BOLLING: In the agreement states, if you have a current procedures manual that you're operating under that has been submitted as part of your licensing package and then approved, whatever extra documentation steps you take in order to formulate this QA program on a voluntary basis for us, you would still be expected to carry out your normal functions that you submitted as far as your license application, and not to do so would put yourselves in jeopardy. Of course, the pilot program is only running for 60 days, so after that 60 days you will be looked at by your regular regulatory agency, and they will not take into account what went on during the pilot program.

I can't think of another specific example like that one, but that will just give you an idea of what's going on.

Also, the regulatory agency heads for Maryland and New York were down to Washington to visit with us back on the 14th of March, so they are aware of what we're doing, and they've had some input into the process so far. If any of you are chosen as a site visit hospital, we would invite them along, although if they felt they couldn't make it for some reason we would still be visiting your site and looking only at the QA program, not at the other aspects of your activities.

MR. TELFORD: Thank you, Lloyd.

MR. BOLLING: Sure.

MR. TELFORD: Next let's hear from Charlie Meinhold to give you sort of a pre-understanding of the evaluation form that we're thinking of using after you've tried the program for 60 days. These are the kind of questions that we want to have you look at. We basically want a grade; tell us it's A, B, C, D, and F for each part of this.

I'll turn it over to Charlie.

MR. MEINHOLD: I guess you could tell just from my comments this morning where I'm coming from. I think this procedure has come a long way from when it started as a

prescriptive way to accomplish quality assurance, and that a performance standard is exactly what the medical community ought to be looking for. Now, the details of it, which John has gone through here, are the issues. I think the iodine question is one that does need to be resolved, but nobody can do this better than you people, telling us what it means, or any of the other issues.

What we tried to do in designing the quality assurance pilot program, as opposed to the visits that you'll be receiving, which for us is a separate part, the visits that John and the state people will be doing to look at the programs of the selected 18. We're interested in the whole 46 plus 22 and how we're going to look at them in terms of what it means to have this quality assurance program.

As a result, we used as our basis the draft regulatory guide, and that for us has all the elements to some degree that are expected to really conform with the rule. You may or may not agree with that, and that's what the pilot program is about.

We've sent you the regulatory guide, and what we will be doing is giving you a form with a format of this type. This is just to give you a flavor of what we've been doing.

What we want you to do is characterize your

answers according to the elements found in the draft regulatory guide. As it turns out, these are not correct as they now stand. To give you an idea, one of these might be the requirement that, before administering a radiopharmaceutical, the authorized user or a physician under the supervision of an authorized user will personally make and date a prescription. Very simple, straightforward. What we want you to do under that category is to look at the benefits: what do we want to know. We say the benefits can go from very likely to avoid errors to something of no value. We will be providing you with a piece of paper that will give you some ideas in terms of this. For instance, when we come to personnel availability, you say, there's always somebody available to do that, there's never anybody available in our institution to do that. We'd like you to think about what kind of people are needed, how many do you need, how many are available to you.

To help you with that, we intend to have you fill out, whenever a problem is a 4 or 5 -- and you get the idea that we're coming from things which make it good, easy, efficient, economical, et cetera, to hard, difficult, unnecessary, onerous, bad for medicine. That's the range we've got here. Whenever you have a 4 or 5, we need a little more information, believe it or not. If you're telling us that this thing won't work at all in your

institution, then we'd like to have some comments on it. We'd like to have you tell us why. We'd like to have you tell us why there's a problem with people, that in your institution a physicist only shows up once every three weeks, or whatever the reason is that makes this particular item that you want to have a 4 or 5, and just to give us an idea of what that problem is.

In all honesty, what we're trying to put together is the impact of this operation on the community. We can't do it unless you give us truth.

Another aspect that I would like to really focus on is that it's not going to be very helpful to you or us or anybody else if all we get is a list of 5's, which is sort of the mind-set of some people that are going to be looking at this program. "I can tell you what the answers are. It's 5's all the way down." That's why we're going to make you fill the questionnaire. You're going to have to work hard to have 5's.

The fact is, we all know that many of these are motherhood statements, and, in a sense, by looking at those you can tell whether or not we've got an answer here which is responsible and professional, which is what we're trying to do. We're trying to provide, through this pilot program, a report to the Commission and to the Staff which says, here's how it really impacts. If we get just nonsense

answers that are all 4's and 5's, it's not going to help anybody, whereas, if we get a distribution that really does key in on the issues that are difficult -- and I think the question with the iodine is an issue that needs to be addressed -- then there need to be some comments, in terms of the particular requirement that would make that 30 microcurie requirement onerous. I think we need to just say that we do 600 of these a month in our institution; the cost of this would add 20 percent to the cost of care for these people, whatever it is that you want to say. That the number of people for this would be more than required to presently staff the entire nuclear medicine center. Whatever it is you think is a responsible comment on any of these particular issues.

MR. ROSEN: Can I just interject for one second?

I would like to think, since this is the first group, because that is a real problem for everybody, we might be able to leave this room today with a consensus and modify what's going to happen with the pilot projects right up front, at least to get something closer to reality, because you've got the time to do it right now.

MR. MEINHOLD: Let's come back to it, but I think we might want to consider that later this afternoon.

All I'm really saying is that we intend to conduct the 60-day test on our project through this form and the

comment sheet, and some descriptive material, to enable us to say what we think is out there. It's clear that not only is a list of all 4's and 5's going to be less useful to us, but we've got a checks-and-balances issue in here, because of course there will be 18 visits by the NRC quality assurance group that will help us understand those 18, so the 18 that are visited in a sense will be an anchor point for us to make the judgements about the remaining facilities that won't have had the visits. We hope that through the visits of the 18 and the answers that you give here, we will be able to provide the Staff and the Commission with a pretty good estimate of what each element of this means in terms of medical care and the ability to prevent misadministrations and the costs and all the rest of it.

I don't know if I need to do any more than that. This is not the exact form that this will be in, but I think it gives you a flavor of what we're trying to do, and we'll get it out to you in a week or so.

John?

MR. TELFORD: The only thing I wanted to add is that it goes without saying that if there is something that didn't work out so well, the thing we want to hear most is how to do it better. Tell us how you would do it, what you would recommend as a better objective or a better criteria.

MR. ROSEN: In that respect, we're going through

the pilot project, how do you feel, how does the Commission feel, about making modifications, adjusting things as we go along, so that at the end of that we presumably come up with a better program. If we put something in in the first few weeks, realize that it's no good, it would be senseless to carry that through for the next six or eight weeks.

MR. MEINHOLD: My personal feeling in terms of the value of this thing would be for you to do whatever changes you want to make, as long as you meet the individual items that are in the regulatory guide, so that you can comment on each of those items. If you don't have it, then we can't find out whether it's a problem. That's different in terms of what we need to sent into the Commission. I'll let John answer that.

MR. TELFORD: We talked about that very question at the break, and we also talked about it over breakfast this morning. The answer is that, if you submit a problem and give your copy of Ed, and before May 1, let's just say, you come up with a better way, something you like better, incorporate that in your program, give us a copy of that page, send it to Ed. Another case: what if you're 30 days into the test program, and by actual use of something that you thought would work, you now know something better. Modify your program. The assumption is that you would be modifying it to make it better, not to decrease it's

effectiveness, but to at least maintain its effectiveness or make it better. Therefore, make the change and send Ed a copy.

Now, the question on that objective involving I-125 and I-131, we'll talk about that at the lunch break and try to give you an answer on what our guidance would be.

MR. STRUBLER: One final question: In addition to the people who fill out the forms will be some of our other designees. Do you need any uniformity in terms of who's going to do this? Do you want us to review the results before it's sent to you?

MR. MEINHOLD: Well, do you want to review the results before it's sent to us? What I'm saying is that the individual, which is you or your designees, are the ones that are sort of doing the overall evaluation. Now, it won't be very helpful to you or anyone else if you've got a disparate group here, because when we meet again, three months from now, we're going to say to you, it's very, very bad here and very good here, and ask for sort of an explanation of that. So I would guess that you'd want to do that before you sent them in. I think that you'd want to be able to defend -- if I can put it that way -- that the representatives that comes to the meeting out to feel that he can defend those answer, understand them -- that's what I mean by defense; I don't mean that you have to believe in

them, but you'd better understand why the answer came back that way, that's all. I'd guess you'd want to review them, myself.

By the way, I did notice that in John's list he said that you would bring your evaluations to the next meeting. I think we would ask you, actually, to send them to us ahead of time, because we do want to do an evaluation, because really the whole point of this thing is to say, on this particular item, checking patient identity, we found that there was general agreement that, although this wasn't the most beneficial item in the package, there seemed to be an acceptable -- in the category 1, 2, or 3 -- for virtually everyone, although we did see that the hospitals in Detroit had a problem here, and their problem was because of a language problem with the Polish people in Detroit. So we say, how are you doing to get around this, and somebody says, well, the way we did it in Texas with the Mexicans is the following. We will get the feedback that way, by having the information ahead of time, so we will be able to do sort of a statistical analysis of the answers for you all at the next meeting, so you'll understand that maybe what was a very serious problem for you wasn't a serious problem for everyone else, and then it will be valuable to ask why, or the reverse: why in your case it was so easy when everyone else said it was so tough.

So we hope this to be a helpful exercise to help us and the Staff and the Commission understand really the situation on each one of these items that's in the guide.

That's basically what we have in mind.

MR. ROSEN: Can you fill out the rest of the outline, then? I remember the 60-day trial being May 1 to June 30. What kind of time frame, then are you expecting these responses? When will we have the second set of meetings?

MR. MEINHOLD: Maybe we should discuss the schedule next.

MR. ROSEN: You did say you'll be sending these out within a week?

MR. MEINHOLD: About another week or so.

MR. TELFORD: The actual trial period we hope to have between May 1 and June 30. Following June 30, we would request that you fill out your evaluations and write up your suggestions. We would request those to be sent in to Ed sometime in July. We would give you at least three weeks before the next workshop, so you can expect the next workshop towards the last week in July or first week in August. We would have just a little bit of time to evaluate what you have. The reason I said, bring them with you, is because we very much want to hear your suggestions and your rationale.

MR. ROSEN: One problem: The original schedule that we got in the letter of January 3 I believe was for a 90-day trial period. Was it not?

MR. TSE: No, 60 days. The beginning of April to the beginning of June.

MR. ROSEN: The beginning of April to the beginning -- oh, the beginning of June. I'm sorry.

MR. TSE: Right, 60 days.

MR. ROSEN: You're talking about doing the evaluation before the end of June?

MR. TELFORD: No. The actual trial period, May 1, to the end of June, June 30, that's a 60-day period. After that's over, then you do your evaluation, during July.

MR. ROSEN: Oh, I understand. I thought you said towards the end of June.

MR. TELFORD: Well, it was a month that begins with J.

[Laughter.]

MR. TELFORD: You have three weeks, roughly, to do your evaluations after June 30. Now, towards the end of July, or the first week in August, is when we expect to have the next workshop for this group.

MR. STRUBLER: Can I interject? In terms of those that are going to the AAPM meeting, which is probably towards the end of July.

MR. KEARLY: And summer school is the week before.

MR. TELFORD: We shall avoid that week.

MR. MEINHOLD: We can be looking at the ones you send to us.

MR. ROSEN: A health physics meeting and summer school. I don't know how many health physics people will be involved here. And you're also in a very heavy vacation period, which is really going to handicap the evaluation process -- or it may handicap.

MR. TELFORD: Well, it may take us the whole month of August before we can schedule all of the five workshops. We will try to work around all the other meetings and avoid conflicts, to the best of our ability.

Any other questions before we break for lunch, or comments?

MS. KELTY: I wanted to make a couple of comments on some of the language, particularly the diagnostic referral being a written request. It's very difficult with outpatients to be 100 percent in compliance with that. We take a lot of our outpatient referrals over the phone, directly from the doctor's office. Sometimes the patient does come in with a written request. Sometimes they do not. Sometimes the patient is not at the doctor's office when the request is being made. I see that as an area that's going to be difficult with, and cumbersome and irritating for

referring physicians.

MR. HELFORD: Well, could you maybe have a procedure for your hospital where you have an overcheck. Your QA program may say what to do if you get an oral referral. It may say, have a physician under the supervision of the authorized user check these over, that it's what this patient have, or make sure the patient gets what they should get, versus, if some non-nuclear physician says, oh, liver scan, ten millicuries of I-131, then your program should have something in it, I would hope, that somebody checks that and says, no, we don't really want that; we want technetium. The definition says it's a written referral, and we're defining what we mean by a referral. The first choice is to have it written, but it you look at the eight objectives of the program, we want the written referral to match with the clinical procedures manual, so whatever you define in your program to make that happen, so that the patient gets what they're supposed to get -- because you have to combine number 1, make sure the patient is getting what they need, with maybe 2 and 3, to say, yes the referral matches the clinical procedures manual, and then 4 or 5, the technologist understands what to do.

MS. KELTY: But if I'm understanding this, by objective number 3 we need a prescription or a diagnostic

referral.

MR. TELFORD: Your choice. The in-house corroborates diagnostic referral.

MS. KELTY: Well, not only that, but oftentimes the authorized physician does not work up the patient or see the patient until after the procedure is finished, and that occurs both in hospitals and private settings, where we take an oral request for an examination, we have a procedure manual, we also have a list of clinical indications for procedures, go ahead and perform the procedure. Radiologists or nuclear medicine physicians are not involved until the endpoint, in a private office setting, and they're not even there sometimes for two or three days.

MR. TELFORD: Well, we're not giving absolutes here. We're saying, this is an objective.

MR. WIEDEMAN: I was just going to mention a case that I was thinking about when you were talking about this. It was about 15 years ago out in California, where the referring physician handed the patient a prescription, told her to go over to the hospital, and he wrote on there, therapy to the right shoulder for arthritis. The patient walked in to the main desk and said, how do I get to the therapy department, and they said, radiation therapy is right down the hallway. They went there, and the girl at the front desk took the prescription, wrote it up, and they

had sort of a standard protocol that -- it was extremely rare to treat bursitis with radiation therapy, but this particular physician, that was one of his favorites, treating benign diseases with radiation. They gave the patient three or four treatments for bursitis of the shoulder. That, at the time -- I don't know if it's still accepted -- was sort of an acceptable procedure. Finally, when the skin started becoming quite red, the radiologist called the referring physician and said, I'm going to discontinue therapy on your patient, because of a skin reaction, and that was when he was told that she was supposed to be over in physical therapy for bursitis.

There's a case where you may have a written prescription, and it's not always 100 percent. It may be, if the physician would have examined the patient and discussed this with the referring physician, it may have been ironed out.

MS. KELTY: Just in my years of experience in diagnostic imaging, a misadministration of unintended dosing has not occurred in the cases that I'm aware of with prescriptions. It usually gets caught by the technologist before that. They're reading the clinical indication and say, this doesn't match; this patient should have an ultrasound, and take the appropriate steps. Where I've seen the misadministrations occur is, the technologist is in a

hurry, prepares the wrong kit, withdraws the wrong vial -- or, when we went to unit dosing, grabbed the wrong unit dose and assayed it, and injected the patient. Having a prescription from the authorized user I don't see as eliminating the misadministrations. I just see it as a difficult point in outpatient settings and, I know, in some hospitals where the outpatient referrals don't come written, and a radiologist is not involved in the process until the endpoint. In a busy radiology department, trying to nail a radiologist to come look at a request, write up a prescription for us, is really going to hamper the throughput and the patient care.

MR. TSE: But a prescription in this proposal is only required for therapy and for iodine greater than 30 microcuries.

MR. ROSEN: It says you need a diagnostic referral or a prescription. If you get a diagnostic referral, a doctor can say simply do a bone scan. If you are missing that piece of paper, now the authorized user or his designee has got to say, now we're going to do a bone scan, you're going to use 20 millicuries of tech-labelled phosphate. You're requiring a much longer list of written material relative to what a simply diagnostic referral is normally used.

MR. TSE: Right, but how come you would miss a

diagnostic referral? Somebody has to refer this patient.

MR. ROSEN: It was done on a phone call. It's not written.

MR. TSE: Oh, you mean the oral.

MR. ROSEN: That's why I asked the question, can we do the diagnostic referral in-house? Can the nuclear medicine physician then take that call and simply say, this patient was referred for a bone scan, period. Because he is an authorized user, does he have to write the full prescription?

MR. TELFORD: He can write the referral. For diagnostics, we try to give you your choice.

MR. ROSEN: Some people would say that's rather unethical, by the way: you shouldn't have self-referrals.

MR. TELFORD: Oh. In some hospitals you have a patient referred from another department, so we had in mind this was a physician in another department or from outside the hospital.

MR. ROSEN: There's always something written in the chart that gets the patient down. Most nuclear medicine departments require a referral slip within the hospital. This is mainly a problem with outside patients, transfers from other facilities, patients coming off the street from a private practitioner.

MR. MEINHOLD: John, I think this is exactly the

kind of thing that we ought to see showing up on the forms, because I think it is an interesting question. Whether or not it's an acceptable practice to the world at large is a very real question. At your institution, they probably would want to at least have some information about that physician and his practice. There's a lot of things involved in that simple statement, and I think if you put on the form that in your institution this would create such and such a problem, I think this can be discussed as a valuable piece of information, but then it would be discussed the other way around: Well, perhaps it would be better in your institution if you had another check and balance against a phoned in prescription, that in fact the nuclear medicine physician or somebody take another step beyond simply just going forward with it. I think it's an open question rather than a closed question, is what I'm saying, and getting it on the floor for discussion I think would be very helpful, even here.

MR. ROSEN: It's one of those areas that would be better discussed before you enter this kind of pilot project. Even the choice of the word "prescription" is a very real problem, because to a physician it means something entirely different than it does in this guide. Let's say diagnostic radiology -- then I don't have to worry about any repercussions nuclear from anyone in the room or in my own

life. When a referring physician writes a prescription for a radiographic examination, that referring physician by far knows his patient best. He says, do this, and in the vast majority of cases it is simply a knee-jerk reaction: the radiologist does it, without question and on a plain radiographic examination doesn't again become involved in the process until the film hits the viewbox. That in general is a prescription.

We have dialogues like this all the time. Our brachytherapy people say, we should be doing the implants. I sometimes put my mind in the head of a patient, and I'll be damned if I'll let anyone in our radiation oncology department do a neural implant. I want a neurosurgeon doing it. They're the only people with the physical skills to put something in someone's brain.

MR. WIEDEMAN: You know as well as I do: Typically in a hospital situation, a small community hospital -- maybe not the larger institutions -- a patient comes into the emergency room, maybe involved in an automobile accident, and maybe the emergency room physician is not available. Who orders the X-rays? The nurse usually makes the decision, well, he needs a brain X-ray, bones, and this and that. But in the NRC-regulated activities, that we hope doesn't go on, even though we do catch them occasionally.

MR. ROSEN: I'll tell you: in some institutions it does go on, particularly in larger practices -- It's quite common in orthopedic areas. Most orthopedists will not look at a patient, other than an extreme trauma, until certain things are done. Normally we're talking about X-rays, but I know individuals who, when someone refers a patient to them -- got joint pain -- won't look at the patient unless a bone scan is done, so now I've got an internist or a general practitioner referring the patient to an orthopedic practice -- and they, by the way, should be the only ones qualified to make that judgement. My nuclear medicine doctor is not an expert in orthopedics or in neurosurgery or neurology or renal -- well, renal disease is a bad choice, because our guy is, one of them -- but they are not experts in the diagnosis of disease in people. They are delivering a tool for the referring physician to utilize in most cases, and they react that way: you want it, you got it, right or wrong.

MR. WIEDEMAN: But you have a physician at least ordering the proper procedure that he wants done on his patient.

MR. ROSEN: Assuming the nurse didn't do it. I think -- Certainly within our hospital it is always the physician, yes.

MR. WIEDEMAN: But we've had cases where

technologists have made the decision to double-dose patients, only because they had an old rectilinear scanner, and someone thought, well, gee, anybody over 60 we'll double-dose them, enter 20 millicuries but we'll really give them 40, and that caused a lot of problems.

MR. ROSEN: You've got to realize that in our institution that technologist would draw their last paycheck that Friday.

MR. WIEDEMAN: In this case, the institution ended up suing the technologist, which was kind of different.

MR. TELFORD: If I could get back to the original question, the intent of these objectives was to have a diagnostic procedure either come to the department with a referral or a prescription, and to suggest that a prescription should be required for therapy. Now, all these say, ensure: do this, do this, do this, but in your quality assurance program, you should tell us how you meet these objectives. You should tell us when you decide to do these absolutely and when you decide that you can't do them absolutely and therefore you've got a fallback procedure, something you do differently. The purpose of the pilot program is to figure out how to do a requirement like this and make it a minimum impact on the institution, but yet be sufficient. If you can tell us how to do it, that'll be of great benefit. I don't want to tie anybody's hands going

in. It's a very open question, like Charlie said, so unless you're real uneasy about those ground rules or if you need further guidance, I'm happy with that.

MR. STRUBLER: I'd just like to ask an open question to the group. In terms of diagnostic studies, what percentage here, as far as they know, actually received a written prescription or written referral.

MR. ROSEN: On every case?

MR. STRUBLER: On all cases, because it says you must have a written document, either referral or prescription.

MR. WIEDEMAN: Are you including requisitions in the hospital?

MR. STRUBLER: Well, anything that qualifies to this definition, a referral that is written, rather than the oral ones that are frequent. I just want to know how frequent they are.

MR. BRAHMAVAR: None of the procedures are done without a written prescription, a written referral, or a requisition. None.

MR. GRAHAM: Same way, in or out? No oral orders

MR. BRAHMAVAR: In fact, that's one of the requirements of JCAH.

MR. GRAHAM: The only time we will do that is if we instruct the physician he has to come in within 24 hours

and sign off on that requisition.

MR. ROSEN: So you do receive orals.

MR. GRAHAM: Well, yes, sure. We require them, and we follow up within 24 hours.

MR. ROSEN: But the process is complete before you've gotten the written order. I think we all accept oral orders.

MR. STRUBLER: This says you must ensure that there's a written. Now, maybe I have to ask again as to when that written comes in. If it's after the fact, maybe it's okay.

MR. TELFORD: Well, obviously for emergencies it is.

MR. ROSEN: These are non-emergencies.

MS. KELTY: Prior to.

MR. TELFORD: It says prior to.

MR. STRUBLER: It's here; I'll add the word "written" because that's the definition: "The written prescription or the diagnostic written referral is understood by the responsible individuals." That's number 4. According to this, we have to ensure that there is a written prescription or referral prior to its use. From what I'm gathering here -- because I'm mostly in oncology, for which there always is -- in the diagnostic are you don't have that much of a field. What I'm having here, always,

but then there's qualifications: well, it will come.

MR. GRAHAM: Well, there are extenuating circumstances.

MR. BUKOVITZ: Read the definition of a diagnostic referral. It says, "written request before a diagnostic medical use." That means the physician must have a written request before he can do the procedure.

MR. ROSEN: That doesn't give us much of an option in terms of prescription administration. For those of us who take things over the phone and require something within 24 hours -- we're not talking about an emergent problem; the person's not going to drop dead tomorrow -- that puts in most cases, I think, in writing a QA program in a contradictory position with respect to that definition right up front, which makes us hesitate, how are we going to handle it. We really could use a response to this before we leave today.

MR. STRUBLER: I don't know right now. That's going to come back to me, well, we can't meet this.

MR. TELFORD: I'll give you an answer, and we'll talk about it at lunch, and I may give you a better answer after lunch.

I like what this gentleman said. Most of the time, or almost all the time, it's written. There are a few cases in which there are extenuating circumstances, and it

can't be written. The doctor doesn't have a fax in his car or her car, and I can't get a written directive, but I'll get it for you. You would define in your program those conditions in which your program would allow that.

MR. STRUBLER: At the freestanding facilities, that's probably more likely the case that there'd be an oral request.

MR. TELFORD: Well, if you get an oral referral, then your program would just say what you do after that, whether or not you get someone to check it before you turn the referral over to a technologist to go to the clinical procedures manual to know what to do. That's what we want to hear, how do you handle it.

MR. STRUBLER: You said revise our programs to comply with these eight basic points, and if there's one here we can't comply with, then it puts us in a tight spot at the outset.

MR. ROSEN: I think I know what the mindset is, by the way. If these were regulations, we would have to apply for an amendment to 10 CFR 35 before we could institute this change. We're sitting here saying, we can't do that now. You're saying, because it's a pilot project, perhaps we can; it's not something we're used to doing.

MR. MEINHOLD: More importantly, we've got to find out if it's sensible.

MR. ROSEN: We don't need a pilot project to discuss that and decide whether it's sensible.

MR. MEINHOLD: Well, I think you do.

MR. ROSEN: That's a major change in medical practice on this one particular item.

MR. STRUBLER: That's true, but we're saying right now from the feedback it would be a major change in the practice of medicine.

MR. TELFORD: What I'm really requesting is that you do the best you can. If you define in your program what are extenuating circumstances to allow deviation, then the benefit of a group like this is, at the next workshop, we'll discuss the evaluations that we get and find out what those folks are doing. We have the benefit of collecting knowledge. You can tell us perhaps you don't need a written.

MR. STRUBLER: I think what I'm saying and some of the others are saying is that we could probably make that decision at the outset, knowing that if you go into the chairman of nuclear medicine or whatever, he says, well, I'm not going to do this. I'm not going to defer the diagnostic studies for two or three days -- or, if people have faxes, which is common nowadays, until I get that referral -- it just disrupts my entire practice, and people might stop making referral to me, because I am imposing this

requirement on them all of a sudden, because I'm participating in a pilot study. I don't do it.

MR. WIEDEMAN: However, maybe after the pilot study is completed we find out it may not be feasible to have that requisition or referral slip immediately before we do the scan, but maybe it is possible that within 72 hours it will be completed by a physician.

MR. STRUBLER: That's what I would probably propose up front, saying this is a discussion of some debate. This is my thinking on it, and what's your thoughts: he says, I can't do that; I'm not going to do it. I'd suggest something like this, which I think is reasonable. He says, sure, I'll go with that.

MR. ROSEN: We're all going to propose it up front. If I do it to my chairman of nuclear medicine, say, you will have a written script before you start, you know what the first thing he's going to say is: we're not going to be part of the pilot program. I know that's what he's going to say, because that is such a radical change from the normal practice of medicine.

MR. BUKOVITZ: All of us could provide documentation of why it won't work.

MR. ROSEN: Correct.

Now, we'll evaluate if we could do better than that as part of this, but we're certainly not going to put

that command in.

MR. TELFORD: Just as a suggestion, you might want to say, okay, I'll take the oral directive, oral referral under certain conditions, or whatever percentage of the time that you now do, but then you may say, well, I want something written in a day or two, so that then you can follow up and find out if what was requested actually got done.

Now, you may make a document, either through getting the referring physician to write it, or maybe you can do that within your department. The basic idea is just to have the goal written down before you attempt to do. We fully expect to learn better ways to write these requirements on written directives. We don't want to have a large impact. I mean, we're really trying to write objectives that fit within the usual practice today, so please tell us how you're going to do it in your program. We're not tying your hands.

MR. BRAHMAVAR: In this pilot program you may find out all 68 participants have the same problem with number 1, and perhaps it's impractical to impose, and you may have to modify that. That may be the outcome of it.

MR. TELFORD: That may be one of them. I expect there will be many.

MR. TSE: Do you have any big problem with

objective 2?

MS. KELTY: Well, if we clarify that iodine-131, because we did do iodine-131 hipuran studies on outpatients. In 85 percent of the cases we do have written referrals, but in some we don't, and we'll never get them.

MR. TSE: Other than that objection to 2, you don't have any big problems.

MS. KELTY: For therapy?

MR. TSE: Yes, therapy and iodine-131, 30 microcuries, other than hipuran.

MS. KELTY: I don't have any problem with that.

MR. WIEDEMAN: Another thing that wasn't mentioned earlier -- it's an up and coming thing, it seems like -- it iodine-123. We've had several cases where someone was referred to the nuclear medicine department for a, quote, "thyroid evaluation." The first thing that came to mind was iodine-123, 300 microcuries, but they grabbed 300 microcuries or millicuries or I-131. Now we've got some problems. That's something that you probably want to consider in your procedures manual: what is a thyroid study. Maybe you should have a written request from that physician on, maybe, that particular item, iodine-123 study.

MS. KELTY: Or if your request is not specific. I mean, if you get something like that, we wouldn't accept that without further clinical information.

MR. WIEDEMAN: That's good. A lot of medical facilities don't have that same philosophy.

MR. KAPLAN: That would be caught under number 1.

MS. KELTY: Right.

MR. ROSEN: That's a simple one to handle. If someone requests a simple thyroid study, it would in no way, shape, or form resemble anything therapeutic.

MR. WIEDEMAN: Well, see, in your institution that probably is the standard procedure, but in another institution a thyroid study may mean something else. Maybe it's strictly a thyroid uptake. Maybe it's a technetium scan of the thyroid. It's a matter of terminology.

MR. TSE: Under objective number 2, a technologist cannot administer any iodine-131 or -125 greater than 30 microcuries without his physician's prescription, and therefore the kind of a problem you cited, if this implemented, cannot happen.

MR. WIEDEMAN: But you see, we're talking about iodine-123, which we do not regulate.

MR. TSE: Right, but the technician says, I'm going to use iodine-131, more than 30 microcuries, and he says, oh, I cannot do that unless I check with my doctor, first.

MR. WIEDEMAN: Fine.

MR. KEARLY: I spend most of my time in oncology,

so I'm not really familiar with the procedures in nuclear medicine. What you're asking in the workshop for the pilot study, what kind of documentation of all of this are you asking for from us? Do you want to see a procedure written into a manual, and then we implement that procedure? Do you want to see that ten patients per day came in to satisfy the criteria of the pilot study, and nine of them were processed the way we wanted them to be, and one of them wasn't, and we keep records like that?

MR. TELFORD: We would be happy with the former, but if you want to do the latter --

MR. KEARLY: That's what I wanted to know.

So if one patient came in who did not have a prescription or a written referral, we don't have to document that that happens in a separate place; we just to have some sort of procedure in place to review that? Or what?

MR. TELFORD: Your procedure should say what you usually require and what you do if that doesn't happen.

MR. WIEDEMAN: You're talking about teletherapy, right?

MR. KEARLY: No. I'm asking about nuclear medicine, actually.

MR. WIEDEMAN: Oh, nuclear medicine. I thought you were talking about teletherapy.

MR. KEARLY: No.

MR. ROSEN: Can I get a rough vote of the participants? If in fact we modify our existing QA program, the formal program in our institution, can you do that within the confines of your radiology, radiation oncology, nuclear medicine programs, or you going to have to go up right through the president of your hospital and legal counsel before you can make those modifications? How many people have to go all the way up the line to make them?

[No hands raised.]

MR. TELFORD: I don't see any hands.

MR. ROSEN: Okay.

You're talking about changing what you're entering in the patient's charts, for instance.

MR. BRAHMAVAR: As I said before, I think for those QA programs we've had in place for so many years, and they're modified from year to year, depending on what regulations change and JCAH requirements, I think we have perhaps 90 percent of what is needed, but it may not be in the same format. So all I need to send is a letter -- I've already given you copies -- showing you where these are satisiied and what page. That's all I'm going to do. I'm not going to modify my program.

MR. ROSEN: But if you have to modify -- We have a QA group in our hospital that typically everything would

go through, and they take six weeks to reply. You can see the problem. Some of us were discussing at the break: if we go to our lawyers, they never replay. Basically, we have one month, basically, when we leave this room, to get everything in place. Presumably the people that are meeting with you at the end of --

MR. TELFORD: The middle of April.

MR. ROSEN: -- the middle of April will have just about finished this process, because they're going to have only two weeks to be able to get something into Brookhaven.

MR. TELFORD: Yes.

MR. ROSEN: I wonder if I could discuss over lunch with some of the participants, do we have enough time to implement this. Again, 90 percent of it, no problem, it's already in place, but it's the other 10 percent, changing and getting the people trained to do it.

We have 30 days to do it. I guess I'm not worried about the other regions, II, III, IV, and V.

MR. STRUBLER: I'll just respond personally. Things are tight. I'm in a process of still revising. I brought my QA to submit, the one for teletherapy and brachy. It's no problem, although mine are huge, so I only bought excerpts: the table of contents and the ones I thought were appropriate to this. The nuclear medicine and other things that I'm less familiar with I've been going over with our

people. There was a lot of concern as I spoke with the two of you about our participation, because the chairman of our department in radiology said, look, I have one individual I don't want to chase away by burdening her any further, in terms of the chief technologist. So I'm still in the process of revising it. I think I can get it done, in terms of what I envision doing and the way I usually doing it.

In terms of compliance for next month, I was thinking along the same lines, that I still feel I have work to do and training process. Depending on what we were told here in the workshop, in terms of our evaluation process and filling out some other forms, and how this is going to be done, it will be tight.

MR. TELFORD: The evaluation is after the 60 days.

MR. STRUBLER: Yes, but I'm just saying the workshop is going to tell us what we need to do. We still have to be concurrent evaluation in terms of our own understanding and feedback before the final evaluation sheets are filled out, and to kind of insure, in our own mind, yes, we're following the pilot study as proposed. I think it will be a little tight.

MR. TELFORD: Let me let you think about that question, to see if you can get ready by May 1. I'll ask it again this afternoon.

Does anybody object to taking a lunch break?

[No response.]

MR. TELFORD: No objection. Let's reconvene at 1:15.

[Whereupon, at 12:10 p.m., the meeting recessed for lunch, to reconvene at 1:15 p.m.]

AFTERNOON SESSION

[1:35 p.m.]

MR. TELFORD: Are we ready to convene?

There were two questions asked this morning that I think we ought to give you some sort of guidance on. The first question is on the use of the written directive. The answer is that the ideal case is a written directive. However, please say in your QA program what you're going to do for those cases which you consider to be extenuating circumstances or conditions under which you would allow oral directives. There's a benefit to that. It allows the pilot program to find out, number one, what people do to accommodate this potential problem, and since we have a lot of people in the pilot program we should get a multitude of answers, most of which I think would be useful. Secondly, it will tell us how many cases we have, because there's a record of this, and we'll find out, for instance, if these are half the cases but it leads to no problems, but, on the other hand, it's half these are half the cases but it leads to 90 percent, it's very informative to us. It would help us to have, quote, "good evidence" to do otherwise. If most people -- say almost all people in the pilot program, or even some of them -- could come up with a good alternative, and they work, that's what we're here for. We'd like to have a sufficient requirement but minimize the impact, so

what you'll be doing for yourself is figure out how to minimize the impact to business. That's exactly what we want to find out.

The second question was on hipuran cases. Let's use an analogue there. The ideal case is to have a prescription if it involves more than 30 microcuries. However, you say in your QA program what you would like to do differently, because the same reasoning holds. If you put in a procedure that works, great. You can say under what conditions you would not use the restriction. Whatever that is for your hospital, just put that in your program and just say, this is what I do here. From both the program evaluations and site visits, we will find out if these work, and you can tell us at the next workshop if the procedure that you used works.

The reason I like that a lot is because you're here talking to us, but your peers are listening, so they'll be able to join in the discussion. It will give us kind of like an unvarnished view of what works. We'd like to find something that really works. For both those cases, don't be too disturbed about them. Just put it in your program, what you'd like to do.

Is that acceptable to everyone?

[No response.]

MR. TELFORD: Nobody's saying no. Okay, good.

Our next order of business this afternoon is to talk about the guide. It was part of the handout this morning. The first page of this handout is the eight objectives. If you flip over about two pages, you'll come to the first page of the guide. I'm going to ask Dr. Anthony Tse to kind of walk through it and hit the high points. The use of this was to help you design a program, and we've gotten this guidance from various places, so today we want to go through to understand the intent. If you find something that's really terrible, please tell us; however, today we're not really at the point of wanting to polish it or make it great. We want to do that at the next workshop; that's when we'll talk about suggestions for how to do it.

The reason I say that is because you're not obligated to use this guide at all. We gave it to you, like, for free. If you want to use it, here it is. We don't for a minute think that we're trying to teach you anything, because we fully realize that you know more than we do. We just offer it because we gave you a proposed rule, so we're obligated to give you a guide.

Let's skip through the guide.

MR. TSE: Thank you, John.

As John said, the guide is essentially to explain what we mean by some of the performance objectives in the regulation, but it's just for a guidance for you to develop

your QA program, and you do not have to follow this guide. You can develop the QA program based on guidance from some other guidance you have. The objectives in the proposed regulation should be considered.

I think that probably I need not to go through this guide page by page, because I guess you have already read this document. I was wondering whether I should just ask you as we go through page by page whether you have any questions or concerns or comments on each of the items. I think that's a better way of utilizing time, instead of having to explain each one.

In that case, I guess does anybody have any questions or comments on page 1?

MR. STRUBLER: I'll start.

MR. TSE: Please.

MR. STRUBLER: I jotted down a few things. This page 4, responsibility and audit, we had discussed earlier the potential of audits conducted by qualified personnel other than the ones who are involved in the activity. That's just a general comment. I thought I'd reiterate that concern because, again, you might have to have some sort of affiliation with another hospital or something of that kind, or outside consultants. Even in not so small facilities, I think this could be a problem to have someone who was, quote, "qualified" to really audit properly.

Another general comment which applies to this first page is that some of the things that are suggested here, recommendations, I think are axiomatic. They're statements that don't necessarily have to be said, in the sense of legible, clear writing, et cetera. Is there an expectation that there be a definitive statement in our quality assurance program to that effect? In general, you assume people -- and it's not an improper presumption, I think -- that when you're writing an instruction, to make it clear and lucid and legible. Obviously, the physician handwriting world, that's not necessarily the norm. I'm just asking, as a general statement, whether some of these things that are axiomatic to all programs and assume good practice, whether there has to be an explicit statement to that effect.

MR. TSE: The guide is just a guidance, as we indicated. You really do not have to have it explicit, unless you want to put it in. The reason we put this item in is that in some cases people write milli, micro, not in an understandable fashion. Sometimes the number is wrong, like 2.38 is not clear and becomes 2.88, things like that.

MR. STRUBLER: I understand, but that's just part of the real world. Whether you have it explicitly or implicitly or not, that mistake will happen, and if the real criterion is that if there's some uncertainty it should be

questioned.

MR. TSE: The idea is that if the management, meaning the licensee, sees that when you write something you know that somebody has to look at it, you should write more clearly. Somebody asked me whether that means typing. Well, that doesn't mean really typing. It's a general statement.

MR. STRUBLER: For example, our recommendation was to make, like many of us who are physicists would do anyone in the past, crossing the 7's, so there wouldn't be a mistake for 2's or 1's or something like that. Some of us do it all the time. A lot of people don't do it. It's kind of difficult to make a mandatory statement that everyone change their writing habits, which you can't do for certain cases. It's just to raise their consciousness about legibility.

It's a continual process. Whether there's going to be a statement made here or not is kind of irrelevant. It's a matter of reinforcing a good practice.

MR. TSE: That's true.

MR. STRUBLER: I realize these are just guidelines, but I'm just asking how we should be guided in these, because most places are not going to accept a statement, you must write clearly and legibly, and how far we should go with our own modifications.

MR. TELFORD: I think the closest we come in the

objective is the one on, make sure that the responsible individuals understand the directive. To the extent that legibility contributes to not understanding, then you will sense that you've got a problem that needs to be fixed, that you can handle on a case-by-case basis. Each licensee could do that or not to institute something that says here's how we will write things or not. It may be a problem in some cases and in some places not a problem.

We don't really say anywhere that you have to do that. This one objective would come close.

MR. ROSEN: It is in fact a problem in every place, because this carries over to the referring physicians, too. That's several thousand people in an institution like mine.

MR. TELFORD: Yes.

MR. WIEDEMAN: We've had quite a few misadministration reports that came in where the technologists had a difficult time reading the physician's order because it was basically scribbled on a piece of paper, so they tried to decipher it, and they took a guess, and the guess was wrong. One way to cover that, I would think, is to include in your procedures manual that if the order is not clear and explicit then someone has to get on the phone and contact that referring physician and say, did you want this; what exactly did you really order -- in a

diplomatic manner, of course.

MR. TSE: Yes, that's one of the items in the guide.

We have some instances like that which cause a misadministration, and these are the general guidance to let the licensees know you need to watch it.

MR. STRUBLER: If it's physician illegibility, we'll put financial fines on that. I'll put that on my program.

[Laughter.]

MR. TSE: Okay. Do you have any other question?

MR. STRUBLER: That's all.

MR. TSE: Does anybody else have comments on these first few pages?

MR. STRUBLER: Let me interrupt again, to come back to the audit. The audit is a yearly audit, and we're not going to audit during the pilot study. You still need some feedback in that regard. I think you've gotten some feedback earlier; I don't know how the others feel about it, but I still have that concern, not that it's a bad thing, but it may be a difficult thing.

MR. TELFORD: Well, at the next workshop, I think it would be fair to ask each licensee how they would do it in their institution if the audit is a problem. That way, all the problem cases would come out, because if you have a

small institution, you work for a small hospital, you can't get people that are qualified that can do the audit, you can tell us: it is a problem, number one; number two, if this were a rule, how you would do it, how it would impact you. If it's a large impact on a large number of small licensees, then we want to rethink that. We want to figure out how to meet the objective of this but not have a heavy impact.

Would that be useful? Can everybody do that?

[No audible response.]

MR. TELFORD: Okay.

MR. MEINHOLD: Anthony, there's only one problem. I notice this morning when we were discussing the objectives that the third objective is not covered in the guide.

MR. TSE: I think every objective is covered in the guide.

MR. MEINHOLD: Show me and I'll be quiet.

MR. TELFORD: I think Kevin was showing me this at lunch. It's on page 5, item 2.4. It covers both the prescription and the referral, and the manual.

MR. MEINHOLD: It seems to me that's only more than 30.

That's not as strong a statement as is in the objective. I mean, I don't think they have any trouble with that one. That just says, is in accordance with the prescription or the diagnostic referral and the clinical

manual. They may take that as a looser statement than the one that's in the objective.

MR. TELFORD: So you're suggesting that we should have a stronger statement in the general requirements in part 2 of the guide.

MR. MEINHOLD: Well, if you intend that. That's the question I'm asking.

MR. ROSEN: The general elements don't cover it. The general elements, right under the heading, say, therapy and diagnostic involving more than 30 microcuries, so presumably none of the general cover the routine use of diagnostic materials.

MR. TSE: No, no. The general elements cover all medical use, but for others have additional.

MR. ROSEN: Okay. It's other services.

MR. TSE: Yes.

I think 2.4 may be not as strong, but it should cover that.

MR. MEINHOLD: Okay.

MR. ROSEN: Okay.

MR. TELFORD: We could certainly strengthen it.

MR. TSE: Actually, the guide is a guide --

MR. TELFORD: Well, what I'm saying is that we could make the statements in the guide in section 2, we could make them more explicit, to say what would be good to

do if you have less than 30 microcuries.

MR. MEINHOLD: I think it's important to tell the people who are having difficulty with this particular issue they will flag it when they see it in 2.4. That's what I wanted.

MR. BRAHMAVAR: The 2.4 is easy to comply with. You can verify by telephone or any other way.

MR. MEINHOLD: That's exactly my point. You can comply with 2.4 and we will never know that you've got trouble with objective 3. I think, for the pilot program to be successful, what it says in the guide has to be as strong as it is in the objectives. That's my point.

MR. BRAHMAVAR: I think in 3, if you make 3 to read like 2.4, people will not have objections.

MR. MEINHOLD: I think they'd rather have 2.4.

All I'm saying is I want to get a good read on the problem in objective 3; we've got to change 2.4 to be stronger, I think. That's all.

MR. TELFORD: Okay.

MR. TSE: Okay. Does anybody else have certain comments or suggestions on the first few pages?

[No response.]

MR. TSE: We are now up to page 5.

[No response.]

MR. TSE: If not, we'll continue to the next

pages. Does anybody have any questions?

MR. STRUBLER: Yes. On page 5, item 3.5, there's a statement there: "After administering a radiopharmaceutical, a qualified person --" -- et cetera -- "-- and this person will record the agreement or lack thereof between the radiopharmaceutical and administration in the prescription. That implies that there has to be some physical demonstration -- a check-off or an initial -- that, yes, this is an agreement, or, no, it is not. This is again for the iodine.

MR. KEARLY: That statement appears several places.

MR. STRUBLER: It appears several places, so it's a little difficult to carry out, particularly if you've looking at teletherapy. Every day there's an entry, and every day it's 180 centigrays or whatever, and they initial that, but then you're saying, is this in agreement with what was prescribed or not? I think technically what we're doing from the teletherapy point of view, or a therapeutic point of view, in the chart the technician initials is satisfactory, but the implication here is that there needs to be something more.

MR. TELFORD: You put down the daily dose is supposed to be 200. Let's say it was 180. Do you have a separate column for the delta, for 20?

MR. STRUBLER: No. You just put in the 180, because it's documented, instead of the 200.

MR. WIEDEMAN: Well, 3.5 only really applies to --

MR. STRUBLER: Yes. I'm saying that that implication about agreement or lack thereof, as Frank was saying, appears elsewhere.

MR. KEARLY: It's in 3 places.

MR. TELFORD: Yes, it does.

MR. STRUBLER: So if it agrees, it implies that you're supposed to have another column that says, agrees with prescription, and each day you initial it. In this case, it's only been one time, if it's a therapeutic installation of iodine. I'm just looking at that one particular phrase and indicating that that would be a difficult thing to carry out from a practical point of view.

MR. TELFORD: You have to look at the guide as sort of the ideal case. If you have a procedure that works in your hospital, but you don't exactly do 3.5 -- maybe you just write down the administered dose -- objective number 8 that's for identifying deviations, if you do that some other time, if that works for your hospital, that's what we'd like to learn. I would look at 3.5 and elsewhere, wherever that appears, as being the ideal case. I mean, what we're saying there, I think, is, if a person had written down, prescription is 200, administered dose 180, difference 20 --

MR. STRUBLER: Even if it's 200 prescribed, 200 given, here it says, you will record the agreement or lack thereof, so every day you write, agrees. There's a redundancy there that's unnecessary in a typical -- very difficult to carry out.

MR. WIEDEMAN: That's normally done anyway, isn't it, on the daily --

MR. STRUBLER: There's a daily entry, but this says, check that the daily entry corresponds to the prescription. The physician writes the prescription, 200 a day to 3,000, and every day you get 200. Then you say, the person will record the agreement, meaning there's a separate step where they said, yes, 200 was given, and I agree.

MR. TSE: Essentially what you're saying is you need an additional column to say the delta is a zero or two or five.

MR. STRUBLER: It's a redundancy, I think, because you're already putting in the 200 every day.

MR. TSE: In your case, if that's clear already, maybe you don't need to do it.

MR. STRUBLER: I'm saying it's unnecessary.

It's the same statement in other places.

MR. TSE: Right. That's one.

Essentially we want to compare the administered dose and the prescribed dose.

MR. KEARLY: When we get to the teletherapy section, I think there might be a better way to say this. There's a role for the techs to play, and there's a way for the physics and dosimetry people to play. This particular role right here is for the physics-dosimetry people, as it's usually done, I think, but the techs are responsible for properly using the information given to them, but they're not the ones that pass judgement as to whether or not those numbers meet the prescription. It's usually the dosimetrists and physicists. So that's not the right question to ask.

I have another question. This is a radiopharmaceutical question. Where you say that it has to agree with the prescription, not everything gets a prescription, right?

MR. TSE: Wait a minute. Which one are you talking about?

MR. KEARLY: About 3.5.

MR. TSE: But 3 is for therapy and diagnostic more than 30 microcuries.

MR. KEARLY: Oh, okay.

MR. TSE: Does anybody else have questions on page 5?

[No response.]

MR. TSE: Otherwise, just continue until somebody

has a question.

MR. KEARLY: Well, on 4.5, the next page, I don't think you want us putting sources into applicators and then taking radiographs.

MR. TSE: I think that's right.

MR. KEARLY: I think you want to say that differently.

MR. TSE: Yes.

MR. ROSEN: Some of the misadministrations that you've documented were sources that were inadequately inserted into the afterloading devices.

MR. STRUBLER: Right.

MR. ROSEN: I also, by the way, am not suggesting hauling someone through the halls with 190 millicuries of iridium in them. You do miss that if you're x-raying dummies.

MR. STRUBLER: That's right.

MR. TSE: But I think that a physician probably has to make a judgement on which is the proper way to do it.

MR. STRUBLER: He's raising a valid point. It's just that I don't think, unless we go to extremes -- We can't, obviously, rule out every single mistake. We all recognize that, and we're trying to minimize mistakes. We'll never eliminated them. Some judgement has to be made as to whether you're going to do that and increase medical

expense and also increase other risks involved.

MR. TSE: But even increased medical expense still cannot be zero error. That's most difficult to get, but we want to minimize errors.

Any other comments on this sheet, page 6?

MR. STRUBLER: I guess I'll quickly -- On the 4.3 here, "a qualified person will verify that the radionuclide and source strength are to be used as prescribed." True, that's required, but the documentation of that -- I mean, he or she is looking at a 10 milligram radioequivalent cesium source and saying, that's what I'm grabbing and putting out in there. But if he chooses the wrong one inadvertently, that's where the mistake is, and to say, well, that's what I intended to do, but I made the mistakes -- It's very difficult to that mistake. We have color-code systems and other ways of handling these things, but you can't document it unless you have someone else verify that I loaded into an applicator tubing is verified by someone else. That's the only real way of documenting it, which becomes impractical.

MR. TSE: Well, I think that this particular item is to essentially have the person -- the technologist or whoever -- who tried to pull the sources out from the storage before delivery to the operating room, we need to verify that these are the sources the physician wants.

There's different ways of verifying, depending on how your QA program -- Each individual licensee has a different way of doing things. That's why we did not say how. We just said a few examples. If you have such a system and procedures to verify, the person should follow your procedures and cannot guarantee no error, but at least we minimize.

MR. STRUBLER: I have no problem with that with the system I have. As it's stated, if we had a specific statement for the QA saying it must be verified, of course you say how it's going to be verified, but usually it's only person verifying him- or herself, which is not strictly a verification. You have a system to show, yes, a 10 milligram is in the ten milligram drawer, and it's color-coded, or it's identified in some way.

But if the system isn't real good, or some other process happens, or the source was put in the wrong drawer or something like that --

MR. WIEDEMAN: I think one of the points he's trying to make is, once you put that particular source in the applicator it's hard to go back and say, yes, I have a 5, 10, and 10 in there. It's in the applicator, and the only way you can find out is to open the applicator up and dump it back out and say, see, 5, 10, and 10.

MR. STRUBLER: The individual who loads it can't

verify what he's done or she's done unless someone else comes out and dumps it out and verifies it, in a strict sense of my reading of this. There are ways of getting around that. As I said, my system right now I feel comfortable applying to this.

MR. BRAHMAVAR: The other indirect implication is that if you know how many sources you can look into your cave and see what is loaded.

MR. STRUBLER: But then is it loaded 5, 10, 10, or 10, 5, 10.

MR. KEARLY: I think Ken is right. The only way to do a decent verification of loading of brachytherapy sources is that one person does it while another person observes while it's being done and verifies the color coding. I don't think you're going to want to look at the serial number.

MR. MEINHOLD: It's an ALARA question.

MR. ROSEN: I don't think it's an ALARA question, but there's an ALARA issue independent.

MR. TSE: I think that each participant can try to do what you do to ensure that these are the correct sources and try to indicate in your QA program.

MR. STRUBLER: I understand the thrust.

MR. TSE: Right. I think the wording --

MR. STRUBLER: But to verify and have a statement

of verification is difficult to document unless you have them out.

MR. WIEDEMAN: Also, if I remember right, under reg guide 10.8 there's a procedure -- and I believe it's in part 35 also -- that you will make a record of the sources that were removed from the safe and placed into the patient, and then you will also state where they're being used. When you return those back to the safe, you will log them back into the safe. That's one way of pseudo-verifying that someone has gone and checked, yes, you have those sources out, and, yes, they're in that patient.

Now, it may be in a wrong configuration, but it has been verified.

MR. TSE: But this item specifically says before implantation a qualified person under the supervision -- and so on -- will verify.

MR. WIEDEMAN: But at the same time, before you implant those in the patient, you make a record of the sources that were removed from the safe, the 5, 10, and 10, and someone could go in and verify, yes, you have -- It's strictly a paperwork verification.

MR. TSE: But it says, to be used as prescribed, 5, 10, 10. The 5 has to go in position A, position B, position C.

MR. WIEDEMAN: That would be the ideal.

MR. TSE: But that's what he's saying: It's difficult to do that unless you pull the sources out, or another person.

The answer is that each volunteer who has a brachytherapy source should propose the best you can verify the brachytherapy sources to ensure they are the correct sources. Use your program, and we can look at your proposal and see whether they can change wording here.

What's the next question or comment?

MR. STRUBLER: Since I keep talking here -- This is primarily therapeutic. On 4.8 in the next page, again, the same issue for small places and qualified people, quote-unquote. Before 50 percent of the prescribed dose has been administered, someone who did not make the original calculation -- There may not be anyone else who fully understands the calculation to check the individual who did.

MR. MEINHOLD: That's what the pilot program should tell us. We'll see how big a problem it is, I think, because I think that is one of the issues that will come out, in terms of people being available.

MR. TSE: Then you could make a kind of verification -- The objective of this is to ensure the calculation is correct. Maybe the person checks on himself, if you do not have other people to check. That's an alternative you could suggest.

The ideal case, of course, is independent check. The person who made the calculation is likely to overlook the errors that were made the first time.

MR. STRUBLER: I'm just referring to the difficulty.

MR. TSE: That's precisely the reason we make it a performance-based rule, because this particular item originally is in the 1987 proposed rule as a requirement, and people made suggestions like you just did, and therefore we would put it in the regulatory guide as a suggestion, so people who cannot do it can find another way to do it, but the purpose is clear.

MR. ROSEN: I think one way to interpret this is a virtual doubling of that aspect of your work, in pulling the patien s charts, pulling all the X-ray films. That is data that is pertinent to this treatment. If they don't go back from scratch and do it all over again, the person may have developed a totally bogus plan, with all correct arithmetic calculations.

MR. STRUBLER: I think that's true, but I think for the most part we wouldn't go to that extreme. We would say, make some assumptions and say, we need to make sure that the keypunch entries are correct and there weren't any gross, glaring errors out of the ordinary, not that someone grabbed the wrong films and had the wrong implant, which is

quite unlikely. What you're suggesting is still a possibility, but not a probability, maybe.

MR. TSE: But that's why, in 4.8.2, we just say correct inputs.

MR. KEARLY: There's an ambiguity in the very last word of 4.9: check of the calculations will be performed within two working days of the beginning/completion/middle of the treatment.

MR. TSE: Where?

MR. KEARLY: Of the treatment. These are a few days. What do you really mean there? Once you allow it to be lapsed for a treatment that's only two or three days long to begin with, it doesn't make much sense to put a requirement on it during the treatment, I guess. So within two days of completion of treatment?

MR. TSE: Yes.

MR. KEARLY: Maybe within a week of the beginning of it.

MR. TSE: Four days. It would be four days, but, again, you have a problem, and if you have a problem, you should let us know during the trial period.

MR. KEARLY: Once you allow it to lapse, it doesn't make much sense to try to get it on the boards.

MR. TSE: The next page?

MR. KEARLY: On 5.2, page 8, treatment volume,

there are some very specific definitions for that sort of thing in the literature. In the planning purposes, treatment volume has a specific definition in the ICRU document or one of those documents from Europe. What do you mean by treatment volumes? It's a little ambiguous. Do you mean treatment site?

MR. TSE: Essentially where you want the radiation to go.

MR. KEARLY: But you don't necessarily mean the volume itself.

MR. TELFORD: Well, if you have a tumor, we mean --

MR. STRUBLER: I'd say it's irradiated volume.

MR. BUKOVITZ: Well, you can't even say that.

MR. KEARLY: The prescription just gives a site, usually. Right now we're treating the lung.

MR. STRUBLER: But the signed film by the physician --

MR. BUKOVITZ: Here's another question. There's target volume, there's tumor volume, there's total irradiated volume. Are we talking about dose to the tumor, dose of a specific type, or are we talking about interval dose.

MR. TSE: No. I think --

MR. STRUBLER: That's why I said this is the

irradiated volume.

MR. BUKOVITZ: If you're irradiating the pelvis -- let's say we're going for a prostate -- you might something the size of a walnut, which is your tumor volume; you've got something the size of a fist, which is your target volume; you've got something the size of three quarters of somebody's pelvis, which is the irradiated volume. What are you talking about?

MR. TSE: I think we're talking about not so detailed in the technical detail, but you have the right place. If it's the left side, you've got to treat the left side; if it's the right side, that. Maybe the treatment site is a better terminology.

MR. KEARLY: I think for this particularly requirement that fits closest to what you would see on the prescription page of the chart.

MR. TSE: Right. We're looking for more gross areas instead of fine; that's not our intention. "Treatment site" -- if that's a better word, maybe we should use that one.

MR. KEARLY: I think.

MR. TSE: Any other?

MR. KEARLY: On 5.4, the question Ken brought up about recording the agreement or lack thereof between --

MR. TSE: Oh, that's the same comment.

MR. KEARLY: It's more appropriate for the technologists who are making the daily records to be sure that the numbers they're using are the numbers that were given to them by the dosimetrists or physicists or both, but not to pass judgement as to whether that number agrees with the prescription. On a weekly basis, we have one, two, or more checks to make sure that the dose being delivered was what was prescribed.

MR. TSE: May I ask you a question? After the treatment, do you record the dose for the fraction?

MR. KEARLY: It's different at different places. Every five days there's a dose number given in our facility, and each day the technologist records the given dose number but not a tumor dose number, and accumulates that. It's just different philosophies. Many places add up the tumor doses on a daily basis.

MR. WIEDEMAN: You would add up the fractionated dose every day, though, wouldn't you, or the technologist would?

MR. KEARLY: The given dose from that beam.

MR. ROSEN: The entrance dose, which is not the tumor dose.

MR. WIEDEMAN: I see.

MR. STRUBLER: I would say that's more --

MR. KEARLY: That's individual. Our physician

brought that habit with him from where he had done it before, and they'd picked it up fro someplace else, and this was the way they wanted to do it. It's not a bad earmark for what you're doing, but it doesn't require the technologist to be responsible for maintaining the total dose. On a weekly basis we require the dosimetrist and myself to make sure it fits.

MR. TSE: But that's not what it says. I think it says that when the technologist is giving certain doses to this patient, before he did that he should know how many doses he's supposed to give to the patient, and then he gives the same dose to the patient, instead of different doses.

MR. TELFORD: We're intending to say the dose administered, not tumor dose.

MR. ROSEN: Out of curiosity, what do you provide the technologist with, then, before they start treating? Do you give them the entrance dose and tell them to aim for that, or do you give them the tumor dose and expect them to back that out of the other?

MR. KEARLY: We give them either a time or a monitor unit for a machine. That's the important number to check.

MR. WIEDEMAN: If there's a way of tracking back what that time of exposure means.

MR. KEARLY: That's right. There's another place for the technologist to look, just to make sure that that number agrees with the number that was calculated by dosimetry to be the proper number in order to deliver the prescribed dose.

MR. TSE: That's what I'm asking. You give the technologist, say this patient needs one minute, and the technologist sets one minute, and it's recorded in the chart, not the dose.

MR. KEARLY: There is a dose number that's also recorded, and it could qualify for the number that you're talking about here.

MR. TSE: I see.

MR. KEARLY: Again, it's not a number that the tech would have any way of knowing whether that number agrees with the description or not. It agrees with what they're given.

In our facility, anyway, it makes sense to require the technologist to know that the numbers that they're using are the numbers that were provided to them by dosimetry. The most common thing to happen, the problem that you would worry about the most, I would think, is that numbers get reversed or a digit gets dropped, something like that. That's the sort of thing that you need to be able to watch for and check.

MR. TELFORD: So what you do is you translate the prescription dose to a time.

MR. KEARLY: Time or monitor unit, right.

MR. TELFORD: So there's a prescribed time and an administered time, so you could record both of those and know whether or not you're really meeting the spirit of this.

MR. KEARLY: Of what you gave?

MR. TELFORD: So you would record the, quote, "prescribed time," and you would report the time used. That's the way that you in your hospital would check to see that things are done correctly.

MR. WIEDEMAN: Hopefully they're the same.

MR. KEARLY: We would record what we gave.

MR. STRUBLER: I think that in every case the spirit of this is being met. We're just kind of focusing on the specific case. The fact that it's difficult to document, and for that to come out on the evaluation form as well, because our QA policy would not say that the person will record the agreement or lack of agreement. We have other ways of insuring that. The spirit of this is being met in every case. It's just that this specific statement here is a little difficult.

MR. WIEDEMAN: Let me ask this: Let's say, for instance, the physician prescribed one and a half minutes.

Your technologist would enter one and a half minutes of therapy.

MR. KEARLY: The physician would prescribe a dose. The dosimetrist will calculate a time to meet that.

MR. WIEDEMAN: That time goes to the technologist. The technologist sees that the dosimetrist determined one and a half minutes. The technologist sets it for one and a half minutes. Let's say, for instance, I go to look at the system and I see that on Monday they gave one minute. Would there be an explanation somewhere why one minute was given rather than the one and a half that was calculated?

MR. BRAHMAVAR: If it is intentional.

MR. WIEDEMAN: Yes. We assume the person was sick that day, nausea, vomiting.

MR. KEARLY: Unless it was a slip of the pen, which is the other type of mistake. If the technologist is supposed to administer 1.5 minutes, delivers 1.5 minutes, and writes down 1.4, that won't get necessarily noted by the technologist that day, but it will get picked up in the reviews that Ken is talking about, looking for appropriateness to the description.

MR. TSE: Well, the technologist at that point should know when he compared to the number given to him, 1.5, and he writes down 1.4, he says, ah, I did something.

MR. KEARLY: But it's inadvertent. When you're

dealing with 50 patients a day, sometimes, somewhere, someplace, even as we speak, that will happen, and someone will catch it, we hope, if certain institutions are checking carefully. They'll come back and say, this is what you wrote down, and they'll say, oh, yes, that was a mistake. I know for sure I gave 1.5. If there's uncertainty, then you make some judgement as to what you're going to do and what you're going to record, but oftentimes it's just a slip of the pen.

MR. MEINHOLD: Do you have a suggested wording? There's two possibilities. One is doing it after each dose fraction, I guess, but completion of the therapy it says is what you do.

MR. STRUBLER: Well, see, the problem I have with some of these things, as I mentioned earlier, it's things that you just do. I mean, if you're going to give someone an injection with a needle, you don't have instructions saying, well, first remove the cap, or something like that. If you're going to give 200 rads, you're going to write it down, and you have charts, and everyone has their own forms of charts that they use.

MR. BRAHMAVAR: Once that dose is delivered, they write that and sign off. The lack of agreement or the agreement, every day they do that, but it's not specifically written every day that they should check and sign off in the

policy of written procedures.

MR. MEINHOLD: Well, there are two issues. One of them may say he does the dose at completion, basically, but not each fraction; the fractions are done by time; the total dose is calculated. The other question is the question that you're asking now, do we care about the fractions and their verification. Do we care about the total dose and the verification -- there are two issues that are seemingly confused in this discussion.

MR. KEARLY: Could I make a suggestion? I think what you're trying to say in 5.4 -- what you would say successfully in 5.4 is that each day the treatment will be recorded, and in 5.5 you'll say, weekly there will be a check to make sure that every treatment that was give was the appropriate treatment, which is not quite what you say. You only say that the dose summations will be checked in 5.5.

And 5.5 is our check to make sure -- should be our check of what we do weekly, to make sure that all the numbers that were used were the correct numbers, and all the treatments give were the ones that we designed to have [illegible].

I would just strike 5.4, unless you just wanted to make sure that every treatment is recorded.

MR. TSE: Still the problem is that when you

record the treatment, either dose or time, would the person want to know that's the same as the one give to him or her? If the dosimetrist told him or her to say 1.5 minutes, after he's finished he writes down 1.5. If somehow he slipped and it becomes 1.7 or 1.4, he notes that, I did not do it the way it's given; I alert other people, or whatever.

The question is not to verify. It's that he needs to write down and to see whether that's -- When we say "prescribed," maybe that's a word that -- It's not really prescribed because, as you say, "prescribed dose," there's a chance for a time, and in this circumstance he should know he was supposed to give certain minutes to this patient, and did he give that many minutes to the patient after the treatment. That's what is intended here.

MR. STRUBLER: That's asking something beyond what you should of the technologist. He does it to check himself, did I do it right? When somebody sets up a field, a 10 by 18, chest, with blocks, did I do it right, did I put the blocks in correctly? That's all part of the procedure. You don't put in the blocks in correctly and then ask yourself, did I put the blocks in correctly. I mean, you have certain assumptions that you're following what's on the chart and you know the patient and what's being done. I don't want to get bogged down in this issue, but it's stating the obvious, I think.

Did I write the patient's name on the front of the chart and spell it correctly?

MR. BUKOVITZ: You can solve it quite simply. In 5.4, right up to the fourth line, just change the semicolon to a period and strike the rest of the sentence.

MR. TSE: That's what I think your comments earlier were for.

MR. MEINHOLD: That doesn't answer the question that was raised over here, because they say daily they don't do the dose administered. I think you need to change "dose administered" to something like "treatment."

MR. WIEDEMAN: They do is in a roundabout way. They do it by way of time. The first thing I would do if I was looking over this program is say, well, now, your technologist gave 1.5 minutes. Now, how do I extrapolate 1.5 to centigrays, rads, or whatever? He will pull out his full calibration and I can spot-check and say, here it is right here. To me, that is the same as the dose administered.

MR. STRUBLER: Here is says, describing the dose. In the letter of the reading, technically, it's okay, as I would read it. They do record a dose. It's just not the tumor dose. We've talked about this.

MR. ROSEN: Will all of your inspectors understand?

MR. WIEDEMAN: Well, I'm sure Josie and I wil

MR. STRUBLER: I don't see a problem in this area. That's why I didn't want to dwell too much on it. We're stating obvious things that people just do automatically, even in the [illegible]ser facilities. I mean, obviously we're not all at the same level. We all like t think we are, perhaps, but everyone has to record that we gave a certain dose. They gave the smallpox vaccine to your son or daughter. It's documented.

MR. WIEDEMAN: Of all the teletherapy facilities I've ever inspected -- and there must be hundreds of them -- I have never seen anybody that doesn't record on a day-to-day basis what they gave the patient as a fractionated dose.

MR. BRAHMAVAR: It's a standard practice. It's one of the basics of standard practice in radiation therapy, record the dose that you delivered every day.

MR. WIEDEMAN: Right.

MR. KEARLY: It depends on which dose you're talking about, though. I can tell you that there's more than one facility. It's the job of the dosimetrist and the physicist to maintain the records so that the doses are being delivered that should be delivered. They're checked routinely, twice a week. It's not the job of the technologist to maintain that dose record. The technologist

carries a give dose, but not against the prescription.

MR. TSE: With the recorded agreement there, or lack thereof, deleted, you still meet the purpose of this section.

MR. STRUBLER: Again, this is just a guide, as you say. I'm just saying that if you look at the very specifics, you'll have difficulty, and we will not write in our instructions all this little detail. I don't think we should or could. It's just saying we're all in agreement; we all make those documentations in here. It's just that this in black and white, and some of them may have certain expectations, and in our QA programs that we have here we will not have an explicit statement of the items.

MR. KEARLY: And in 5.5, if you could change, instead of daily cumulative dose summations, to daily treatments records or something like that.

MR. TSE: Would that make a difference?

MR. KEARLY: This doesn't cover, in my facility, the fact that a number might have been dropped or altered, a treatment number. The dose numbers are not treatment numbers. The minutes are treatment numbers.

MR. STRUBLER: But this just says, to detect errors in the daily cumulative dose. You're still looking at the cumulative dose, are you not, in your system?

MR. KEARLY: But technically we're looking at the

time one for the machine, and that that number is correct.

MR. ROSEN: You've got to go back and look at the dailies, because in conjunction with this there's a redefinition of a misadministration. It used to just be the sum -- it's currently the sum of the total dose. Now, in fact, you can have a misadministration on a daily record.

MR. TSE: Not now, but in the proposed rule.

MR. ROSEN: On the proposed rule.

MR. STRUBLER: The proposed rule still says, for a daily.

MR. KEARLY: That's only a local -- You only refer to management, instead of to NRC.

MR. ROSEN: Well, nevertheless, a lot of misadministrations don't get reported to NRC but have to be documented for their review. It's not too local.

[Laughter.]

MR. TSE: But let's get back to whether you have a problem with the words, daily cumulative dose summations when you review weekly.

MR. KEARLY: I don't have any problem with doing that, but I think you have to make it a little more general, to say that you're looking at the numbers.

MR. STRUBLER: You're looking at your time or monitor units primarily.

MR. KEARLY: In addition, we add the dose up, but

those are two different processes, and somebody who adds the dose up correctly may have used the wrong units.

MR. STRUBLER: But the ultimate reason you're looking at the monitor unit summation is to get the proper dose.

MR. KEARLY: To get the proper dose.

MR. STRUBLER: I think I could still let it stand as it is. It's still qualifies, in my interpretation.

MR. TSE: Any others?

MR. BUKOVITZ: Yes, 5.6. There are certain cases where only three fractions will be given, three high-dose fractions. It's a common procedure. If you have one treatment, you're hit 33 percent.

MR. TSE: In that case, can you make verifications before the treatments start, or is it difficult to do so?

MR. STRUBLER: Well, I think we all try to do that.

MR. BUKOVITZ: We try to, but if you have a site that only has one perso.. there, then the physician may calculate it, and the physicist or dosimetrist may be somewhere else, and the physician says, if you see the patient, treat him, and they treat him.

MR. STRUBLER: I think the wording here would be "ordinarily" to cover those exceptions. Ordinarily we like to have it checked before the first treatment, and probably

most of us do that.

MR. TSE: That's another example.

MR. STRUBLER: Let me remove the emergent case.

MR. BUKOVITZ: This is not even necessarily an emergency.

MR. STRUBLER: Yes.

MR. TELFORD: What would you change the 25 percent to? Would you get rid of it?

MR. BUKOVITZ: The way we've done it is, if you're delivering a dose more than 250 rads, check the next day. If you're delivering a dose more than 500 rads, you check it that day, before delivery.

MR. STRUBLER: So you qualify, but you're suggesting the possibility that you can't.

MR. BUKOVITZ: I'm suggesting a possibility, right.

MR. STRUBLER: That's what I'm saying: In ours, too, but in those cases where you're going to check it the next day, it would fall to 33 percent. You just can't do it the first day. Even in your system you say there may be exceptions to that 500 rads.

MR. BUKOVITZ: Right.

MR. WIEDEMAN: Normally, I assume, high-dose, short-term therapy is really done in large institutions, isn't it?

MR. BUKOVITZ: No.

MR. STRUBLER: When you give hormonal therapy for prostate disease, one of the side effects is gynecomastia, so you give them 5 times 3.

MR. BUKOVITZ: Fifteen hundred total.

MR. TSE: So maybe in your case you might want to say, you're going to check after the first day.

MR. STRUBLER: But he says he already has that in his program.

MR. BUKOVITZ: I have that in the program, but even if I do check it the next day, I still exceed the 25 percent.

MR. TELFORD: So you have to exceptions to 5.6 One is that if the dose is greater than 250 you check the next day; if dose is greater than 500 you check that day.

MR. BUKOVITZ: Well, no. I check the next day every day, but the thing is, if you exceed a certain dose limit, you cannot treat the first day, period.

MR. TSE: Therefore, if you have three fractions, you can check after the first.

MR. BUKOVITZ: Right.

MR. TSE: Do you have any kind of proof fractions?

MR. BUKOVITZ: No.

MR. TSE: No.

For these special case, you'll have to use the

best way to meet the intent.

MR. STRUBLER: Well, I think, again, we're all covered. It's just that we don't meet when looking at the strict application in some exceptional cases.

MR. TSE: Well, maybe later I may even want to change a little bit here in the final, if we go to final.

MR. STRUBLER: Maybe that would be covered again under the emergent-case subscript here, although that may not quite qualify as emergent, maybe.

MR. TSE: Okay.

Any other comments on page 8 or 9?

[No response.]

MR. TSE: Or 10.

MR. KEARLY: On 10, 5.10 is kind of funny.

MR. TSE: Let's see. Which do you think --

MR. KEARLY: Well, I don't know who has measured at eight angles to isocenter, the data that you're looking for us to compare.

MR. TSE: First of all, do you have a question about comparing?

MR. KEARLY: Well. I think that doing some comparisons is terrific.

MR. TSE: Somebody has a problem and says, after the full calibration measurement, what do you compare. Do you have a question of this nature?

MR. KEARLY: No. I believe that requirement is a good one.

MR. TSE: Therefore the question is, how should we do it, which is the next few sentences.

MR. KEARLY: Right. How much should we do, and what you put in here is, to my mind, not do-able.

MR. TSE: What do you suggest as the best way to do this.

MR. KEARLY: As a minimum, there would be central-axis comparison, profile measurement. Not everybody can take isodose data.

MR. BUKOVITZ: You can do it by the standard computer-generated dose, using a standard water phantom. That is how you verify your software on the computer.

MR. TSE: There are three items that we said in here. Which one do you think that not everybody can do?

MR. TELFORD: You're talking about 5.10.i, those eight angles. You're saying you would suggest, in alternative to the isocenter, to allow some other --

MR. KEARLY: Actually, I missed the term "in air" when I read this. I was thinking that this was a phantom measurement that you wanted to make of isodoses rather than just a single measurement in air.

MR. TSE: The first item is the air.

MR. KEARLY: Okay.

MR. TELFORD: Now that you see that, what do you say?

MR. KEARLY: Let me think about this just a moment.

MR. STRUBLER: That one actually just refers to the commissioning of the machine, not to the computer program.

MR. TELFORD: That's right. You start with the machine.

MR. TSE: Let me explain this item.

MR. BUKOVITZ: I don't understand that, and I didn't understand it three times before.

MR. TSE: Okay. Let me explain this.

There's an incident that some hospital changed a source of the cobalt-60 unit, but they did not change the source strength of one of the computer programs. Then they used that computer program for treatment planning; of course they got wrong doses. Therefore this is essentially trying to prevent those kinds of occurrences. You have a new program coming. Somebody may tell you that it works.

MR. BUKOVITZ: I understand that.

MR. TSE: Okay. What happens?

MR. BUKOVITZ: For one, a depth-dose calculation in an open field and in air and angles --

MR. TSE: Oh, you mean that.

MR. BUKOVITZ: To me, one, it doesn't make sense. You're not going to do a depth dose in air.

MR. ROSEN: That has nothing to with the computer. You're either testing isocentricity of the machine or gravitational effects on photons, one or the other.

[Laughter.]

MR. TSE: The computer has to make a calculation under certain geometry conditions, how many doses to deliver to that point,

MR. BRAHMAVAR: But computer software is written on the issue in the water phantom, so you've got to make this measure in a water phantom or some kind of a medium, not in air.

MR. TSE: I see.

MR. TELFORD: So we should say, in water, rather than, in air.

MR. BRAHMAVAR: In a phantom, perhaps.

MR. STRUBLER: But not for eight different angles.

MR. BRAHMAVAR: Not for eight different angles.

MR. STRUBLER: In order to correct the problem you were faced with, which is a serious problem that's happened more than once, one would do an output calibration of the unit where the new source is, and then you want corroboration of the computer program so that the appropriate change is in effect.

MR. TSE: That's right.

And if they did not make the change, the result would not match, so you know of some problem.

MR. STRUBLER: You shouldn't even word it this way, "before the first use of computer programs." You have it kind of front to back. Whenever there is a source change or another physical change of your teletherapy unit -- of course, this will be extended to the agreement states for linear accelerators, but it won't be a source change -- that an appropriate full calibration will be conducted and that there will be, then, verification of the computer program using the appropriate new calibration data.

MR. BRAHMAVAR: The computer doesn't take the output and calculate the times for you. It doesn't do that. You have to do that.

MR. KEARLY: But the thing that you want to get at is the computer programs that give you the times. That's all you're addressing; is that right?

I thought also, as he did, that what you were trying to get at was, do they give you a realistic dose distribution, which is what most of us use computers for. A few times people used computers to actually generate a number that you'll use for treatment. Some places may do that often. I don't know. That's too different things.

If you use the computer to generate a number for

treatment --

MR. BRAHMAVAR: Then you check.

MR. KEARLY: That's one kind of a check. If you're concerned about, is it giving you realistic dose distributions, that's a completely different kind of situation. That's what I thought you were talking about.

MR. TSE: Well, we said here that if you've involved with hand calculations, then that shall be part of the check. Eventually you come down to a single, what is the number you're looking at. That you can check with a measurement, to see whether they are in agreement or not in agreement.

MR. KEARLY: That's checking the depth dose. Is that what you mean?

MR. TSE: No.

MR. KEARLY: That's what full calibration is.

MR. TSE: No. Wait a minute. Full calibration is measurement of the output under certain conditions. The computer program is go calculate a dose under certain conditions. They are two independent things.

MR. KEARLY: You want us to make sure that we put a chamber in water at a certain depth, to check the dose delivered at some depth.

MR. TSE: That's the full calibration, but how do you know your program matches this measurement? For

example, just the case that if a cobalt-60 source is changed, the value of curies have not been changed.

MR. BRAHMAVAR: That's the point. The software doesn't ask you any curies. It doesn't ask you.

MR. TSE: But has that case happened in one of the hospitals?

MR. BRAHMAVAR: No. A particular software program did require the wedge factors to be included, the source curies to be included. Most of them give you the linear distribution, and you've got to calculate the time.

MR. KEARLY: I think what you are primarily after would be solved by saying, after a source change or a full calibration, the output from a computer that provides numbers for treatment will be checked against a manual calculation.

MR. BRAHMAVAR: Essentially, right.

MR. KEARLY: I think that's what you want.

MR. TSE: Right.

MR. KEARLY: Then this eight-angle business is --

MR. TSE: Somebody said that was a good way of doing it.

MR. BRAHMAVAR: It should be reworded. If a computer program calculates the time used to deliver the radiation dose on a cobalt unit, then this verification should be done. Most of the software programs do not

calculate that.

MR. TELFORD: How do you verify the other ones?

MR. BRAHMAVAR: Which other ones?

MR. TELFORD: The ones that you don't do that for?

MR. BRAHMAVAR: The other ones give you the distribution. They don't ask for the output of your machine.

MR. KEARLY: It's all relative.

MR. BRAHMAVAR: It's relative to whatever that point is.

MR. BUKOVITZ: These is essentially a moot point, because I would say 95 percent of the cases where a computer is used to do the treatment time calculation, that treatment time calculation is then verified by a manual calculation.

MR. KEARLY: But it won't hurt to say this.

MR. TSE: But in some cases they did not do that.

MR. WIEDEMAN: Let me give you an example that resulted in a multimillion dollar lawsuit. A hospital in Cleveland, Ohio, has a large cobalt teletherapy department. They also have a remote satellite facility. The patient was to receive like 5,000, 6,000 rads breast therapy. They went to the computer, they entered the data into the computer. It gave them back their treatment plan, so many fractions. However, later on, after a couple of days, the patient asked the physician, said, well, I can go to the remote satellite

facility; it's much closer to my house. He said, no problem at all.

So the patient, I think after the second treatment, went over to the remote satellite facility. They transferred the chart, but the only problem was there was like 5,000 curies in the hospital cobalt unit, and there was like 9,000 curies in the remote satellite facility, so they caused a misadministration. It was because of mix-up in the computer program or the error on the person's part.

MR. BRAHMAVAR: They had the proper computer program. It was a mix-up because they didn't change the output going from 5,000 to 9,000. It was a calculational error, not the software program.

MR. WIEDEMAN: The program was correct, if they would have used the right machine.

MR. ROSEN: Excuse me. Did the patient take the treatment plan with them? Had the treatment plan been run independently on both computers I presume there would have been no misadministration.

MR. WIEDEMAN: You're right, but that didn't happen.

MR. ROSEN: Okay, so it is not an issue about computers, and it is not an issue about entry into computers. Someone took a treatment plan from one machine and applied it to another machine. That has nothing to do

with anything other than human stupidity. It's not a machine problem. All the testing on the machines will not catch that.

MR. BUKOVITZ: There's an easy way out of this. If you're using a computer to calculate treatment time, you manually verify it.

MR. BRAHMAVAR: I think that will catch everything.

MR. ROSEN: Now, if you introduce a new computer program, are we talking about testing the software to make sure that the 70 percent isodose line is where you expect it to be? That's testing the computer program?

MR. KEARLY: That's a big issue.

MR. TSE: I don't think we intended in this item to do that. We just intended to make sure that the dose is correctly computer.

MR. ROSEN: So we assume the vendor supplying us with the software has done a proper job in development of the software.

MR. TSE: I think that this item would not say that, but I think as a licensee or as a user, you really should verify that the computer program has no error. You should verify yourself, it seems to me.

MR. BRAHMAVAR: The manufacturers go one step further on any teletherapy machine they sell you. They give

you what they call the prototype isodose curve, and it is the physicist's and the institution's responsibility to verify before you deliver a dose to a patient. We have an obligation to check that it's giving you the right depth dose.

MR. TSE: But this particular program we call the basic quality assurance program, which intends to address the human errors which occur.

MR. ROSEN: So, while we do that, we're not required to include that as part of the QA program.

MR. BRAHMAVAR: Well, the first time it should be.

MR. ROSEN: Do you make a decision on time on a 60-percent isodose line, or do you do it on the central axis?

MR. BRAHMAVAR: If your computer calculates the time, yes, because you haven't changed the output in the computer.

MR. ROSEN: You do the time, I presume, when the dose is the center of the tumor volume, not on some point well outside that volume.

MR. KEARLY: It comes down to what is a full calibration for the entire department. The computer is certainly a part of that. Whether you guys want to jump into that fray or not --

MR. ROSEN: It also comes down in part to what's

the definition of a misadministration now, with the change in the wording. If the prescribed dose is 5,000 rads to the 50 percent line or the center of the tumor volume, and you've got a field that has blocks in it, and you leave a block out one day, it does not alter the prescribed dose. Is that a mis-A? You've delivered a little extra radiation off the corner of the field.

Now, you are worried about something outside of the 15 percent or the 30 percent or the 20 percent line, even though that's not what you're using to define the time.

Is that covered by the word "geometry" in the guide?

MR. TSE: I think later you will get the proposed rule regarding the misadministration. We will ask for comment, and I think it's a chance for any comments or suggestions on how misadministrations or events can be better defined. Please let us know. I do not think that we should discuss misadministrations at this time.

MR. ROSEN: It's part of quality assurance.

MR. TSE: Right, but you can say that's part, whether you should report or not report to NRC.

MR. ROSEN: Okay.

MR. TSE: So 5.10, for that I think you might want to write your positions for what you think the best way to

do it is. We'll look at these so we can modify accordingly.

MR. KEARLY: But your intent, again, is just to verify those computer programs that provide the number that's used for treatment.

MR. TSE: Our intent is to verify the computer that you use, such that the dose calculated would be the same to the dose delivered.

MR. BRAHMAVAR: Only if the program calculates dose.

MR. TSE: Only then. If it's relative, then -- We said that additional manual calculation is needed to determine the dose.

MR. KEARLY: That goes without saying.

MR. TSE: So that you still have this dose match from the calculation and from the measurement. The problem is whether the calculation describes what you actually measured.

MR. KEARLY: Are you going to rewrite 5.10?

MR. TSE: For now, no. We do not have to rewrite 5.10 now, but you can select what you think is the best to describe your QA program. After we look at all this information, maybe we can rewrite a better section.

MR. BRAHMAVAR: I think 5.10 will say not applicable. It's not applicable in air.

MR. TSE: Okay.

Any others on page 10? Any other comments?

[No response.]

MR. TSE: Then we can move to 11. That's the end.

MR. KEARLY: In 5.11 is the same issue, checks. "Within two working days of the treatment"

MR. TSE: Right.

MR. KEARLY: What treatment?

MR. BRAHMAVAR: Completion of the treatment. It's the same wording.

MR. ROSEN: Shall we wait 30 days, 32 days?

MR. KEARLY: You mean initial treatment, probably, or first treatment.

The ACR has a recommendation for just that for every calculation, that it be checked within two days of the initial treatment.

MR. TSE: Well, this applies to 5.6 and 5.9. There are some percentages indicated in there; therefore it may be the treatment you're supposed to computer, but if you cannot do it, then you have two days after that time.

MR. KEARLY: Two days past 25.

MR. TSE: Right. Otherwise, it would be more stringent than the 25 percent. If you have 10 fractions, then 25 percent is like equally. You can do it within two fractions. But if you have the first fraction, then you could have a shorter time, so I think that applies to the

required time. You have actually two days.

MR. KEARLY: You mean two days past the 25 percent of the treatment.

MR. TSE: Right.

MR. KEARLY: So it's not two days of the treatment. It's two days of 25 percent of the treatment.

MR. TSE: Any other general comments or general questions on the guide?

MR. KEARLY: Can I ask, are the TLD services accredited? Is that officially accredited?

MR. STRUBLER: What do you mean by accredited?

MR. KEARLY: I don't know. That's what they're acquiring. Either we have another qualified physicist come in with a completely new dosimetry system to check our output after you have a new source put in, or you have an accredited TLD check.

MR. STRUBLER: What section is that?

MR. KEARLY: It's 5.7.

Is there such a thing as an accredited TLD service? I don't know. I honestly don't know.

MR. WIEDEMAN: The ones that we've accepted in the past were M.D. Anderson in Wisconsin.

MR. KEARLY: What's the accrediting?

MR. BRAHMAVAR: Regional accreditation labs and the AAPM. They certify them.

MR. WIEDEMAN: At one time there were about five, but some of them have lost their accreditation, their approval, or whatever.

MR. MEINHOLD: Are they prepared to handle this load?

MR. WIEDEMAN: Well, I really don't know.

MR. ROSEN: By the way, our medical physicists say this particular phrase and that particular phrase is ridiculous. We're going to do everything within 2 percent. Why the hell would I want to check it with a system that's only good to 5 percent. I want to check with another system that's good within 2 percent. Otherwise it's meaningless to me.

MR. KEARLY: In which case it's another expense. You have to bring in a consultant team, generally, to do this sort of thing. I don't know how many facilities have multiple physicists to draw from.

MR. STRUBLER: It's the same thing as the daily checks to be performed are not 2 percent. We're trying constancy, so this is just to catch gross error.

MR. ROSEN: I know. That's what I tried to explain to him, but, don't waste my time looking for gross problems when I worry about little problems. I said fine; we'll do everything within 2 percent.

MR. TSE: I think we included a second

alternative, essentially, for these facilities that may have that problem.

MR. ROSEN: It's hard to tell from the documentation I have in here. In the period of 1980 to '84 and then from '84 to '88, there was a significant increase in the absolute number of misadministrations. Was, in fact, there an increase in the rate of misadministrations?

MR. WIEDEMAN: It's difficult to answer. Probably not, one could speculate, because in a lot of the facilities there was some speculation that maybe they weren't reporting misadministrations, not because they didn't want to, just because they didn't know they were supposed to. When you look at the number of citations the NRC has issued for failure to report misadministrations, there's quite a few.

MR. ROSEN: This one I'm going to regret asking, but we would all like to see zero misadministrations. What in the Commission's eyes should we be aiming for? What is an acceptable rate? A thousandth of a percent? That's roughly where we are right now. Last year there was something like, in terms of individual administrations of therapeutic about 2.5 million therapeutic doses given.

MR. TELFORD: Notice that proposed 35.35, paragraph A, has the phrase "high confidence." The objective of the basic quality assurance program is to provide high confidence that errors in medical use will be

prevented. At the next workshop, I'll give you the opportunity to tell me what you would like to see for high confidence. How can we, number one, propose a level that would be reasonable, and secondly, how can we defend it. I'd really like to know.

MR. ROSEN: Well, as a consumer, I can give you a simple answer. I want to see zero error. As a generator, I just stop to think that if I apply the same philosophy across the board in my hospital, I'll have to shut the doors and lock it up.

MR. TELFORD: Just part of your hospital, that's all. That's all we address.

MR. ROSEN: No, I'm just saying that for practical purposes. What is so unusual in the use of ionizing radiation that it requires this -- it is extra-special treatment; it is not even special treatment.

MR. TELFORD: The NRC regulates it.

[Laughter.]

MR. STRUBLER: I support the question he's raising, as I expressed to some of you earlier. It comes down to the heart. We all are in here for the same purpose. We all agree quality assurance programs are necessary, and we want to minimize errors, but, again, this same application from regulatory agencies is not applied uniformly in the medical environment. Because of the public

perception of concerns with radiation and the perception that risk is up here, when in reality it's down here, it precipitates a lot of this. The question that Jerry raises, rightly -- and I'm sure you've heard it many times before -- is what percent confidence level do we want to have that we're really minimizing these things. We only have so many resources in our society, and if we're going to be focusing on protecting our society from radiation without the concerns about the medical usages that are probably far more serious and have far greater consequences, in terms of the applications of drugs or medicines or other forms of therapy. It's an interesting philosophic question, perhaps, but I think it is an appropriate one, because we do channel a lot of our resources into reducing, as I said earlier, a real tiny number to even tinier. That's not to say we should be making that effort, but perhaps at the expense of neglecting some other areas, in which the profits are going to be far greater, the benefits from focusing some of this.

I know this has been addressed to you by other members and some of your advisory things, but I think it still needs to be spoken and raised again.

MR. ROSEN: The radiation industry has taken the lead in many of these areas, in terms of human health. It may be better to take people that have been so skilled in bringing the rate of misadministrations of pharmaceuticals,

in particular, down to a tenth or a hundredth or a thousandth of a percent out of nuclear medicine and get them to work elsewhere in the hospital to save some very real lives.

The question came to me the other day -- I was talking to our chairman of nuclear medicine. He said, why are you concerned about this? He says, we use 20-some non-nuclear drugs as adjuncts to nuclear medicine, all of which can kill in a matter of moments, for diagnostic uses. He said, the marketplace takes care of those issues. Why aren't we concerned more about them? Why don't we have rules and regulations? And I didn't have an answer.

MR. TSE: May I ask a question on your philosophical point? If a patient comes in to have either diagnosis or therapy and turns out, because of some obvious human errors to get thyroid damage or big doses in some places or the wrong place, or the patient not even going in for radiotherapy, what do you feel about that? Should it be avoided, or because it is only one out of so many thousands we don't have to worry too much.

MR. ROSEN: Absolutely it should be avoided. Absolutely we should have quality assurance programs. Absolutely the controls should be there. Now, I might ask myself, should it be a regulatory issue? Personally, I don't think so. It is; I will abide by it; we will

implement it. We would implement in general anyway.

MR. TSE: That's why our statement said that maybe 80 or 90 percent of hospitals have those kinds of procedures implemented. However, maybe there are some hospitals or some physicians that may not have such a QA program.

MR. ROSEN: No one wants a $10 million lawsuit.

MR. TSE: But misadministrations to occur, and therefore the effect of the proposed rule, if it becomes a final rule, will force those people to have a good QA program. The way we structured the impact analysis --

MR. ROSEN: Oh, I understand fully the reasoning for the program. We were just talking philosophy for the moment. We probably should have said, let's go off the record.

MR. TSE: Any other questions about the regulatory guide?

MR. KEARLY: I still think that you need to check to see whether or not the term "accredited TLD service" is appropriate, because the services I'm aware of are accredited to calibrate our chambers, but whether there is an accreditation process for the services providing for TLDs I'm not sure.

MR. WIEDEMAN: Maybe we could change it to "acceptable."

MR. STRUBLER: I think we're all in agreement that

that's satisfactory. I think we're always more comfortable having somebody else check us, anyway.

MR. BRAHMAVAR: That is the only way that is mentioned. There are many other ways of checking the same thing. Why should it be just TLD service? There may be some other ways.

MR. WIEDEMAN: I think the AAPM, when they first got into this, because there was some concern that the small community hospitals that have one medical physicist that covers a 200-, 300-mile area doesn't have any way of dual-verifying. This would be a good way of doing a dual check.

MR. KEARLY: You are making a lot of business for many of us, because what this is going to functionally mean is that every unit that we have, accelerators included, is going to have to have two people involved with every annual calibration. That's what's going to happen. People will subscribe to TLD services also, perhaps, but I bet the bulk of what happens is that somebody will hire me, and I'll hire them.

MR. TSE: It's not annual.

MR. KEARLY: Full calibration it says.

MS. PICCONE: "That resulted from a source change."

MR. TSE: Or you have 5 percent spot-check

difference, and so on. Annually you can double-check by decay, but if you change the source, you really cannot double-check by decay. It's a small impact.

MR. WIEDEMAN: There is an annual requirement in there, but that's for the audit from someone that's not the one that did the activities.

MR. TSE: We are talking about independent check after a full calibration measurement.

MR. WIEDEMAN: Yes.

MR. TSE: The only time you need an independent check after the full calibration measurement are those full calibration measurement when you change sources, or maybe you have a problem of verifying the differences. Not applied to annual calibration.

MR. STRUBLER: That's true, but sometimes one of the words get dropped from the state regulations that cover the linear accelerators, and annual calibration remains with independent verification.

MR. TSE: I see. If the state likes to be more restrictive, I think they can.

MR. STRUBLER: I know.

MR. TSE: But this is not one word. This is a long phrase to indicate it only applies to those cases.

MR. ROSEN: This issue of certified versus qualified, Frank's got a chamber that's good within two

percent. I presume he has a TLD. Can I order up a chip from him and sound it down to him to verify? He's qualified, by your definition. I presume he's qualified by your definition.

MR. KEARLY: "Accepted" was the word that they used. I don't know if I'm an accepted supplier.

MR. ROSEN: You raised a question about, should it be "accepted" or "certified"; could "qualified" be adequate.

I mean, I could bring him in what that same chamber and ask him to check my machine within five percent, so I presume he must be qualified to do it.

MR. TSE: Are you talking about the TLD?

MR. ROSEN: Yes. It would save me paying his transportation expenses, if nothing else.

MR. TELFORD: Would there by any objection to taking about a ten-minute break? We need to talk about schedule and then concluding remarks, and then I think we're done.

MR. KEARLY: I thought you were going to go through this.

MR. TELFORD: I'm going to hand it out and ask for you to review it, to discuss it at the next workshop -- discuss the reporting requirements at the next workshop.

MR. STRUBLER: That would still qualify for the time frame?

MR. TELFORD: Oh, yes.

We can go off the record.

[Break.]

MR. TELFORD: In the final session, we want to cover the schedule, turning in the copies of the QA programs, and any concluding remarks.

First let's address schedule. Of the handout you had this morning -- the first page is the eight objectives -- please turn to the last page. That was the original schedule. That still has to be revised because we had more difficult than we expected in rounding everybody up. Where it says, start pilot program, can you do that May 1? Let me ask for a show of hands. Who can start May 1?

MR. STRUBLER: I think maybe this group can, but the groups later on --

MR. TELFORD: I know.

MR. STRUBLER: You're only asking for this group.

MR. TELFORD: This group.

How many of you can start May 1.

[Show of hands.]

MR. TELFORD: One hand not up.

How about two weeks later? Can everybody start -- Let me get my calendar.

Let go off the record for a minute.

[Pause.]

MR. TELFORD: Okay. May 14 is a Monday. Show of hands: who can start the pilot program May 14?

[Show of hands.]

MR. TELFORD: We have everybody's hand up. All right. Everybody likes May 14. That's good.

That would mean we would start on May 14, and we would move forward 13 days. Instead of ending on June 30, we would end on July 13.

MR. KEARLY: That's a Friday?

MR. TELFORD: That's a Friday, July 13.

[Laughter.]

MR. TELFORD: It's okay for an end, not for a beginning.

Would you please turn to the last page, and where it says, start pilot program, put May 14. Where it sends, end pilot program, put July 13.

Participants' evaluation information back to Brookhaven would be approximately two weeks after. The end of July.

MR. MEINHOLD: August 1. That's the end of July.

MR. TELFORD: Two weeks later would be July 27. Let's just say July 31. It's close enough to July 31.

The second set of workshops, then, would be approximately two weeks later. This will be mid-August for the second set of workshops, roughly, keeping in mind that

we would have to avoid the conflicts that we could avoid and schedule five of these.

MR. MEINHOLD: QAs to BNL, presumably, the second week in May.

MR. TELFORD: Is everybody with me on schedule?

MR. MEINHOLD: John, just a projection: If this group needs to move it two weeks, why won't the Texas group need to move it another two weeks? Why don't we start with that assumption?

MR. TELFORD: Because we're going to write them a letter tomorrow, telling them about this schedule.

MR. MEINHOLD: They don't feel as comfortable as this group does with what we're doing, you see. There's a lot more people smiling here now than there were four hours ago.

MR. TELFORD: I think the difference is how much notice. This is our first workshop, so if today is the 29th of March, a one-month advance notice between now and the start of your actual trial period gives you a certain amount of time -- roughly a month -- to finalize your program, do the training, change your procedures. That means that the other people also need a month and a half. We can provide that month and a half. They will, in fact, get more.

Now, the QA programs, could everybody make the modifications to their QA program such that it meets

proposed 35.35, send a copy to Ed -- if you haven't done so already, could you do that within two weeks from today?

[Inaudible responses.]

MR. TELFORD: Everybody says yes? Two weeks would be May 15.

Excuse me. This is March. I misspoke. April 15. That's a Sunday.

MR. KEARLY: April 15 is another day, isn't it?

[Laughter.]

MR. ROSEN: The original schedule gave us about seven weeks after the workshop to provide you with that. Now you're asking for it two weeks after the workshop.

MR. TELFORD: Ah, but when did you get your first letter?

MR. ROSEN: The first letter didn't ask me to do anything, really. We did a lot of thinking about it, but we didn't necessarily commit anything to paper at the time.

MR. TELFORD: Oh, okay. Are you saying that you couldn't get your program --

MR. KEARLY: Getting the program together is a major amount of work.

MR. ROSEN: There wasn't a need to, according to your original schedule. You said you were going to have a workshop at the beginning of February, and then you needed paperwork at the end of March.

MR. TELFORD: I'm asking if you could do that. You're saying no. How about the end of April

MR. ROSEN: I'm saying, just give me until you start the pilot project, which is what you had. You had end of March get the paperwork, beginning of April, basically the same time. Let's just leave it there. We'll get it to you at the beginning of May. That keeps you on the same schedule.

MR. TELFORD: There's one small problem: that for the 18 sites that we're going to go to, we need to start the site visits very soon after the start of the pilot program, very soon after May 14. Some of those -- and your site might be one -- we would need about a week to look at your program before we come to your site.

MR. ROSEN: I'm only concerned right now because we've done a tremendous amount of talking, and we're reviewing, but we have not committed the kind of stuff to paper that I think needs to be committed. I will have to pull resources both out of radiation oncology and nuclear medicine for almost, then, a solid two weeks, and I can see the need in that case of having to actually shut down machines or run into some serious questions about misadministrations.

MR. TELFORD: So you're saying May 14.

MR. ROSEN: That would keep up on the same

proposed schedule that you've got on paper. That's mentally and physically what we were working for.

MR. TELFORD: Well, let me request May 7. If the best you can do is May 14, that's the best you can do. The only reason I would request it May 7 is because we would need a week to digest the first set of those that we go to, and we plan to take those in groups, northeast, southeast, et cetera, and review those programs before the QA team would actually go to the site.

Can everybody live with that?

[Inaudible responses.]

MR. TELFORD: Okay.

MR. KEARLY: Can I ask a quick question, John? Do we get feedback from any of the other workshops? They're going to get feedback from our workshop, I take it. Do we get feedback from theirs as well, changes or comments about what we considered what was possible?

MR. TELFORD: If there is some earth-shaking thing, some large thing that happens as a result of other workshops, we'll certain inform you.

That's schedule, that's turning in the copies of the written programs. We're up to concluding remarks.

My concluding remark is that I want to thank you all for coming and for agreeing to participate. I'm very encouraged with your interest and your level of detail and

your level of questions, because I think if you keep that up the next workshop should be very helpful in telling us how to write a better rule and a better guide so that we can have a sufficient requirement and yet one that would hopefully have a minimal impact.

We do have a copy of the Federal Register notice for you that contains the reporting requirements as well as the rest of the notice, what we call the statement of considerations, the preamble to the rule.

[Handouts distributed.]

MR. TELFORD: I want to call your attention to that and ask you to look over the reporting requirements, because the next workshop we want to go over those, too. I'm sure that you'll have a big interest in those, because every time I've ever talked about thing and I go over those reporting requirements, that's where I get a lot of flak. We admit they're not perfect, and we want to hear suggestions for how to improve those.

MR. KEARLY: Your official comment period ends April 12. How does our workshop factor into that?

MR. TELFORD: The official comment period for written comments from the public ends April 12. You can send written comments to the Secretary of the Commission by that date, or you can bring your comments to the next workshop. Because we're keeping a transcript of these

meetings, your comments at the next workshop will be part of the official record for this rulemaking, so have no fear. Your comments will be official entered.

For concluding remarks, why don't we just go around the room and let everybody say whatever they want to saw as concluding remarks. Does anybody have an airplane flight that's 4:30 or 5:00?

[No response.]

MR. TELFORD: All right. Then we'll give everybody five or ten minutes, then, if they want that much. I'll just cut you off after ten minutes in the interest of the next person.

We'll start over here.

MR. DORING: I don't have any comments right now.

MS. MOORE: Just glad to be here.

MS. KELTY: It's been very informative. I enjoyed listening to all the discussions. We've raised some interesting questions and caused a lot of thought process for some of the written documentation on how we're going to be able to go about doing that. I think it's admirable, and I certainly hope we can strive to collect written requests on all patients. You've given me ideas for alternative provisions for the few cases where that might not be possible.

MR. BUKOVITZ: I've made all my comments.

[Laughter.]

MR. BRAHMAVAR: I think it's a very workshop, so far as I see it. It's very helpful to know, also, that whatever we have been doing for the last 10 to 15 years, at least we meet 90 percent of the proposed standard, so we don't have to change many more things. Hopefully some particular document will come out of all this that will be usable, so that we do not get tangled up with the paper-shuffling.

Just another comment: Can we get a copy of all the participants, their names and addresses so that we know who participates?

MR. TELFORD: We'll take that under advisement. I'm not sure of the answer to that.

MR. BRAHMAVAR: Thank you.

MR. STRUBLER: My previous comments notwithstanding, I think that the proposal is certainly justified on the basis that quality assurance programs should be in existence in all facilities of the kind that we're talking about. I would still reiterate the comments that we made at the very close of the last session regarding the basic thrust, and to put all of the regulatory process into a proper perspective, as I try and do when I lecture on low-level radiation effects, that to put radiation effects and the biologic effects of radiation into perspective of

all the other risks in our lives. so from a regulatory point of view I think it's important that something like this be required, as not only the agreement states, but all of the NRC facilities that are using byproduct materials, but to put it into a larger perspective in terms, as I said before, the resources that are plowed into reducing radiation risks and accidents that are already very low and well regulated to even lower levels still is a little bit disturbing to me as we see things evolving.

MR. BOLLING: Whenever we get together like this, licensees and regulators, it brings to mind an accident that occurred up in Missassauga, Canada, a couple of years ago. I think it was a chlorine tank train car or something that went off the tracks, and some 250,000 people were evacuated. I can't help thinking that if there was one atom anywhere nearby, that the people responsible would still be in jail. I think the hysteria about radiation is something that we all have to keep in mind. I think we all do a pretty good job of what we do. There is room for improvement.

MR. WIEDEMAN: I just want to thank everybody for coming out today. It's been very enjoyable listening to your comments and concerns, and I've got quite a few notes here that I have taken throughout the day. I'm sure that a good, close, working relationship that we can iron out these differences of opinions, and we'll end up with a good,

working program.

Once again, thank you very much.

MR. TSE: Thank you very much for coming. My telephone number and name is on the sheet we just handed out. If you have any questions or request any documents relating to this program, please give me a call. I appreciate the comments you've given us. We will be seriously considering all that. Of course, the pilot program is the most important results; we will consider those, too, when we revise or promulgate the rulemaking.

Thank you.

MS. PICCONE: I just will echo Darrel and Tony, then, in thanking the people who have consented to participate in the pilot program. Certainly with this rule we asked for your help, and we are looking very much forward to your constructive comments and criticisms at the end of the pilot study.

MR. KAPLAN: I would like to thank you all for being so nice as to answer my letters and to responding as well as you did on the phone, as professional as you are. If I could just throw one pitch in: Please give us a good road map when you send us your QA program, so that we can ferret as easily as possible which parts of your program meet which of the eight objectives.

Thank you.

MS. FRANKLIN; Well, I would just like to say that I think this is interesting, and it's been informative. I think it's interesting to see NRC people as real people, rather than people who come in our department and everybody goes, it's NRC.

That's all.

MR. GRAHAM: I would just express my gratitude for being given the opportunity to participate in this program. Echoing what she was talking about, we hear a lot about all these various organizations, but the only time you see them is really in kind of a negative situation, so I think it's a very positive thing, if nothing else. I think the other important factor that did come out during these discussions was the regulatory agencies' working together and trying to get one uniform set of directions, which I think is imperative to my trying to perform business in a logical manner.

Thank you.

MR. KEARLY: That's very similar to what I'd like to say. I'd like to see that. I don't know that it's happening, but I'd like to see that. I think it's very important that the NRC and the other agencies that are regulating us really do have good communication and try not to duplicate each other in different ways. It gets very confusing and difficult. But I was very happy to see the

receptiveness to change and the altering the direction of the things that did not look like they would be reasonable.

MR. ROSEN: Again, thanks for the communications. Irrespective of what I might have sounded like today, I think Ed will confirm, when he made the request we jumped right in and said we would do it. I still have no regrets in volunteering.

MS. KIRTLAND: I don't really have any comments at this time. I am very happy to be able to participate in the pilot study, though.

MR. NELSON: I'd just like to thank all of you for coming and reiterate what Ed said, in that when you do submit your quality assurance programs try to indicate which aspects of your quality assurance programs meet the requirements of the rule or of the regulatory guide. It would be very beneficial to us, for those people that have to go through those, to be able to identify those specific areas quickly.

MR. MEINHOLD: Just a couple of observations. I guess the first one is that I was intrigued to see the tension that was in this room when we started this morning, the us against them, and sort of the way that's turned around through the day, with the feeling that we could all talk about this together, rather than think we were enemies.

The other side, going back to what was said

earlier, is that your participation, your organization volunteering is incredibly important, it seems to me, in terms of getting the community to represent all of the people in the medical areas and help the Commission and its Staff understand the practical problems. I don't see any other way that this could be done as well as your volunteering to do this. I think it's really a remarkable service that your organizations are doing, and I think it will help a great deal.

MR. TELFORD: With that, let's conclude this meeting.

[Whereupon, at 4:00 p.m., the meeting was concluded.]

REPORTER'S CERTIFICATE

This is to certify that the attached proceedings before the United States Nuclear Regulatory Commission

in the matter of:

NAME OF PROCEEDING: NY Workshop Pilot Program

DOCKET NUMBER:

PLACE OF PROCEEDING: East Elmhurst, NY

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.

Mark Handy

MARK HANDY
Official Reporter
Ann Riley & Associates, Ltd.

PILOT PROGRAM OBJECTIVES:

1. TO UNDERSTAND HOW LICENSEES DEVELOP THEIR SPECIFIC QA PROGRAM FOR THEIR INSTITUTIONS WHICH MEETS THE PERFORMANCE OBJECTIVES OF PROPOSED § 35.35.

2. TO UNDERSTAND HOW LICENSEES CONDUCT THEIR "35.35 QA PROGRAM" IN ACTUAL PRACTICE.

3. TO DETERMINE IF THE PERFORMANCE OBJECTIVES OF PROPOSED § 35.35 HAVE THE EFFECT OF PREVENTING OR CATCHING MISTAKES WHICH COULD LEAD TO MISADMINISTRATIONS, IF NOT CORRECTED.

4. TO DETERMINE IF PROPOSED § 35.35, IF PROPERLY IMPLEMENTED, CAN PROVIDE HIGH CONFIDENCE THAT ERRORS IN MEDICAL USE CAN BE PREVENTED.

PILOT PROGRAM OUTLINE

1. INVITATIONS TO VOLUNTEERS DURING JANUARY AND FEBRUARY 1990. INVITATION PERIOD CLOSED MARCH 9, 1990.

2. VOLUNTEERS: REVIEW PROPOSED § 35.35 AND DETERMINE THAT THEIR QA PROGRAM MEETS PROPOSED § 35.35 OR MODIFY THEIR QA PROGRAM TO MEET PROPOSED § 35.35 DURING MARCH 1990.

3. PRETEST WORKSHOPS ON MARCH 29, APRIL 4, 6, 18, AND 20, 1990. VOLUNTEERS BRING COPIES OF THEIR QA PROGRAM TO THE WORKSHOP.

4. VOLUNTEERS DEVELOP WRITTEN INSTRUCTIONS OR TRAIN PERSONNEL, IF REQUIRED, DURING APRIL TO PREPARE FOR QA PROGRAM 60-DAY TRIAL.

5. VOLUNTEERS CONDUCT 60-DAY TRIAL, DURING THE PERIOD MAY 1 TO JUNE 30, 1990, OF THEIR "35.35 QA PROGRAM" AND RETAIN SPECIFIC RECORDS; THE NRC QA TEAM WILL VISIT 18 VOLUNTEERS FOR ONE DAY AT EACH SITE.

6. POST-TEST WORKSHOPS WILL BE DURING THE PERIOD FROM LATE JULY THROUGH AUGUST 1990. VOLUNTEERS BRING COPIES OF THEIR EVALUATIONS. VOLUNTEERS WILL DISCUSS THEIR "35.35" EXPERIENCE, EVALUATIONS, AND SUGGESTIONS FOR IMPROVEMENTS TO PROPOSED § 35.35, THE REGULATORY GUIDE, AND THE RECORDKEEPING AND REPORTING REQUIREMENTS. THE NRC QA TEAM WILL DISCUSS: (A) THE CRITERIA USED TO EVALUATE THE 18 QA PROGRAMS, (B) THE RESULTS FROM THE EVALUATION OF 18 QA PROGRAMS, (C) THE CRITERIA USED TO EVALUATE 18 SITES, AND (D) THE FINDINGS FROM THE 18 SITE VISITS.

WHAT THE PARTICIPANTS CAN EXPECT

1. TO UNDERSTAND THE CRITERIA THAT WERE USED TO EVALUATE THE "35.35 QA PROGRAMS."

2. TO LEARN THE RESULTS OF THE EVALUATION OF THEIR PROGRAM.

3. TO UNDERSTAND THE CRITERIA THAT WAS USED TO EVALUATE THE QA PROGRAMS DURING THE 18 SITE VISITS.

4. TO LEARN THE RESULTS FROM THE 18 SITE VISITS.

5. TO HAVE THE NRC QA TEAM LISTEN CAREFULLY TO THEIR EVALUATION OF THE PROPOSED RULEMAKING.

6. TO HAVE THE NRC QA TEAM LISTEN CAREFULLY TO THE SUGGESTIONS AND COMMENTS OF THE PARTICIPANTS ON HOW TO IMPROVE THE PROPOSED RULE-MAKING.

WHAT IS EXPECTED OF THE PARTICIPANTS

1. DEVELOP A QA PROGRAM TO MEET PROPOSED § 35.35.

2. ATTEND A PRETEST WORKSHOP.

3. PROVIDE WRITTEN INSTRUCTIONS AND TRAIN PERSONNEL, AS NECESSARY, TO PREPARE FOR THE 60-DAY TRIAL.

4. CONDUCT A 60-DAY TRIAL OF THEIR "35.35 QA PROGRAM."

5. EVALUATE THE PROPOSED RULEMAKING AND PROVIDE SUGGESTIONS FOR IMPROVEMENT.

6. ATTEND A POST-TEST WORKSHOP.

Enclosure 1

Purposes and Specific Objectives of the Quality Assurance Program

§ 35.35 Basic quality assurance program

(a) Each applicant or licensee under this part shall establish a written basic quality assurance program to prevent, detect, and correct the cause of errors in medical use. The objective of the basic quality assurance program is to provide high confidence that errors in medical use will be prevented. This basic quality assurance program must include written policies and procedures to meet the following specific objectives:

(1) Ensure that any medical use is indicated for the patient's medical condition;

(2) Ensure, prior to any medical use, that a prescription[5] is made for any therapy procedure and any diagnostic radiopharmaceutical procedure involving more than 30 microcuries of I-125 or I-131;

(3) Ensure, prior to any medical use, that a prescription or a diagnostic referral[5] is made for any diagnostic procedure not involving more than 30 microcuries of I-125 or I-131;

(4) Ensure, prior to any medical use, that the prescription or the diagnostic referral and clinical procedures manual is understood by the responsible individuals;

(5) Ensure that any medical use is in accordance with a prescription or a diagnostic referral and clinical procedures manual;

(6) Ensure, prior to any medical use, that the patient's identity is verified as the individual named on the prescription or the diagnostic referral;

(7) Ensure that any unintended deviation from a prescription or a diagnostic referral and clinical procedures manual is identified and evaluated, and

(8) Ensure that brachytherapy and teletherapy treatment planning is in accordance with the prescription.

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[5] If, because of the emergent nature of the patient's condition, a delay in order to provide a written prescription or diagnostic referral would jeopardize the patient's health, an oral instruction may be acceptable, but a written record (containing the information specified in § 35.2 for a prescription or diagnostic referral) shall be made in the patient's record within 24 hours.

Enclosure 2

Relevant Definitions in Proposed Section 35.2

§ 35.2 Definitions

"Basic quality assurance" means, for the purposes of this part, the aggregate of those planned and systematic actions designed to prevent the occurrence of any error in medical use produced by, made by, caused by, or attributable to any individual acting on behalf of the licensee (including omissions or commissions).

* * * * * * * * *

"Clinical procedures manual" means a collection of written procedures in a single binder that describes each method (and other instructions and precautions) by which the licensee performs clinical procedures; each diagnostic clinical procedure approved by the authorized user for medical use includes the radiopharmaceutical, dosage, and route of administration.

* * * * * * * * *

"Diagnostic referral" means a written request dated and signed by a physician before a diagnostic medical use that includes the patient's name, diagnostic clinical procedure, and clinical indication.

* * * * * * * * *

"Prescribed dosage" means the quantity of radiopharmaceutical activity as documented before administration of the radiopharmaceutical, either (a) on the prescription or (b) in the clinical procedures manual if the procedure is performed pursuant to a diagnostic referral.

* * * * * * * * *

"Prescribed dose" (a) in teletherapy, means the quantity of the radiation absorbed dose stated on the prescription, as documented before administration, or (b) in brachytherapy, means the quantity of the radiation absorbed dose or equivalent stated on the prescription, as documented before administration and as revised to reflect actual loading of the source or sources immediately after implantation.

* * * * * * * * *

"Prescription" means a written direction or order for medical use for a specific patient, dated and signed by an authorized user or a physician under the supervision of an authorized user, containing the following information: (a) for diagnostic use of radiopharmaceuticals: the radioisotope, dosage, chemical form, and route of administration; (b) for radiopharmaceutical therapy: the radioisotope, dosage, physical form, chemical form, and route of administration; (c) for teletherapy: the total dose, number of fractions, and treatment site; or (d) for brachytherapy: the total dose (or treatment time, number of sources, and combined activity), radioisotope, and treatment site.

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U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REGULATORY RESEARCH

December 1989
Task DG-8001
Division 8

DRAFT REGULATORY GUIDE

Contact: A. Tse (301) 492-3797

BASIC QUALITY ASSURANCE PROGRAM FOR MEDICAL USE

A. INTRODUCTION

The NRC has proposed amendments to the regulations at 10 CFR Part 35, "Medical Use of Byproduct Material." A new § 35.35, "Basic Quality Assurance Program" (54 FR , November , 1989), if promulgated, would require medical use licensees to establish and implement a written basic quality assurance (QA) program to prevent, detect, and correct the cause of errors in medical use.*

This draft regulatory guide, published for public comment concurrently with the proposed regulation, provides guidance for licensees on developing a written basic QA program that would be acceptable to the NRC staff for meeting the proposed regulation. Medical use licensees may use this guidance as they develop a basic QA program specific for their clinical situation.

The NRC staff will start a pilot program during the public comment period to determine the impact and efficacy of the proposed basic QA program and procedures developed by participating licensees and to determine whether the rule and procedures would interfere with or could be incorporated into licensees' medical practice. Based on public comments and the results of the pilot program, the NRC staff plans to revise this regulatory guide as necessary. The

*"Medical use," as currently defined in 10 CFR 35.2, means "the intentional internal or external administration of byproduct material, or the radiation therefrom, to human beings in the practice of medicine in accordance with a license issued by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico." This definition applies whenever this term is used in this regulatory guide.

This regulatory guide is being issued in draft form to involve the public in the early stages of the development of a regulatory position in this area. It has not received complete staff review and does not represent an official NRC staff position.

Public comments are being solicited on the draft guide (including any implementation schedule) and its associated regulatory analysis or value/impact statement. Comments should be accompanied by appropriate supporting data. Written comments may be submitted to the Regulatory Publications Branch, DFIPS, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Copies of comments received may be examined at the NRC Public Document Room, 2120 L Street NW., Washington, DC. Comments will be most helpful if received by

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final regulatory guide may contain more general guidance on the design and implementation of a basic QA program, or it may contain specific QA procedures that were developed and tested by licensees during the pilot program.

The NRC will publish a final regulatory guide when the final regulation is published, which licensees may use to develop a basic QA program. The NRC staff is soliciting comments on this draft regulatory guide to ensure timely publication of a useful, practical, and effective final regulatory guide.

Any information collection activities mentioned in this draft regulatory guide are contained as requirements in the proposed amendments to 10 CFR Part 35 that would provide the regulatory basis for this guide. The proposed amendments have been submitted to the Office of Management and Budget for clearance that may be appropriate under the Paperwork Reduction Act. Such clearance, if obtained, would also apply to any information collection activities mentioned in this guide.

B. DISCUSSION

Radiopharmaceuticals contain small quantities of byproduct materials and are used in nuclear medicine to locate tumors, assess organ function, or monitor the effectiveness of a treatment. Larger quantities of radiopharmaceuticals are administered to treat various medical conditions (e.g., hyperactive thyroids). Sealed sources containing byproduct material are used in radiation therapy to treat cancer. Teletherapy machines can be adjusted to direct a shaped radiation beam to the part of the patient's body that is to be treated. In brachytherapy, smaller sealed sources with less radioactivity than teletherapy sources are inserted or implanted directly into a tumor area or applied to the surface of an area to be treated. An estimated 7 million diagnostic nuclear medicine procedures are performed annually in the United States. In addition, there are about 30,000 radiopharmaceutical therapy patients, about 100,000 cobalt teletherapy patients, and about 50,000 brachytherapy patients treated annually.

Every year the NRC receives reports of misadministrations in medical use. These misadministrations usually involve errors produced by or attributable to an individual, such as using the wrong radiopharmaceutical, treating the wrong target organ, using the wrong calculation, or treating the wrong patient. They may result in treatment or doses very different from what was prescribed.

Although the occurrence rate of such misadministrations is low, the NRC staff believes that most such misadministrations could have been prevented if an appropriate and effective basic QA program had been followed by the licensee involved.

Section 35.35, if adopted as an amendment, would require medical use licensees to establish and implement a written basic QA program to prevent, detect, and correct the cause of errors in medical use. To provide the flexibility needed by medical use licensees to practice medicine, this requirement is proposed in the regulation without specifying detailed QA procedures. This flexibility is to prevent or reduce any interference with the delivery of medical care.

Implementation of QA procedures based on the guidance contained in this regulatory guide does not in itself satisfy all QA requirements and recommendations pertaining to medical use. The QA procedures in this draft guide pertain only to preventing, detecting, and correcting the cause of errors in medical use. There are other QA procedures in 10 CFR 35, with the focus on QA for equipment such as a dose calibrator or teletherapy machine. Examples of the existing QA requirements include 10 CFR 35.50, "Possession, Use, Calibration, and Check of Dose Calibrators"; 10 CFR 35.51, "Calibration and Check of Survey Instruments"; 10 CFR 35.632, "Full Calibration Measurements"; and 10 CFR 35.634, "Periodic Spot-Checks."

C. REGULATORY POSITION

This regulatory guide provides guidance for developing a basic QA program acceptable to the NRC staff for complying with the proposed regulation, § 35.35. The NRC staff believes that most errors in administering byproduct material could be prevented by implementing a basic QA program designed by the licensee based on guidance contained in this guide. However, a licensee may propose a basic QA program based on other sources of guidance. The NRC staff would review such a program on a case-by-case basis.

The licensee's basic QA program is to contain the elements listed in the following sections, or alternative elements approved as license conditions.

1. RESPONSIBILITY, AUTHORITY, AND AUDIT

1.1 The responsibility and authority to establish and implement the basic QA program, as well as audits, evaluation, and corrective measures, will be documented in written policies and procedures. The management ("management" in this regulatory guide means the licensee's management) will regularly review the efficacy and adequacy of the basic QA program.

1.2 The basic QA program will include scheduled audits at intervals no greater than 12 months to evaluate the adequacy and effectiveness of the basic QA program and applicable management controls. Audits will be conducted following approved written policies and procedures by qualified personnel who are not involved with the activity being audited. The audit schedules and the audit personnel qualifications will be determined by management. Audit results will be documented, reviewed by management, and available for NRC inspectors. Deficient conditions requiring corrective action will be followed by management and re-audited as necessary. Audit reports will be distributed to appropriate management and organizations for review and follow-up.

2. GENERAL ELEMENTS FOR ALL MEDICAL USE -- DIAGNOSTIC AND THERAPY
(See Regulatory Positions 3, 4, and 5 for additional specific elements for radiopharmaceutical therapy and diagnostic use involving more than 30 microcuries of I-125 or I-131, brachytherapy, and teletherapy, respectively.)

2.1 Records (i.e., prescriptions,* diagnostic referrals,* and other written instructions or records) relating to medical use will be legible and written clearly, precisely, and in a manner to minimize the likelihood of misunderstanding.

2.2 All workers involved in medical use will request clarification from an authorized user or a physician under the supervision of an authorized user if any element of a prescription, diagnostic referral, and other written instruction or record is unclear, ambiguous, or apparently erroneous.

*The terms "prescription" and "diagnostic referral" are defined in proposed 10 CFR 35.2.

2.3 All workers will stop the medical use on a patient and seek guidance if there is an apparent discrepancy in records, observations, or physical measurements that may result in a diagnostic or therapy event (except in emergent situations). The worker may resume use after resolving the discrepancy.

2.4 Before medical use, the person administering the byproduct material will verify that the medical use is in accordance with the prescription or the diagnostic referral and clinical procedures manual.*

3. SPECIFIC ELEMENTS FOR RADIOPHARMACEUTICAL THERAPY AND DIAGNOSTIC PROCEDURES INVOLVING MORE THAN 30 MICROCURIES OF I-125 OR I-131
(See Regulatory Position 2 for general elements.)

3.1 Before writing a prescription, the authorized user or the physician under the supervision of an authorized user will personally review the patient's case to establish that the medical use is indicated for the patient.

3.2 Before administering a radiopharmaceutical, the authorized user or the physician under the supervision of an authorized user will personally make and date a prescription.

3.3 Any change in the prescription will be made by the authorized user or the physician under the supervision of an authorized user, will be recorded in writing in the patient's chart or in another appropriate record, and will be dated and signed.

3.4 Before administering a radiopharmaceutical, the identity of the patient, the radiopharmaceutical, and the dosage will be confirmed by the person administering the radiopharmaceutical to establish agreement with the prescription.

3.5 After administering a radiopharmaceutical, a qualified person under the supervision of the authorized user will make, date, and sign a written record in the patient's chart or other appropriate record describing the dosage administered, and this person will record the agreement, or lack thereof, between the radiopharmaceutical administration and the prescription.

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*The term "clinical procedures manual" is defined in proposed 10 CFR 35.2.

4. SPECIFIC ELEMENTS FOR BRACHYTHERAPY
(See Regulatory Position 2 for general elements.)

4.1 Before prescribing a procedure, the authorized user or the physician under the supervision of an authorized user will personally review the patient's case to establish that the medical use is indicated for the patient's medical condition.

4.2 Before administering byproduct material, the authorized user or the physician under the supervision of an authorized user will personally make and date a prescription.

4.3 Before implanting the sealed sources, a qualified person under the supervision of an authorized user will verify that the radionuclide and source strength of the sources to be used are as prescribed. (Note: The licensee may use any appropriate verification method, such as checking the serial number behind a shield, using a radiation detector, or using clearly marked storage spaces for each type of sealed source.)

4.4 Any change in the prescription will be recorded in writing in the patient's chart or in another appropriate record and will be dated and signed by the authorized user or the physician under the supervision of an authorized user.

4.5 After implanting the brachytherapy sources, radiographs will be obtained and used as the basis for calculating the delivered dose (this may not apply to sources used for surface application).

4.6 After implantation, a qualified person under the supervision of an authorized user will promptly update and sign the patient's record to reflect the actual loading of the sealed sources and record any change in the prescription.

4.7 After administering the brachytherapy dose, a qualified person under the supervision of an authorized user will make, date, and sign a written record in the patient's chart or in another appropriate record describing the

administered dose; and this person will record the agreement, or lack thereof, between the brachytherapy administration and the prescription.

4.8 Before 50 percent of the prescribed dose has been administered, a qualified person under the supervision of an authorized user (e.g., a physicist, physician, dosimetrist, or technologist) who did not make the original calculations will check the dose calculations.

4.8.1 Manual dose calculations will be checked for:

(1) Arithmetic errors,

(2) Correct transfer of data from the prescription, tables, and graphs,

(3) Correct use of nomograms (when applicable), and

(4) Correct use of all pertinent data in the calculations.

4.8.2 Computer-generated dose calculations will be checked by examining the computer printout to ensure that the correct inputs for the patient were used in the calculations. Alternatively, the dose will be manually calculated to a key point and the results compared.

4.8.3 If the manual calculations are performed using computer outputs or vice versa, the manual portion of the calculations will be checked as stated in 4.8.1 and the computer portion of the calculations will be checked as stated in 4.8.2. Particular emphasis will be placed on verifying the correct output from one type of calculation (e.g., computer) to be used as an input in another type of calculation (e.g., manual).

4.9 If the prescribing physician determines that delaying treatment in order to perform the checks of dose calculations (see Regulatory Position 4.8) would jeopardize the patient's health because of the emergent nature of the patient's condition, the prescribed treatment may be provided without first performing the checks. The prescribing physician will make a notation of this determination in the records of the administered dose. The checks of the calculations will be performed within two working days of the treatment.

5. SPECIFIC ELEMENTS FOR TELETHERAPY
(See Regulatory Position 2 for general elements.)

5.1 Before prescribing a teletherapy procedure, the authorized user or the physician under the supervision of an authorized user will personally review the patient's case to establish that the medical use is indicated for the patient's medical condition.

5.2 Before administering a teletherapy dose, the authorized user or the physician under the supervision of an authorized user will personally make and date a prescription and approve a treatment plan that includes the treatment modality, the treatment volume, the portal or field arrangement, the total dose at a specified location, and the dose per fraction or the number of fractions.

5.3 Any change in the teletherapy prescription will be recorded in writing in the patient's chart or in another appropriate record and will be dated and signed by the authorized user or a physician under the supervision of an authorized user.

5.4 After administering a dose fraction, a qualified person under the supervision of an authorized user will personally make, date, and sign a written record in the patient's chart or in another appropriate record describing the dose administered; and this person will record the agreement, or lack thereof, between the teletherapy administration and the prescription.

5.5 A weekly check will be performed to detect errors in the daily cumulative dose summations and in implementing any changes in the prescription that have been made in the patient's record.

5.6 Before 25 percent of the prescribed dose has been administered, a qualified person under the supervision of an authorized user (e.g., a physicist, physician, dosimetrist, or technologist) who did not make the original calculations will check the dose calculations.

5.6.1 Manual dose calculations will be checked for:

(1) Arithmetic errors,

(2) Correct transfer of data from the prescription, tables, and graphs, and

(3) Correct use of all pertinent data in the calculations.

5.6.2 Computer-generated dose calculations will be checked by examining the computer printout to ensure that the correct inputs for the patient were used in the calculations. Alternatively, the dose will be manually calculated to a key point and the results compared.

5.6.3 If the manual calculations are performed using the computer outputs or vice versa, the manual portion of the calculations will be checked as stated in 5.6.1 and the computer portion of the calculations will be checked as stated in 5.6.2. Particular emphasis will be placed on verifying the correct output from one type of calculation (e.g., computer) to be used as an input in another type of calculation (e. g., manual). Parameters such as the transmission factors for wedges and the radioactivity of the sealed source used in the calculations will be checked.

5.7 Independent checks of certain full calibration measurements will be conducted as follows.

5.7.1 After a full calibration measurement that resulted from changing the source or whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay, an independent check of the output for a single specified set of exposure conditions will be performed. The independent check will be performed within 30 days following the full calibration measurement.

5.7.2 The independent check will be performed by either:

(1) An individual who did not perform the full calibration by using a dosimetry system other than the one that was used during full calibration (the individual will meet the requirements specified in 10 CFR 35.961 and the dosimetry system will meet 10 CFR 35.630(a)), or

(2) A teletherapy physicist (or a physician, dosimetrist, or technologist who has been instructed by a teletherapy physicist) using an accredited thermoluminescence dosimetry service available by mail that is designed for confirming teletherapy dose rates and that is accurate within 5 percent.

5.8 The annual full calibration measurements will include the determination of transmission factors for the beam modifying devices (for example: trays, wedges, stock material that is used for making compensators, blocks, boluses, and the recastable block material).

5.9 Before 25 percent of the total prescribed dose has been administered, a physical measurement of the output will be made if the patient's dose calculations include (1) field sizes or treatment distances that fall outside the range of those measured in the most recent full calibration, or (2) a beam modifying device (except blocks, boluses, or stock material) not measured in the most recent full calibration measurement.

5.10 Before the first use of a computer program for dose calculations or after performing full calibration measurements pursuant to 10 CFR 35.632(a)(1) and (a)(2), depth dose calculations will be made with each computer program that could be used for therapy dose calculations for the following exposure conditions: (1) an open field in air at eight angles to the isocenter: 0 degree and seven other angles with 45-degree increments; (2) a field with and without the wedge of greatest angle into water at a 45-degree angle; and (3) an irregular mantle field into water. The results of the computer calculations will be checked against phantom measurements with the same exposure conditions. (For computer programs involving relative dose calculations, additional manual or computer calculations may be needed to determine doses.)

5.11 If the prescribing physician determines that delaying treatment in order to perform the checks of dose calculations (Regulatory Position 5.6) or physical measurements (Regulatory Position 5.9) would jeopardize the patient's health because of the emergent nature of the patient's condition, the prescribed treatment may be provided without first performing the checks of dose calculations or physical measurements. The prescribing physician will make a notation

of this determination in the records of the administered dose. The checks of the calculations or physical measurements will be performed within two working days of the treatment.

D. IMPLEMENTATION

The purpose of this section is to provide information to medical use licensees and applicants regarding the NRC staff's plans for using this regulatory guide.

This draft guide has been published for public comment to encourage public participation in its development. Except in those cases in which a licensee or an applicant proposes an acceptable alternative method for complying with specified portions of the NRC's regulations, the guidance in the final regulatory guide reflecting public comments will be used by the NRC in the evaluation of basic QA programs for medical use.

DRAFT REGULATORY ANALYSIS

A separate regulatory analysis was not prepared for this draft regulatory guide. A regulatory analysis was prepared for the proposed amendments to 10 CFR Part 35 (54 FR), and it examines the costs and benefits of the proposed rule as implemented by the draft guide. A copy of this regulatory analysis is available for inspection and copying for a fee at the NRC Public Document Room, 2120 L Street NW., Washington, DC, under file 54 FR .

Enclosure 4

TENTATIVE SCHEDULE FOR PILOT PROGRAM
(Note: this schedule reflects periods of time, a more detailed schedule will follow in about one month.)

Mid-January ..... Notice of proposed rule published in Federal Register

End-January ..... Finalized list of attendees; arrangements made with hotels at sites of workshops (tentatively NY, Atlanta, Chicago, Dallas, San Francisco)

Beginning-February .... Send workshop details and information packets to participants.

End-February ..... First set of workshops (1-day each)

Beginning-March ..... Revised information (incorporating workshop results) sent to participants

End-March ..... Participants QA programs sent to BNL

Beginning-April ..... Start pilot program

Beginning-June ..... End pilot program

Mid-June ..... Participants' evaluation information sent to BNL

Mid- to End-July ..... Second set of workshops (2-days each)

NRC considers results of pilot program and workshop comments in revisions to proposed rule and draft regulatory guide.